UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SANOFI-AVENTIS U.S., LLC, *Plaintiff,* *v.* UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, *Defendants.*	Civil Action No. 3:21-cv-634 Motion day: June 21, 2021 Oral argument requested

NOTICE OF CROSS-MOTION FOR SUMMARY JUDGMENT

PLEASE TAKE NOTICE that Plaintiff Sanofi-Aventis U.S., LLC ("Sanofi") will move before the Honorable Freda L. Wolfson, Chief Judge of the U.S. District Court for the District of New Jersey, on June 21, 2021, or on such other date as the Court orders, for summary judgment pursuant to Federal Rule of Civil Procedure 56.

In support of its Motion, Sanofi relies on the accompanying Memorandum of Law, Declaration, and accompanying Exhibits. Sanofi also submits the accompanying Proposed Order. Sanofi respectfully requests oral argument on its Motion.

Dated: May 10, 2021

Respectfully submitted,

s/ Jennifer L. Del Medico

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PLAINTIFF'S MEMORANDUM OF LAW IN SUPPORT OF CROSS-MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

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INTRODUCTION

In the closing weeks of the last Administration, the U.S. Department of Health and Human Services ("HHS") rushed out two new rules radically altering the 340B drug program (the "340B Program"). These two rules work in tandem to expand the scope of the 340B Program and create a novel administrative process to enforce new extra-statutory requirements that exceed the agency's authority. Both rules should be vacated on multiple independent grounds.

Section 340B of the Public Health Service Act requires pharmaceutical manufacturers to offer discounted drug pricing to fifteen types of "covered entities" specifically enumerated in the statute. The covered entities are all governmental and non-profit entities that mostly provide care for underserved areas or populations. Instead of dispensing 340B-priced drugs themselves, however, many covered entities enter into agreements with for-profit contract pharmacies (such as Walgreens and CVS) whereby the covered entities direct manufacturers to provide the 340B-discounted drugs to the contract pharmacy, which then dispenses them to patients and is able to profit from the sale of the manufacturers' drugs.

These contract pharmacy arrangements have created many problems, some of them prohibited by Section 340B itself. Most significantly, these arrangements make it much harder to detect unlawful "duplicate discounting," which occurs when 340B-priced drugs also receive a Medicaid rebate. Duplicate discounting can result in

manufacturers being forced to sell their drugs far below cost and is explicitly prohibited by Section 340B. But duplicate discounting has nonetheless spiked as the use of contract pharmacies has exploded in recent years—with HHS unfortunately having done nothing about it.

To address concerns about duplicate discounting, Sanofi announced an integrity initiative that took effect on October 1, 2020. Under this initiative, Sanofi continues to offer 340B pricing to all covered entities, but (with certain exceptions) Sanofi now requires covered entities to submit minimal claims data for 340B-priced drugs acquired and dispensed by contract pharmacies. Using this anonymized data, Sanofi can better identify and prevent duplicate discounts.

HHS responded to Sanofi's integrity initiative by issuing two new rules that together improperly prohibit Sanofi's initiative and authorize HHS officials to penalize Sanofi. In the Administrative Dispute Resolution Rule (the "ADR Rule"), HHS empowered panels of HHS employees to wield full judicial authority when adjudicating claims that drug manufacturers have overcharged for or imposed conditions on 340B-priced drugs delivered to contract pharmacies. Then, in Advisory Opinion 20-06, HHS required drug manufacturers to provide 340B-priced drugs to contract pharmacies and prohibited any conditions on these sales. Coupled together, the ADR Rule and the Advisory Opinion expose Sanofi to money damages and an injunction for continuing to operate its integrity initiative. But nothing in Section

340B or any other source of law requires manufacturers to provide their drugs to contract pharmacies or to accept these abuses of the 340B Program. As explained below, HHS's two new rules should be set aside because they violate the Administrative Procedure Act ("APA") and the United States Constitution.

In defending the new rules, the government reveals a fundamental misunderstanding of Sanofi's integrity initiative. Far from trying to "drastically restrict" or "end reliance" on contract pharmacies (as the government misleadingly argues), Sanofi will provide 340B-priced drugs to *all* contract pharmacies so long as the covered entity provides the requested data—which is not remotely "onerous." Mot. 1, 14. For all its heated rhetoric, the government is attacking a program that Sanofi has not even adopted—and, regrettably, has doubled down on a badly misguided attempt to stop an initiative that will unquestionably promote statutory compliance without having any adverse impact on patient care.

BACKGROUND

I. The 340B Program

A. Statutory Background

Established in 1992 by Section 340B of the Public Health Service Act, 42 U.S.C. § 256b, the 340B Program seeks to reduce pharmaceutical costs for "public hospitals and community health centers, many of which provide safety-net services to the poor." ADVOP_000001. The statute specifically enumerates categories of health

care providers—termed "covered entities"—that are eligible to receive discounts under the 340B Program. When Section 340B was enacted, there were twelve categories of covered entities, *see* Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602(a), 106 Stat. 4943, 4967; today, there are fifteen, *see* 42 U.S.C. § 256b(a)(1), (4)(A)–(O). Only Congress can expand this list of covered entities; HHS lacks authority to do so. *See Pharm. Rsch. & Mfrs. of Am. v. HHS*, 43 F. Supp. 3d 28, 35 (D.D.C. 2014) (holding HHS lacks general rulemaking authority under Section 340B).

Manufacturers that want to participate in Medicaid and Medicare Part B—among the Nation's largest healthcare programs—must also participate in the 340B Program. *See Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 113 (2011). As a result, although manufacturers are not formally required to participate in the 340B Program, they have little choice but to do so. Manufacturers' participation in these programs is governed by a contract with the government known as a pharmaceutical pricing agreement ("PPA"). *See* ADVOP_000044. The PPA's terms are not negotiable but do not waive any of a manufacturer's rights under federal and state law. *See* ADVOP_000052.

As enacted in 1992, Section 340B required the Secretary to ensure, through PPAs, that "the amount required to be paid . . . to the manufacturer for covered outpatient drugs . . . purchased by a covered entity" does not exceed a maximum price determined through a prescribed formula. 42 U.S.C. § 256b(a)(1). In 2010, as part of

the Affordable Care Act, this provision was amended to further specify that PPAs must "require that the manufacturer *offer* each covered entity covered outpatient drugs for purchase at or below" the statutory maximum price. *See* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 7102(b), 124 Stat. 119, 827 (2010), *codified at* 42 U.S.C. § 256b(a)(1) (emphasis added). This is known as the "must offer" provision.

If a manufacturer does not comply with this obligation, the government may institute enforcement actions, seek civil monetary penalties, and even terminate the PPA—and with it the manufacturer's participation in Medicaid and Medicare Part B. *See* 42 U.S.C. §§ 256b(d)(1)(B)(vi), 1396r-8(b)(4)(B)(v); ADVOP_000384–85. But covered entities do not themselves have a private right of action to file suits under Section 340B against manufacturers. *See Astra*, 563 U.S. at 113.

Section 340B also includes provisions that aim to prohibit program waste and abuse. Specifically, Section 340B prohibits "duplicate discounts or rebates," which occur when the same prescription receives both a 340B discount and a Medicaid rebate—as covered entities' patients are frequently insured by Medicaid, such that their prescriptions are eligible for Medicaid rebates. 42 U.S.C. § 256b(a)(5)(A). Section 340B also prohibits "diversion," which occurs when covered entities resell or transfer discounted drugs to persons other than their patients. *Id.* § 256b(d)(2)(A).

B. The Explosive Growth of Contract Pharmacy Arrangements and Accompanying Abuses

Congress did not include contract pharmacies in the statutory list of covered entities entitled to 340B discounts. Nor did Congress define any role for contract pharmacies in Section 340B or otherwise mention them in the statute. But HHS and its agency the Health Resources and Services Administration ("HRSA") have nonetheless taken the position that covered entities may use contract pharmacies in the 340B Program through nonbinding sub-regulatory guidance, first in 1996 and then in 2010.

Explaining that Section 340B has "many gaps" and "is silent as to permissible drug distribution systems," the 1996 guidance took the position that the agency would allow any covered entity without its own in-house pharmacy to contract with a maximum of one third party to provide pharmacy services for 340B drugs. Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,550, 43,555 (Aug. 23, 1996) (ADVOP_000370–71, 376). The 2010 guidance expanded this supposed authorization, expressing HHS's view that *all* covered entities—including those with their own in-house pharmacies—could contract with an *unlimited* number of outside pharmacies. *See* Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,273 (Mar. 5, 2010) (ADVOP_000387). Neither the 1996 nor 2010 guidance purported to be binding or to impose legal obligations on manufacturers. Moreover,

both predated the Affordable Care Act's amendments to Section 340B (which, as noted, added the "must offer" provision).

Covered entities' use of contract pharmacies exploded following the 2010 guidance. The number of for-profit contract pharmacies participating in the 340B Program increased from 1,300 in 2010 to 20,000 in 2017 and then to 28,000 last year, with more than 100,000 arrangements between contract pharmacies and covered entities.[1] Indeed, some covered entities contract with pharmacies thousands of miles away from their locations.[2] Not surprisingly, this extraordinary expansion of contract pharmacy arrangements has been accompanied by significant waste and abuse.

For one thing, contract pharmacies often keep sizable portions of the discounts that Congress intended for non-profit covered entities and their patients.[3] Although contract pharmacies acquire the 340B drugs at a significant discount, they charge the

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[1] *See* U.S. Government Accountability Office ("GAO"), Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement, GAO-18-480, at 1, 2, 16 (June 2018), https://www.gao.gov/assets/700/692697.pdf ("GAO Report"); Adam J. Fein, Walgreens and CVS Top the 28,000 Pharmacies Profiting from the 340B Program. Will the Unregulated Party End?, Drug Channels (July 14, 2020), https://www.drugchannels.net/2020/07/walgreens-and-cvs-top-28000-pharmacies.html; PhRMA, 340B Contract Pharmacy 101 (Sept. 2020), https://phrma.org/-/media/Project/PhRMA/ PhRMA-Org/PhRMA-Org/PDF/0-9/340B-Contract-Pharmacy-101-Deck_Sept-2020.pdf; PhRMA, Petition for Rulemaking at 5–6 (Nov. 24, 2020) ("PhRMA Petition") (ADVOP_001383–84).

[2] *See* GAO Report, *supra*, at 22.

[3] *See* GAO Report, *supra*, at 30; HHS Office of Inspector General, Memorandum Report: Contract Pharmacy Arrangements in the 340B Program, OEI-05-13-00431, at 2 (Feb. 4, 2014) ("HHS Report") (ADVOP_001404); PhRMA Petition, *supra*, at 7–9 (ADVOP_001385–87).

insurer or patient at the standard commercial rate. This yields a large profit margin over the 340B price (which can be as low as a penny)—much of which is often pocketed by contract pharmacies, which pay a smaller, pre-negotiated amount to the covered entity for each discounted drug dispensed.[4]

Because a patient's 340B status is not determined by a contract pharmacy until *after* a drug is dispensed, contract pharmacies typically treat covered entities' patients like the general public—using the same supply of drugs to fulfill *all* prescriptions, and then "replenish[ing] [those drugs] with 340B drugs [at 340B prices] once 340B patient eligibility is confirmed and can be documented through auditable records."[5] Partly because of how contract pharmacies commingle 340B-priced drugs with other drugs, the expansion of contract pharmacy arrangements has led to widespread duplicate discounting, in direct violation of Section 340B. *See* 42 U.S.C. § 256b(a)(5)(A). The

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[4] *See* PhRMA, New Analysis Shows Contract Pharmacies Financially Gain From 340B Program With No Clear Benefit to Patients (Oct. 8, 2020), https://phrma.org/Press-Release/New-Analysis-Shows-Contract-Pharmacies-Financially-Gain-From-340B-Program-With-No-Clear-Benefit-to-Patients; PhRMA, For-Profit Pharmacies Make Billions Off 340B Program Without Clear Benefit to Patients (Oct. 7, 2020), https://phrma.org/Graphic/For-Profit-Pharmacies-Make-Billions-Off-340B-Program-Without-Clear-Benefit-to-Patients; PhRMA Petition, *supra*, at 7–9 (ADVOP_001385–87).

[5] HRSA, Statutory Prohibition on Group Purchasing Organization Participation, 340B Drug Pricing Program Release No. 2013-1, at 3 (Feb. 2013), https://www.hrsa.gov/sites/default/files/opa/programrequirements/policyreleases/prohibitionongpoparticipation020713.pdf.

government has also noted that contract pharmacy use "creates more opportunities for drug diversion compared to in-house pharmacies."[6]

Duplicate-discounting problems stem in part from an information gap. Requests for Medicaid reimbursement are made by the pharmacy that fills the prescription, not the covered entity. But HRSA has only partial insight into which covered entities use which contract pharmacies, and only incomplete information on which covered entities use 340B-priced drugs for Medicaid-insured patients.[7] Likewise, based on publicly available information, there is no effective or comprehensive (much less timely) way to know whether a contract pharmacy's prescriptions are being submitted for *both* a 340B discount and a Medicaid rebate. The government itself has recognized this gap, noting that contract pharmacy arrangements "create complications in preventing duplicate discounts,"[8] and government audits have uncovered numerous violations linked to contract pharmacies.[9] The government has also recognized that "duplicate discounts can often

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[6] GAO, *Manufacturer Discounts in the 340B Program Offer Benefits, But Federal Oversight Needs Improvement*, GAO-11-836, at 28, (Sept. 2011), https://www.gao.gov/assets/gao-11-836.pdf.

[7] *See* GAO Report, *supra*, at 36; HRSA OPA Policy Release, Clarification on Use of the Medicaid Exclusion File (Dec. 12, 2014), https://www.hrsa.gov/sites/default/files/opa/programrequirements/policyreleases/clarification-medicaid-exclusion.pdf.

[8] HHS Report, *supra*, at 1–2 (ADVOP_001403–04).

[9] HRSA, Program Integrity: FY19 Audit Results (updated Apr. 28, 2021), https://www.hrsa.gov/opa/program-integrity/audit-results/fy-19-results (finding widespread duplicate discounting at contract pharmacies).

best be identified from a review of claims level data by the manufacturers."[10] To that end, Sanofi has discovered significant duplicate-discounting violations when analyzing Medicaid rebates for its own drugs and is seeking claims data to promote 340B compliance.

II. Sanofi's Integrity Initiative

Sanofi shares the government's concerns about the unlawful duplicate discounting that has accompanied the explosion in covered entities' use of contract pharmacies. Accordingly, on July 28, 2020, Sanofi announced an integrity initiative to prevent duplicate discounts and other waste and abuse. Under the integrity initiative, which took effect on October 1, 2020, Sanofi continues to offer discounted pricing to all covered entities. The program involves one simple change: Sanofi now requests that covered entities submit minimal, de-identified claims data for 340B-priced drugs dispensed by contract pharmacies, subject to limited exceptions. *See* Declaration of Jennifer L. Del Medico ("Del Medico Decl.") Ex. 1, Letter from G. Gleeson, Vice President & Head, Sanofi US Market Access Shared Services (July 2020) (ADVOP_002127–28); *id.* Ex. 2, Letter from A. Gluck to Secretary Azar (Aug. 13, 2020).

[10] Centers for Medicare and Medicaid Services, Best Practices for Avoiding 340B Duplicate Discounts in Medicaid (Jan. 8, 2020), https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/cib010820.pdf.

The information requested by Sanofi is just a subset of what third-party payors require from covered entities for insurance reimbursement and, similarly, is only a subset of what drug manufacturers require from insurance companies when paying rebates on prescriptions. *See id.* Ex. 7, "Understanding Sanofi's 340B Data Reporting Requirements." In other words, Sanofi is not asking covered entities to do anything more than they are already doing to get reimbursed—indeed it is less. With this information, Sanofi can identify and halt impermissible duplicate discounts that would otherwise go undetected as a result of the current information gap by comparing the claims data to Medicaid payor data. *See id.*; *id.* Ex. 6, "Sanofi's New Initiative Combats Waste and Abuse in the 340B Program."

On February 1, 2021, Sanofi further announced that, as of March 1, 2021, any covered entity without its own in-house pharmacy may designate a single contract pharmacy at which its patients can receive 340B-priced drugs—regardless of whether the covered entity provides the data Sanofi requests through the integrity initiative. *See id.* Ex. 8, Program Announcement. This policy thus aligns with HRSA's initial, non-binding 1996 guidance on contract pharmacies.

In sum, under its integrity initiative, Sanofi now offers 340B-priced drugs to all covered entities in three ways: (i) through the covered entity's own in-house pharmacy; (ii) through a single, designated contract pharmacy, if the covered entity

has no in-house pharmacy; and (iii) through multiple contract pharmacies, if the covered entity provides the data Sanofi requests.

Many covered entities have registered to provide claims data to Sanofi's integrity initiative. But, as unobtrusive as the integrity initiative is, many more covered entities have refused to participate—and have instead clamored for HHS to shut down Sanofi's integrity initiative. Covered entities (or their associations) began by urging HHS to take enforcement action against Sanofi and other manufacturers who have employed various approaches to combat waste and abuse at contract pharmacies. *See, e.g.*, *id.* Ex. 11, Letter from American Hospital Association, et al. to Secretary Azar (Aug. 26, 2020); *id.* Ex. 12, Letter from T. Nova to J. Jehnke. Then, in late 2020, covered entities took the matter to federal court, seeking to compel enforcement action by HHS. *See Ryan White Clinics for 340B Access v. Azar*, No. 20-cv-2906 (D.D.C.); *Am. Hosp. Ass'n v. HHS*, No. 20-cv-8806 (N.D. Cal.).

Tellingly, none of these plaintiffs argued that participating in Sanofi's integrity initiative would be unduly burdensome or "onerous," Mot. 1. Nor did any allege that Sanofi's program improperly discriminated against covered entities as compared to commercial customers. Nor, for that matter, has any of these covered entities ever denied the importance of the fight against duplicate discounting or the value of Sanofi's integrity initiative in that battle—if only they would cooperate and provide the requested data.

III. The Missing ADR Process

Covered entities have tried to force HHS to act on these matters because they cannot sue Sanofi directly. *See Astra*, 563 U.S. at 113–14. Under Section 340B, a covered entity that wishes to seek relief directly from a manufacturer must file a claim in an ADR process established by HHS. *See* 42 U.S.C. § 256b(d)(3)(A). Until January 2021, however, that process simply did not exist.

The Affordable Care Act set a deadline of September 20, 2010 for HHS to establish an ADR process—but HHS missed that deadline by *over a decade*. *See id.* It was not until the statutory deadline that HHS even issued an advance notice of proposed rulemaking regarding an ADR process. *See* 340B Drug Pricing Program Administrative Dispute Resolution Process, 75 Fed. Reg. 57,233 (Sept. 20, 2010) (ADR_000001). And it took another six years, until 2016, for HHS to issue a notice of proposed rulemaking ("NPRM") for an ADR rule. *See* Notice of Proposed Rulemaking, 340B Drug Pricing Program Administrative Dispute Resolution Process, 81 Fed. Reg. 53,381 (Aug. 12, 2016) (ADR_000004). After that proposed ADR rule drew comments, including from Sanofi, HHS abandoned the rulemaking effort, withdrawing the NPRM on August 1, 2017, after the change in presidential administration. *See* Office of Information and Regulatory Affairs, RIN 0906-AA90 (Spring 2017), https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201704&RIN=0906-AA90 (last accessed May 9, 2021) ("Unified Agenda"). In the

years that followed, HHS took no public action regarding an ADR process. In March 2020, an official speaking on behalf of the agency even explained that HHS "d[id] not plan to move forward on issuing a regulation." *Eli Lilly & Co. v. Cochran*, No. 21-cv-00081, 2021 WL 981350, at *8 (S.D. Ind. Mar. 16, 2021) (quoting Tom Mirga, HRSA: 340B Dispute Resolution Will Stay on Hold Until We Get Broader Regulatory Authority, 340B Report (Mar. 12, 2020)).

Due to this decade-long delay, covered entities asked federal courts not only to compel HHS enforcement action against Sanofi and other manufacturers, but also to compel HHS to promulgate the long-overdue ADR regulations.[11] *See Ryan White Clinics for 340B Access*, No. 20-cv-2906 (D.D.C.); *NACHC v. Azar*, No. 20-cv-03032 (D.D.C.); *Am. Hosp. Ass'n*, No. 20-cv-8806 (N.D. Cal.). In late 2020, some of these plaintiffs filed motions for preliminary injunctions, seeking such relief from the government on an expedited basis. *See* Dkt. 24, *Ryan White Clinics for 340B Access*, No. 20-cv-2906 (D.D.C.) (filed Nov. 23, 2020); Dkt. 7, *Am. Hosp. Ass'n*, No. 20-cv-8806 (N.D. Cal.) (filed Dec. 11, 2020).

[11] Covered entities and state officials asked HHS to take enforcement actions, including the assessment of civil monetary penalties, against Sanofi and other drug manufacturers that had implemented policies to combat duplicate discounts and diversion at contract pharmacies. *See* Del Medico Decl. Ex. 9, Letter from California Attorney General Becerra to Sec'y Azar; *id.* Ex. 11, Letter from Am. Hosp. Ass'n to Sec'y Azar.

IV. HHS Hastily Issues Two New Rules

With these lawsuits pending against HHS in multiple courts, and in the waning months of the Trump Administration, HHS answered the covered entities' demands in a swift two-step action against manufacturers. Before the government had to respond to any of the covered entities' complaints or motions for injunctive relief, HHS—over the span of just a few weeks—hastily issued the long-delinquent ADR Rule to administer covered entities' claims against drug manufacturers and then effectively preordained the outcome of those claims against Sanofi and other manufacturers in the Advisory Opinion.

A. The ADR Rule

On December 14, 2020, HHS promulgated the ADR Rule, which took effect on January 13, 2021. *See* 340B Drug Pricing Program; Administrative Dispute Resolution Regulation, 85 Fed. Reg. 80,632 (Dec. 14, 2020) (codified at 42 C.F.R. pt. 10) (the "Rule" or the "ADR Rule") (ADR_000012). The ADR Rule purports to be authorized by Section 340B's requirement that HHS create an ADR process for the resolution of certain claims—but the Rule in fact stretches beyond the statute's terms. *See* 42 U.S.C. § 256b(d)(3)(A). Specifically, Section 340B authorizes administrative resolution of only *two* types of claims: (i) "claims by covered entities that they have been overcharged for drugs purchased under" the 340B Program; and (ii) claims by manufacturers, after conducting an audit, that a covered entity has violated the

prohibitions on duplicate discounts and diversion. *Id.* § 256b(d)(3)(A). But the ADR Rule further extends to cover claims that manufacturers have limited covered entities' abilities to purchase 340B-priced drugs. *See* 42 C.F.R. § 10.20.

Section 340B also requires regulations that "designate or establish a decision-making official or decision-making body within [HHS] to be responsible for reviewing and finally resolving claims." 42 U.S.C. § 256b(d)(3)(B)(i). Under the ADR Rule, the Secretary will establish an ADR Board "consisting of at least six members appointed by the Secretary with equal numbers" from HRSA, the Centers for Medicare and Medicaid Services ("CMS") (like HRSA, an HHS agency), and the HHS Office of the General Counsel. 42 C.F.R. § 10.20. From this Board, the HRSA Administrator selects three-member panels with "relevant expertise and experience" to adjudicate claims. *Id.* §§ 10.20, 10.21(c). Members can be removed from a panel only "for cause," and the only grounds for removal identified by the ADR Rule are specified "conflicts of interests." *Id.* § 10.20(a)(1)(ii), (2).

The ADR Rule vests the panel members with "wide latitude" and "significant discretion" to exercise substantial authority. 85 Fed. Reg. at 80,635, 80,636, 80,639 (ADR_000014–16, 19–20). Based on their determinations of whether the parties have violated Section 340B, ADR panels have jurisdiction to resolve claims seeking "monetary damages" and "equitable relief." 42 C.F.R. § 10.21(a)–(c). And under the ADR Rule, "[e]ach 340B ADR Panel will necessarily have jurisdiction to resolve all

issues underlying any claim or defense, including, by way of example, those having to do with covered entity eligibility, patient eligibility, or manufacturer restrictions on 340B sales that the 340B ADR Panel deems relevant for resolving an overcharge, diversion, or duplicate discount claim." 85 Fed. Reg. at 80,636 (ADR_000016).

In exercising this authority, an ADR panel may "determine, in its own discretion, the most efficient and practical form of the ADR proceeding," may issue instructions governing proceedings as "necessary or desirable," and may "determine the proper course" of each proceeding. 42 C.F.R. § 10.23; *see also* ADR_000016 (emphasizing that panels have "wide latitude" to define the "scope of the process" and "proper course of conduct"). Further, an ADR panel has "discretion in admitting evidence and testimony," may conduct "evidentiary hearing[s]," and may "in its sole judgment request additional information from the parties." 85 Fed. Reg. at 80,636 (ADR_000016); 42 C.F.R. §§ 10.22(b), 10.23(a). Like federal courts, an ADR panel employs the Federal Rules of Civil Procedure and Evidence. 42 C.F.R. § 10.23(b)–(c); *see also* 85 Fed. Reg. at 80,641 (ADR_000021). And if the panel finds that a party did not adequately comply with its requests, the panel may impose formidable sanctions. 42 C.F.R. § 10.22(c) (authorizing panel to exclude evidence, preclude a party from presenting or contesting a particular issue, or even enter judgment as a sanction).

The ADR panel's decision is HHS's last word on the parties' claims. When promulgating the ADR Rule, HHS expressly declined to "incorporate an

[administrative] appeals process." 85 Fed. Reg. at 80,641 (ADR_000021). Instead, the Rule provides that each panel decision "constitutes a final agency decision that is precedential and binding on the parties involved unless invalidated by an order of a court of competent jurisdiction." 42 C.F.R. § 10.24(d); *see also id.* § 10.20 (ADR panels "make precedential and binding final agency decisions"); 42 U.S.C. § 256b(d)(3)(C) (stating that the "administrative resolution" of claims "shall be a final agency decision and shall be binding upon the parties involved, unless invalidated by an order of a court of competent jurisdiction"). Based on the ADR panels' final agency decisions, manufacturers may also be subject to additional enforcement actions, including "refunds, penalties, removal, or referral to appropriate Federal authorities." 42 C.F.R. § 10.24(e).

In its rush to act after the covered entities' lawsuits were filed, HHS chose not to solicit comments on the ADR Rule before finalizing it. Instead, HHS decided that the ADR Rule was covered by an *earlier* notice-and-comment period on a different ADR regulation that was proposed in the 2016 NPRM—even though that NPRM had been withdrawn almost four years earlier. *See* 85 Fed. Reg. at 80,633 (ADR_000013).

B. The Advisory Opinion

The ADR Rule was HHS's first response to the covered entities' complaints. Next came the HHS Office of General Counsel's Advisory Opinion 20-06, which was

issued on December 30, 2020—less than three weeks after the ADR Rule was promulgated. *See* ADVOP_000001. The Advisory Opinion answered the covered entities' litigation claims that Sanofi and other manufacturers were improperly refusing to provide 340B-priced drugs to contract pharmacies—and, thus, gave the covered entities much of what they sought in their lawsuits.

Indeed, the Advisory Opinion dooms Sanofi's integrity initiative within the ADR process, without ever giving Sanofi an opportunity to defend its program. Like the ADR Rule, moreover, the Advisory Opinion was never subject to public notice and comment, even though it imposes legal obligations on drug manufacturers.

First, in the Advisory Opinion, HHS concludes—for the first time—that Section 340B legally obligates drug manufacturers to provide 340B-priced drugs to contract pharmacies. It reached this conclusion notwithstanding both its earlier acknowledgment that Section 340B was silent on the use of contract pharmacies as well as the widespread recognition (including by HHS itself) of waste and abuse at contract pharmacies. Without addressing its departure from past guidance, the Advisory Opinion reasons that drugs delivered to contract pharmacies are "purchased by" covered entities and thus subject to 340B pricing regardless of where the drugs are delivered, including even the "lunar surface." ADVOP_000001, 03, 06. This conclusion appears to have rested on HHS's understanding of state agency law—and,

specifically, that typically "contract pharmacies are acting as agents of a covered entity." ADVOP_000001, 08.

Second, the Advisory Opinion prohibits manufacturers—again, for the first time—from imposing conditions on the delivery of 340B-priced drugs to contract pharmacies. In particular, HHS concluded that "private actor[s]" like drug manufacturers are not "authorized by Section 340B to add requirements to the statute." ADVOP_000002. Thus, according to the Advisory Opinion, "'[m]anufacturers cannot condition sale of a 340B drug at the 340B ceiling price because they have concerns or specific evidence of possible non-compliance by a covered entity.'" ADVOP_000005 (quoting preamble to the 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1210, 1223 (Jan. 5, 2017) (ADVOP_000075)).

Covered entities promptly seized on the Advisory Opinion to challenge Sanofi's integrity initiative. The day the ADR Rule took effect, an association of 328 covered entities filed an ADR petition against Sanofi and other manufacturers that invoked the Advisory Opinion and sought a preliminary injunction barring Sanofi from operating its integrity initiative. *See* Del Medico Decl. Ex. 15, Petition for Declaratory and Injunctive Relief; *id.* Ex. 16, Motion for Preliminary Injunction. Other covered entities wrote letters to Sanofi arguing, on the basis of the Advisory

Opinion, that Sanofi's integrity initiative was unlawful. *See id.* Ex. 13, Letter from W. Schultz to C. Lee; *id.* Ex. 14, Letter from W. Allen to A. Gluck.

V. Procedural History

On January 12, 2021—the day before the ADR Rule took effect—Sanofi filed this action against HHS, HRSA, and the HHS General Counsel. *See* ECF 1. On February 2, 2021, Sanofi filed the operative amended complaint, which challenges both the ADR Rule and the Advisory Opinion. *See* ECF 17. Other manufacturers and a trade association have filed similar lawsuits. *See Eli Lilly & Co. v. Cochran*, No. 21-cv-00081 (S.D. Ind.) (challenging both); *AstraZeneca Pharms. LP v. Becerra*, No. 21-cv-00027 (D. Del.) (Advisory Opinion only); *Pharm. Rsch. & Mfrs. of Am. v. Cochran*, No. 21-cv-00198 (D. Md.) (ADR Rule only); *Novo Nordisk Inc. v. HHS*, No. 21-cv-00806 (D.N.J.) (Advisory Opinion only).

On February 2, 2021, with an ADR petition having been filed against it, Sanofi moved for a preliminary injunction seeking to block enforcement of the ADR Rule. *See* ECF 19. On March 16, 2021, while Sanofi's motion was still pending, a district court in the Southern District of Indiana granted the drug manufacturer Eli Lilly's motion for a preliminary injunction against the ADR Rule, holding that the Rule violated the APA. *See Eli Lilly*, 2021 WL 981350 (Mar. 16, 2021). With this Court's approval, Sanofi and the government agreed to hold Sanofi's motion for a preliminary injunction in abeyance and to expedite the briefing on the merits. *See* ECF 46, 49.

The petition filed against Sanofi in the ADR process remains pending. As of the filing of this brief, however, the members of the ADR Board have yet to be named, nor has the ADR process with respect to Sanofi otherwise moved forward.

STANDARD OF REVIEW

Under the APA, a "reviewing court shall … hold unlawful and set aside agency action, findings, and conclusions found to be:" either (A) "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; (B) "contrary to constitutional right, power, privilege, or immunity;" (C) "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;" or (D) "without observance of procedure required by law." 5 U.S.C. § 706(2).

When reviewing an agency's interpretation of a statute it has been entrusted to administer, courts consider whether to defer to the agency's view under the familiar framework established in *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). But *Chevron* deference is appropriate only "when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority." *United States v. Mead Corp.*, 533 U.S. 218, 226–27 (2001). Agency interpretations "contained in opinion letters" and "policy statements" are not entitled to "*Chevron*-style deference." *Mercy Cath. Med. Ctr. v. Thompson*, 380 F.3d 142, 154–55 (3d Cir. 2004).

ARGUMENT

I. The Court Should Set Aside the Advisory Opinion.

In the Advisory Opinion, HHS expanded the scope of the 340B Program by requiring drug manufacturers to deliver 340B-priced drugs to contract pharmacies and by prohibiting those manufacturers from imposing even reasonable conditions on such deliveries. The Court should set aside the Advisory Opinion for three reasons.

First, the Advisory Opinion exceeds HHS's statutory authority because nothing in Section 340B requires drug manufacturers to provide 340B-priced drugs to contract pharmacies. Nor does Section 340B prohibit manufacturers from imposing conditions on doing so, particularly where those conditions are designed to aid compliance with the statute's other provisions and are reasonable. Sanofi's integrity initiative fully complies with Section 340B because Sanofi continues to "offer" 340B-priced drugs to all covered entities. Even if manufacturers must provide 340B-priced drugs to contract pharmacies, Sanofi complies with the statute because it will ship 340B-priced drugs to contract pharmacies under reasonable conditions that are not burdensome and that do not discriminate against covered entities as compared to commercial customers.

Second, the Advisory Opinion is arbitrary and capricious because HHS failed to support its conclusion that contract pharmacies act as agents of covered entities; failed to reasonably explain its conclusion that Section 340B prohibits manufacturers from

imposing even reasonable conditions on contract pharmacy arrangements; and failed even to acknowledge (much less adequately explain) the change in its views regarding the meaning of Section 340B.

Third, HHS improperly issued the Advisory Opinion without following the APA's notice-and-comment requirement. That requirement applies because the Advisory Opinion contains a legislative rule having the force and effect of law that imposes new obligations not found in Section 340B—namely, that manufacturers shall provide 340B-priced drugs to contract pharmacies and shall not impose conditions on these sales. Contrary to the government's argument, the agency's 1996 and 2010 contract pharmacy guidance did not impose—and could not have imposed—either (much less both) of these binding legal obligations on drug manufacturers.

A. The Advisory Opinion Is Contrary to Section 340B.

The Advisory Opinion's interpretation of Section 340B—which the government tellingly defends on largely procedural grounds—is wrong.

1. Section 340B Does Not Require Drug Manufacturers to Deliver Discounted Drugs to Contract Pharmacies.

Section 340B imposes one duty on drug manufacturers—to "offer each covered entity covered outpatient drugs for purchase at or below" discounted prices calculated according to a prescribed statutory formula. 42 U.S.C. § 256b(a)(1). The statute's exhaustive list of fifteen types of healthcare providers that qualify as

"covered entities" does not include "contract pharmacies," a term that appears nowhere in Section 340B. *Id.* § 256b(a)(4); *see supra* pp. 4–6. In the Advisory Opinion, however, HHS "conclude[d] that to the extent contract pharmacies are acting as agents of a covered entity, a drug manufacturer in the 340B Program is obligated to deliver [340B-priced] drugs to those contract pharmacies and to charge the covered entity no more than the 340B ceiling price for those drugs." ADVOP_000001, 08. But that conclusion represents a stark departure from the plain meaning of Section 340B and is not entitled to *Chevron* deference, because Congress has not delegated HHS authority to make rules "to carry out all the provisions of the 340B program." *Pharm. Rsch. & Mfrs. of Am.*, 43 F. Supp. 3d at 42; *see also Mercy Cath. Med. Ctr.*, 380 F.3d at 155.

(a) The Statute's Text, Structure, and Legislative History Refute HHS's Contract Pharmacy Rule.

Congress took care in delineating the categories of covered entities entitled to receive 340B discounts. And the statutory text shows that this list is exclusive, because the statute states that the term "covered entity" "*means*" the itemized list of provider categories. 42 U.S.C. § 256b(a)(4) (emphasis added). Particularly when Congress used "means" and not a more open-ended verb like "includes," the list is exclusive. *See Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 162 (2012) ("Congress used the narrower word 'means' in other provisions … when it wanted to cabin a definition to a specific list of enumerated items."); *see also Robinson v.*

Napolitano, 554 F.3d 358, 365 (3d Cir. 2009) (applying *expressio unius* canon, which "informs a court to exclude from operation those items not included in a list of elements that are given effect expressly by the statutory language.").

The exclusive nature of the list is underscored by the fact that the enumerated covered entities themselves are similar— "providers of safety net services"—and together quite different from large commercial entities like contract pharmacies. *Pharm. Rsch. & Mfrs. of Am. v. HHS*, 138 F. Supp. 3d 31, 34 (D.D.C. 2015) (quoting *Astra*, 563 U.S. at 113); *see Barnhart v. Peabody Coal Co.*, 537 U.S. 149, 168 (2003) (explaining that where "items expressed are members of an associated group or series," courts infer that "items not mentioned were excluded by deliberate choice, not inadvertence") (internal quotation marks omitted). Section 340B even draws careful distinctions between *types* of covered entities: Where a covered entity "is a distinct part of a hospital, the hospital shall not be considered a covered entity." 42 U.S.C. § 256b(a)(6). Nor has that list been static. In 2010, Congress amended Section 340B to add three categories of providers—certain types of "children's hospital[s]," "free-standing cancer hospital[s]," and "critical access hospital[s]"—to the list of covered entities. *See id.* § 256b(a)(4)(M)–(O). To add for-profit contract pharmacies to this list of enumerated covered entities would obliterate Congress's careful work.

The statutory text and structure further demonstrate that Section 340B's enumerated list of covered entities does not *also* sweep in the covered entities' agents,

as the Advisory Opinion suggests. For one thing, a different provision of Section 340B specifically addresses agents acting on behalf of covered entities. *See id.* § 256b(d)(3)(B)(b)(i) (addressing claims asserted "on behalf of covered entities by associations or organizations representing the interests of … covered entities"). Moreover, in another portion of the same law that created Section 340B, Congress specifically prescribed special treatment for commercial agency arrangements. *See* Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 603(a)(1), 106 Stat. at 4974, *codified at* 38 U.S.C. § 8126(h)(3)(A) (addressing treatment for discounted drugs purchased by a federal agency but "delivered through … a commercial entity operating under contract with such agency"). And Section 340B likewise prescribes rules for "distributors" and "wholesalers" acting on behalf of covered entities. *See* 42 U.S.C. § 256b(d)(2)(B)(iv) (describing an identification system for "distributors"); *id.* § 256b(d)(1)(B)(v) (describing an auditing system for "wholesalers").

Congress thus plainly addressed agency and agency-type relationships elsewhere in Section 340B and related statutes. Yet when listing the entities to which manufacturers must "offer" 340B-discounted drugs, Congress specified only an enumerated list of covered entities without mentioning covered entities' agents—which thus represents a deliberate choice that the Advisory Opinion disregards by expanding the list to include contract pharmacies. *See Barnhart v. Sigmon Coal Co.*, 534 U.S. 438, 452 (2002) (where "Congress includes particular language in one section of a

statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion") (internal quotation marks and citation omitted); *In re Visteon Corp.*, 612 F.3d 210, 224 (3d Cir. 2010) ("[I]t is generally presumed that Congress acts intentionally and purposefully when it includes particular language in one section of a statute but omits it in another." (quoting *BFP v. Resol. Tr. Corp.*, 511 U.S. 531, 537 (1994)).

Moreover, Section 340B's remedial provisions illustrate that 340B pricing extends only to covered entities—and not to contract pharmacies. Under Section 340B, manufacturers that fail to offer discounted drugs may face administrative "claims by covered entities that they have been overcharged." 42 U.S.C. § 256b(d)(3)(A). HHS likewise can impose penalties on a manufacturer that knowingly and intentionally "charges a covered entity a price for purchase of a drug that exceeds the [statutory] maximum." *Id.* § 256b(d)(1)(B)(vi)(III). But when a manufacturer declines to provide a 340B discount (and instead charges standard commercial prices) for drugs shipped to a contract pharmacy, a covered entity is not "overcharged"—indeed, it typically is not charged at all under the standard "replenishment" model described above. This underscores that such arrangements fall outside the scope of manufacturers' statutory obligations.

Finally, legislative history confirms that Congress did not intend to require manufacturers to provide 340B-priced drugs to contract pharmacies. In 1992, when

reviewing the bill that eventually enacted Section 340B, Congress considered expressly requiring manufacturers to provide discounts for drugs "purchased and dispensed by, *or under a contract entered into for on-site pharmacy services with*," a covered entity. S. Rep. No. 102-259, at 2 (1992) (quoting S. 1729, 102d Cong. (1992)) (emphases added). Because Congress explicitly *declined* to require 340B pricing for prescriptions dispensed by on-site contract pharmacies, Section 340B cannot be interpreted as requiring manufacturers to deliver 340B-priced drugs to *all* contract pharmacies.

(b) The Advisory Opinion's Contrary Interpretation of Section 340B Is Wrong.

Ignoring the statute's plain meaning, the Advisory Opinion reasons that drugs delivered to contract pharmacies are nevertheless "purchased by" covered entities and subject to 340B pricing. ADVOP_000001, 06. According to HHS, when 340B-priced drugs are "purchased by" covered entities, manufacturers must agree to provide them to *any* location, including even the "lunar surface."[12] ADVOP_000003.

But Section 340B's only requirement of manufacturers is that they "offer" discounted drugs to covered entities. *See* 42 U.S.C. § 256b(a)(1). Section 340B separately requires the Secretary to enter into PPAs addressing what manufacturers

[12] Section 340B's prohibition on diversion belies this conclusion. Congress expressly disallowed the transfer of 340B-priced drugs to entities other than the statute's enumerated covered entities. *See* 42 U.S.C. § 256b(a)(5)(B).

should be paid for drugs "purchased by" a covered entity, *id.*, but that requirement imposes no obligation on manufacturers.

The Advisory Opinion also relies on principles of state agency law to insist that a drug is "purchased by" a covered entity when the prescription is filled at a contract pharmacy and provided to a patient. *See* ADVOP_000001, 06. Even assuming contract pharmacies are the agents of covered entities—a leap that HHS made without support or reasoned explanation, and for which no deference is warranted, *see Knapik v. Ashcroft*, 384 F.3d 84, 88 (3d Cir. 2004); *United Food & Com. Workers Int'l Union Loc. 400 v. NLRB*, 222 F.3d 1030, 1035 (D.C. Cir. 2000)—the plain language of the statute indicates that Congress did *not* require manufacturers to provide 340B-priced drugs to entities falling outside the categories of covered entities specifically listed in the statute. Because Section 340B only requires manufacturers to "offer" 340B-priced drugs to a defined list of covered entities, the Advisory Opinion's rule to provide such drugs to contract pharmacies is contrary to Section 340B.

2. Section 340B Does Not Prohibit Manufacturers From Imposing Conditions on Providing Discounted Drugs to Contract Pharmacies.

Nor does Section 340B restrict manufacturers from imposing conditions on the provision of 340B-priced drugs to contract pharmacies. The Advisory Opinion thus again conflicts with Section 340B by concluding otherwise. *See* ADVOP_000002, 05. Nothing in the statute supports HHS's naked assertion that a drug manufacturer's

offer of 340B pricing cannot include reasonable conditions on the delivery of the drugs (as, for example, Sanofi has done in its integrity initiative).

When stating that manufacturers must "offer" discounted pricing to covered entities, Section 340B does not define the term "offer." The word thus carries its ordinary meaning. *See Abraham v. St. Croix Renaissance Grp.*, 719 F.3d 270, 277 (3d Cir. 2013). To "offer" means to "manifest[] … willingness to enter into a bargain," Restatement (Second) of Contracts § 24 (1981), or to "present[] something for acceptance," *Offer*, Black's Law Dictionary (11th ed. 2019); *see also Fletcher-Harlee Corp. v. Pote Concrete Contractors, Inc.*, 482 F.3d 247, 250 (3d Cir. 2007) (repeating Second Restatement definition). In other words, an offer is one party's "propos[al] to the other [of] the promise which it will make for a certain consideration, or … the consideration which it will give for a certain promise." 1 Williston on Contracts § 4:3 (4th ed. May 2021 update).

The ordinary meaning of the word "offer" hardly precludes imposing conditions on accepting a covered entity's requests that Sanofi provide 340B-priced drugs to contract pharmacies. Except for the price, Section 340B does not purport to specify any of the terms under which manufacturers must "offer" 340B-priced drugs to covered entities. There is thus no support in the statute for the Advisory Opinion's conclusion that any additional conditions are impermissible.

Indeed, even HHS concedes that *some* conditions on a manufacturer's offer are permissible under Section 340B. For example, HHS has long advised that manufacturers may condition an offer of 340B-priced drugs on a covered entity's provision of "standard information." Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. 25,110-01, 25,114 (May 13, 1994) (ADVOP_000367). HHS has also opined that manufacturers may require that covered entities agree to "the manufacturer's normal business policies." *Id.* at 25,112, 25,113–14 (ADVOP_000363–64, 367). And HHS guidance has approved of manufacturers placing limits on the quantity of drugs offered at a discounted price during shortages, so long as "340B providers are treated the same as non-340B providers." 340B Drug Pricing Program Notice, Release No. 2011-1.1 (May 23, 2012) (ADVOP_000394).

Sanofi's integrity initiative is another example of a permissible condition on the delivery of 340B-priced drugs. Sanofi places no conditions of the provision of 340B-priced drugs either to a covered entity's own in-house pharmacy or to a single, designated contract pharmacy, if the covered entity has no in-house pharmacy. For "those covered entities that do not have access to appropriate 'in-house' pharmacy services," Sanofi's integrity initiative is thus fully consistent with HHS's 1996 guidance, which permitted covered entities to use "one pharmacy contractor per entity" to receive 340B-discounted drugs. 61 Fed. Reg. at 43,555 (ADVOP_000376).

The only condition Sanofi imposes is that covered entities must provide the minimal data Sanofi requests if they wish to use additional contract pharmacies. *See* Del Medico Decl. Ex. 1, Letter from G. Gleeson (July 2020) (ADVOP_002127–28); *id.* Ex. 2, Letter from A. Gluck to Secretary Azar (Aug. 13, 2020); *id.* Ex. 3, Letter from G. Gleeson (Aug. 2020); *id.* Ex. 4, Letter from G. Gleeson (Sept. 2020); *id.* Ex. 5, Letter from A. Gluck and G. Gleeson (Sept. 2020); *id.* Ex. 7, "Understanding Sanofi's 340B Data Reporting Requirements." This is plainly a reasonable condition, when providing this information through Sanofi's program imposes no logistical or financial burden on covered entities (who already provide this information to insurance companies), and when no party has ever denied that Sanofi's program can help eliminate duplicate discounting—which Congress expressly prohibited. *See* 42 U.S.C. § 256b(a)(5)(B). Particularly when manufacturers are not even required to offer 340B-priced drugs to covered entities through contract pharmacies, Sanofi's integrity initiative is a permissible condition under Section 340B—and illustrates how the Advisory Opinion's contrary rule improperly departs from the statute.

B. The Advisory Opinion Is Arbitrary and Capricious.

Not only is HHS's interpretation of Section 340B incorrect, but the Advisory Opinion is arbitrary and capricious in at least three respects.

1. The Administrative Record Contains No Evidence Supporting an Agency Relationship Between Covered Entities and Contract Pharmacies.

The linchpin of the Advisory Opinion is HHS's conclusion that "contract pharmacies are acting as agents of a covered entity." ADVOP_000001, 06. But the administrative record contains no evidence supporting this critical assumption—no exemplar contracts between covered entities and contract pharmacies, no facts on how such relationships typically operate, and not even any recognition that these relationships can vary. The absence of evidence in the record supporting this critical finding is arbitrary and capricious. *See Prometheus Radio Project v. FCC*, 373 F.3d 372, 390, 408, 419, 435 (3d Cir. 2004) (holding arbitrary and capricious an agency decision based on an "unsupported" or "unjustified assumption" rather than "substantial evidence"); *Christ the King Manor, Inc. v. HHS*, 730 F.3d 291, 314 (3d Cir. 2013) (holding agency action arbitrary and capricious because court could not "discern from the record a reasoned basis for the agency's decision").

The Advisory Opinion's only support for this critical point is the bald assertion from HHS's 1996 guidance that "the covered entity and contract pharmacy … function as principal-agent." ADVOP_000006. But that 1996 guidance expressly disclaimed any sort of blanket conclusion about covered entities' relationships with contract pharmacies, instead recognizing that "the form of the relationship" between

each contract pharmacy and covered entity may vary and "will be dictated by the terms of the contract." ADVOP_000375.

Given this earlier guidance, HHS had an obligation to gather evidence on the nature of covered entities' relationships with contract pharmacies before stating any definitive conclusions on the matter. But the administrative record inexplicably provides no basis for HHS to conclude that covered entities typically fulfill "[a]n essential element of agency"— "the principal's right to control the agent's actions." *Hollingsworth v. Perry*, 570 U.S. 693, 713 (2013) (quoting Restatement (Third) of Agency § 1.01, cmt. f (2006)). The Advisory Opinion provides no explanation or examples of why state agency law compels the conclusion that contract pharmacies act as agents of covered entities identified in Section 340B. Nor could such an interpretation be applied in a consistent way. The status of any particular relationship between a covered entity and a contract pharmacy is fact-specific and dependent on potential variations in state law and the individual contracts. But the government has identified no evidence that it considered how even *one* such arrangement amounted to an agency relationship in reaching its conclusions. The crux of the Advisory Opinion—that contract pharmacies act as covered entities' agents—thus rests on a house of cards, supported by a mere assumption as opposed to record evidence and reasoned decision-making. *See Christ the King Manor, Inc.*, 730 F.3d at 314.

Nor can this crucial assumption be justified as a matter of "agency expertise," as the Advisory Opinion attempts. *See* ADVOP_000004–05. HHS lacks any special expertise in state agency law, and a "vague reference to 'experience' is not a 'reasoned explanation for [the agency's] assumption,'" *Larry Grant Constr. v. Mills*, 956 F. Supp. 2d 93, 98 (D.D.C. 2013) (quoting *Nat'l Gypsum Co. v. EPA*, 968 F.2d 40, 44 (D.C. Cir. 1992)).

2. HHS Failed to Reasonably Explain Its Conclusion That Section 340B Prohibits Any Conditions on the Delivery of 340B-Priced Drugs.

In concluding that Section 340B prohibits drug manufacturers from imposing *any* conditions on the delivery of discounted 340B-priced drugs to contract pharmacies, ADVOP_000005, HHS failed to appreciate that not all conditions are the same. Some conditions unquestionably *are* permissible despite not being mentioned in Section 340B, as even HHS has previously recognized.

Every delivery of 340B-priced drugs must be subject to some conditions—for example, the time and place of delivery, means of payment, who will accept the drugs upon delivery, etc. And HHS has also previously opined that routine data collection efforts are permissible under Section 340B. *See* 59 Fed. Reg. at 25,114 (ADVOP_000367) (noting that manufacturer requirements that "request standard information" are "appropriate contract provisions"). But according to the Advisory Opinion, even these straightforward conditions would now be unacceptable additions

to the requirements of the statute. Such a wooden rule is not the result of reasoned decision-making when the agency blinded itself to the facts and did not consider whether such conditions could be permissible.

Take Sanofi's integrity initiative, for example. This program was plainly on the agency's mind when it issued the Advisory Opinion. Indeed, when formulating the Advisory Opinion, HHS considered a letter sent by the American Hospital Association ("AHA") to Secretary Azar that complained about Sanofi's integrity initiative (among other things). *See* ADVOP_001084. Yet HHS inexplicably did *not* consider Sanofi's letter to Secretary Azar responding to AHA's concerns or Sanofi's other explanations of how the integrity initiative operated—as the Administrative Record does not include these materials.[13] The agency's choice to consider only some evidence, while ignoring evidence of how Sanofi's integrity initiative actually worked, was arbitrary and capricious. *See, e.g.*, *Genuine Parts Co. v. EPA*, 890 F.3d 304, 312–13 (D.C. Cir. 2018) ("It was arbitrary and capricious for EPA to rely on portions of studies in the record that support its position, while ignoring cross sections in those studies that do not."); *Cape Cod Hosp. v. Sebelius*, 630 F.3d 203, 211 (D.C. Cir. 2011) (an

[13] For example, Sanofi rebutted AHA's concerns about Sanofi's integrity initiative by explaining that duplicate discounts have become a widespread problem, that Sanofi's initiative does not burden covered entities, and that Sanofi's initiative complies with Section 340B. *See* Del Medico Decl. Ex. 2, Letter from A. Gluck to Secretary Azar (Aug. 13, 2020).

agency may not "deliberately or negligently exclude[] documents that may have been adverse to its decision" (internal quotation marks omitted)).

Had HHS actually considered how Sanofi's integrity initiative operates, it would have seen that the program requests anonymous, de-identified information that is a subset of what covered entities already provide to insurance companies—and, moreover, that covered entities incur no meaningful financial or logistical burden by participating in Sanofi's integrity initiative. The agency would also have seen that Sanofi's integrity initiative is highly effective in protecting against unlawful duplicate discounts. But HHS closed its eyes to all of this when issuing the Advisory Opinion, which was arbitrary and capricious. *See Prometheus Radio Project*, 373 F.3d at 389.

Moreover, the Advisory Opinion bizarrely doubted whether manufacturers were expressing "sincere concerns" about the problem of the duplicate discounting. *See* ADVOP_000005 n.5. But the government itself has recognized that contract pharmacy arrangements "create complications in preventing … duplicate discounts,"[14] and government audits have uncovered numerous violations linked to contract pharmacies.[15] Sanofi and other manufacturers drew HRSA's attention to those findings when explaining the reasons for their new initiatives. *See* Del Medico Decl.

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[14] HHS Report, *supra*, at 1–2 (ADVOP_001403–04).

[15] HRSA, Program Integrity: FY19 Audit Results (updated Apr. 28, 2021), https://www.hrsa.gov/opa/program-integrity/audit-results/fy-19-results (finding widespread duplicate discounting at contract pharmacies).

Ex. 2, Letter from A. Gluck to Secretary Azar (Aug. 13, 2020); ADVOP_001077, 1047–49, 1144, 1370. HHS's failure to consider the problem of duplicate discounting—or to explain why that problem does not justify reasonable conditions like Sanofi's integrity initiative, when HHS has said manufacturers' review of claims data is the "best" way to identify duplicate discounts—was arbitrary and capricious. *See supra* p. 10 & n.10; *Jicarilla Apache Nation v. Dep't of Interior*, 613 F.3d 1112, 1119 (D.C. Cir. 2010) (holding agency action was arbitrary and capricious where the agency "failed to consider an important aspect of the problem").

In short, by concluding that any and all conditions not mentioned in Section 340B are impermissible, the Advisory Opinion was arbitrary and capricious. Some such conditions are unquestionably permissible, including with respect to the delivery of 340B-priced drugs to contract pharmacies. But HHS did not even *consider* these factual scenarios, including the facts about how Sanofi's integrity initiative actually operates. This was not reasoned decision-making.

3. HHS Failed to Acknowledge Its Shifting Position on Contract Pharmacies.

The Advisory Opinion also fails to acknowledge that HHS changed positions on contract pharmacies. As explained *infra* § I.C, the Advisory Opinion for the first time *requires* drug manufacturers to deliver 340B-priced drugs to an unlimited number of contract pharmacies and prohibits drug manufacturers from imposing reasonable conditions on their delivery of such drugs to contract pharmacies. Until the Advisory

Opinion, HHS had never construed the "must offer" provision to impose a binding obligation on manufacturers to ship 340B-priced drugs to contract pharmacies—indeed, the "must offer" provision did not exist when HHS issued its 1996 and 2010 guidance. Far from acknowledging its change in position, the Advisory Opinion insists that its new position has actually been "[t]he Department's consistent position over the past 24-plus years." ADVOP_000004. HHS's refusal to "display awareness that it is changing position," let alone to attempt to offer "good reasons for the new policy," is a hallmark of arbitrary and capricious agency action. *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009); *see also Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016).

C. The Advisory Opinion Is Procedurally Improper, Because It Did Not Go Through the APA's Notice-and-Comment Process.

Even if it were consistent with Section 340B and not arbitrary and capricious, the Advisory Opinion still must be set aside because it is procedurally improper—as it is a legislative rule that HHS issued without following the APA's notice-and-comment requirement. To suggest otherwise, the government mischaracterizes the extent to which the Advisory Opinion broke new ground for HHS.

1. The Advisory Opinion Contains a Legislative Rule Subject to the APA's Notice-and-Comment Requirement.

Agencies must comply with the APA's notice-and-comment procedure before issuing a "legislative rule." *Kisor v. Wilkie*, 139 S. Ct. 2400, 2420 (2019); *Perez v. Mortg.*

Bankers Ass'n, 575 U.S. 92, 96, 101 (2015). For such rules, agencies must publish a notice of "proposed rulemaking" in the Federal Register, respond to public comments, and publish the final rule in the Federal Register. 5 U.S.C. § 553(b)–(c). By contrast, agencies need not comply with this notice-and-comment procedure before issuing an "interpretative rule." *Id.* § 553(b)(A).

Whether a rule is "legislative" or "interpretive" is thus critical for purposes of the applicable procedural requirements. The distinguishing feature of a legislative rule is that it effects a "change in substantive law or policy," imposed through "binding obligations." *Gen. Elec. Co. v. EPA*, 290 F.3d 377, 382–83, 385 (D.C. Cir. 2002). An interpretive rule, in contrast, merely interprets existing obligations without imposing obligations with the force and effect of law. *See Dia Navigation Co. v. Pomeroy*, 34 F.3d 1255, 1264 (3d Cir. 1994) ("The critical difference between legislative and interpretative rules" is that "the former have the force and effect of law while the latter do not.") (internal quotation marks and citation omitted).

The Advisory Opinion contains a legislative rule because it imposes new obligations on drug manufacturers with the force and effect of law. In the Advisory Opinion, HHS used "mandatory language" through which "a binding intent is strongly evidenced." *Gen. Elec. Co.*, 290 F.3d at 383. On the first page of the Advisory Opinion, HHS states that drug manufactures are "*obligated* to deliver [their] covered outpatient drugs to … contract pharmacies." ADVOP_000001 (emphasis

added). The Advisory Opinion goes on to prohibit manufacturers from "condition[ing] sale of a 340B drug." ADVOP_000005. And it concludes by stating that manufacturers "may not refuse" to offer 340B pricing for drugs delivered to contract pharmacies. ADVOP_000008.

Moreover, the Advisory Opinion uses this mandatory language to fill what HHS itself has called "gaps" in Section 340B. 61 Fed. Reg. at 43,550 (ADVOP_000371). As explained above, nothing in Section 340B requires drug manufacturers to provide 340B-priced drugs to contract pharmacies. *See supra* pp. 24–28. Notwithstanding the government's strident claim that Section 340B displays a "total absence of ambiguity," Mot. 28, HHS itself has previously acknowledged that Section 340B has "many gaps" and "is silent as to permissible drug distribution systems" for 340B-priced drugs, 61 Fed. Reg. at 43,549, 43,550 (ADVOP_000370, 371)—meaning that Congress did *not* address whether drug manufacturers must distribute 340B-priced drugs to contract pharmacies. As the Third Circuit has held, "filling in gaps and resolving inconsistencies" in a "statutory scheme involves legislative rulemaking." *Dia Navigation Co.*, 34 F.3d at 1265.

Moreover, HHS will "accord[]" the Advisory Opinion "weight in the adjudicatory process" through the ADR Rule, which is another hallmark of a legislative rule. *See Shalala v. Guernsey Mem'l Hosp.*, 514 U.S. 87, 99 (1995). In the Advisory Opinion, the General Counsel of HHS spoke on behalf of the Department,

exercising authority delegated by the Secretary. *See* Statement of Organization, Functions, and Delegations of Authority, 85 Fed. Reg. 54,581-02, 54,583 (Sept. 2, 2020) (authorizing the Office of General Counsel to issue "advisory opinions to the public on questions of law"). The pool of ADR panelists will consist exclusively of HHS employees (including at least two members from the Office of General Counsel itself), *see* 42 C.F.R. § 10.20(a), who will all undoubtedly enforce the Advisory Opinion against drug manufacturers that allegedly fail to deliver 340B-priced drugs to contract pharmacies or impose conditions on such delivery.

The Advisory Opinion thus contains a legislative rule because it creates "a norm" by which drug manufacturers must "shape their actions," *Gen. Elec. Co.*, 290 F.3d at 383, to avoid sanctions and civil monetary penalties, 42 U.S.C. § 256b(d)(1)(B)(vi). The Advisory Opinion is procedurally unlawful as a result, because HHS undisputedly failed to comply with the APA's notice-and-comment requirement before issuing the Advisory Opinion. *Perez*, 575 U.S. at 96, 101 (explaining that legislative rules must be issued through notice and comment). For similar reasons, the Advisory Opinion violates the agency's Good Guidance Rule. *See* Dep't of Health and Human Servs., Good Guidance Practices, 85 Fed. Reg. 78,770-02 (Dec. 7, 2020).[16] And even more fundamentally, the Advisory Opinion exceeds the

[16] Although it became effective after the Advisory Opinion, the Good Guidance Rule prohibits HHS from "us[ing]" improper guidance documents in the future. *See* 85 Fed. Reg. at 78,785–86; 45 C.F.R. § 1.3(a)(2). That is exactly what HHS

scope of HHS's limited rulemaking authority in Section 340B because "HHS has not been granted broad rulemaking authority to carry out all the provisions of the 340B program." *Pharm. Rsch. & Mfrs. of Am.*, 43 F. Supp. 3d at 42 (noting that HHS's rulemaking authority under Section 340B is limited to establishing an ADR process, "precisely defin[ing] standards of methodology for calculating ceiling prices," and providing for "imposition of monetary civil sanctions").

2. The Government's Attempt To Downplay the Advisory Opinion Mischaracterizes HHS's Earlier Guidance.

The government contends that the Advisory Opinion does not contain a legislative rule because it merely restates HHS's prior interpretations of Section 340B in the agency's 1996 and 2010 guidance. *See* Mot. 21–24. The government's characterization of that earlier guidance is wrong for multiple reasons.

First, the Advisory Opinion is the first time that HHS prohibited manufacturers from imposing any conditions on the delivery of 340B-priced drugs to contract pharmacies. It is undisputed that the 1996 and 2010 guidance documents did not address in any way conditions on the delivery of 340B-discounted drugs to contract pharmacies.[17] The Advisory Opinion's prohibition on conditions also departs from

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will do by enforcing the Advisory Opinion in ADR proceedings. The government is thus wrong to suggest that the Advisory Opinion "could not possibly be subject to" the Good Guidance Rule. *See* Mot. 27.

[17] The government's reliance on a 2017 civil monetary penalties regulation is misplaced. Mot. 30. By its own terms, the regulation addresses only circumstances in which a manufacturer seeks to charge a "covered entity a price above the 340B ceiling

HHS's longstanding position that manufacturers *are* permitted to impose certain conditions, such as reasonable data-collection requests. *See* 59 Fed. Reg. at 25,112, 25,114 (ADVOP_000364, 367) (approving of requests for "standard information"). HHS's policies have sought to ensure merely that manufacturers did not "single out covered entities from their other customers for restrictive conditions that would undermine the statutory objective"—indicating that other conditions *are* permissible, in the agency's view. 340B Drug Pricing Program Notice, Release No. 2011-1.1 (May 23, 2012) (ADVOP_000394). Until the Advisory Opinion, HHS never sought to prohibit reasonable data-collection requests like those Sanofi makes through its integrity initiative.

Second, HHS's 1996 and 2010 guidance did not interpret—indeed, could not possibly have interpreted—manufacturers' obligation to "offer each covered entity covered outpatient drugs for purchase at or below" the statutory maximum price. 42 U.S.C. § 256b(a)(1). That language was added to Section 340B only in March 2010, *after* HHS had issued both guidance documents. *See* Pub. L. No. 111-148, § 7102, 124

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price" based on evidence of statutory noncompliance. 82 Fed. Reg. at 1223 (ADVOP_000075). That regulation separately contemplates explicitly "that the 340B discount [will be] provided through distribution arrangements made by the manufacturer"—indicating that a manufacturer can require that a covered entity agree to such "arrangements." 42 C.F.R. § 10.11.

Stat. at 825 (Mar. 23, 2010). Thus, the Advisory Opinion's interpretation of the "must offer" provision carries no historical pedigree.

Third, HHS previously conceded in the 1996 guidance that Section 340B has "many gaps" and is "silent as to permissible drug distribution systems." 61 Fed. Reg. at 43,550, 43,555 (ADVOP_000371, 376). Given the statute's silence as to the means of distribution, HHS maintained—*as late as 2020*—that it could not enforce any requirement that manufacturers deliver 340B-priced drugs to contract pharmacies: "HRSA Communications Director Martin Kramer wrote via email on July 8, 2020[,] that although the agency 'strongly encourages all manufacturers to sell 340B priced drugs to covered entities through contract pharmacy arrangements,' 'HRSA's current authority to enforce certain 340B policies … is limited' because Congress has not granted it 'comprehensive regulatory authority' 'to develop enforceable policy that ensures clarity in program requirements.'" *Am. Hosp. Ass'n v. HHS*, 2021 WL 616323, at *3 (N.D. Cal. Feb. 17, 2021); *see* Tom Mirga, HRSA Says Its 340B Contract Pharmacy Guidance Is Not Legally Enforceable, 340B Report (July 9, 2020) (ADVOP_001592–93) (quoting similar statement from HRSA). In a December 2020 report, moreover, the GAO noted that HRSA had stopped auditing contract pharmacies for diversion violations "because the 340B statue does not address

contract pharmacy use."[18] As a result, the Advisory Opinion's claim that the statute imposes an unambiguous and unqualified requirement that manufacturers deliver 340B-priced drugs to contract pharmacies cannot be understood to reiterate a prior agency position. Previously, the agency stated that such a rule was *not* enforceable under the statute.

Fourth, the Advisory Opinion departs from the 1996 and 2010 guidance by articulating for the first time that Section 340B *requires* manufacturers to deliver 340B-priced drugs to an *unlimited* number of contract pharmacies. As noted above, the 1996 guidance *permitted* covered entities to use only one contract pharmacy. *See* 61 Fed. Reg. at 43,551 (ADVOP_000372). The 2010 guidance then *permitted* covered entities to use an unlimited number of contract pharmacies. *See* 75 Fed. Reg. at 10,273 (ADVOP_000387). But it was only in the Advisory Opinion—issued, as the government admits, Mot. 11, in response to covered entities' complaints—that HHS *required* manufacturers to deliver 340B-priced drugs to *all* contract pharmacies.

Fifth, HHS's 1996 and 2010 guidance are themselves inconsistent, belying the government's assertion that the statute is unambiguous, Mot. 24; ADVOP_000002. The 1996 guidance permitted covered entities to use one contract pharmacy—but

[18] GAO, *HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements*, at 15–16, GAO-21-107 (Dec. 2020), https://www.gao.gov/assets/gao-21-107.pdf

rejected a proposal that "[c]overed entities should be permitted to contract with more than one site and contractor." 61 Fed. Reg. at 43,551 (ADVOP_000372). By declining to permit covered entities to use an *unlimited* number of contract pharmacy arrangements, that guidance would thus violate the government's current position on Section 340B and is also inconsistent with the 2010 guidance. *See* 75 Fed. Reg. at 10,273 (ADVOP_000387). Thus, HHS's claim that the Advisory Opinion reflects its "consistent position over the past 24-plus years," ADVOP_000004, is plainly incorrect.

Finally, the isolated sentences that the government cherry-picks from the 1996 and 2010 guidance documents do "not reflect the agency's fair and considered judgment on the matter in question." *Christopher*, 567 U.S. at 155; *Huerta v. Ducote*, 792 F.3d 144, 154 (D.C. Cir. 2015) ("[A]textual interpretations, unaccompanied by any reasoned agency analysis, deserve no judicial deference."). True, the 1996 and 2010 guidance stated that "the statute directs the manufacturer to sell the drug at the discounted price" and "we see no basis on which to conclude that section 340B precludes this type of transaction or otherwise exempts the manufacturer from statutory compliance." 61 Fed. Reg. at 43,549–50 (ADVOP_000370–71); 75 Fed. Reg. at 10,278 (ADVOP_000392). But those offhand remarks are not accompanied by any reasoned statutory interpretation supporting the government's present assertion that Section 340B required manufacturers to provide 340B-priced drugs to

contract pharmacies. Indeed, the Advisory Opinion itself noted "numerous requests" for an explanation of HHS's position on that question—which would not have been necessary if the earlier guidance actually resolved the matter. ADVOP_000001.

In stark contrast to the 1996 and 2010 guidance, the Advisory Opinion's eight pages of statutory interpretation speak with authority as HHS's definitive interpretation of manufacturers' obligations under Section 340B. As a matter of common sense, HHS's General Counsel would have had no reason to waste his time writing the Advisory Opinion if the agency had previously covered the same ground years earlier. The government's interpretation of its earlier guidance is thus nothing more than a convenient litigating position entitled to no weight. *See Christopher*, 567 U.S. at 155.

Because the Advisory Opinion broke new ground, the government's attempt to characterize it as an interpretive rule is unavailing. "Courts have long looked to the *contents* of the agency's action, not the agency's self-serving *label*, when deciding whether statutory notice-and-comment demands apply." *Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1812 (2019); *see also Limerick Ecology Action v. U.S. Nuclear Reg. Comm'n*, 869 F.2d 719, 735 (3d Cir. 1989). This is not the first time HHS has attempted to recast a legislative rule addressing Section 340B as mere interpretive guidance without legal force "independent of any binding effect that the statute itself may have." *See Pharm. Rsch. & Mfrs. Ass'n*, 138 F. Supp. 3d at 44. But as the court held on HHS's last

attempt, the agency may not "express its definitive position on a general question of statutory interpretation" through "a purportedly non-binding Interpretive Rule." *Id.* at 47. And "the agency overseeing Medicare can't evade its notice-and-comment obligations for new rules that bear the 'force and effect' of law," like the Advisory Opinion, "by the simple expedient of 'call[ing]' them mere 'statements of policy.'" *Allina*, 139 S. Ct. at 1819. Because the Advisory Opinion likewise imposes binding new legal obligations on drug manufacturers, *see supra* pp. 41–44, the Advisory Opinion is a legislative rule regardless of the government's label for it.[19]

3. The Advisory Opinion Is Final Agency Action.

The government's contention that the Advisory Opinion is not final agency action fails for similar reasons.[20] The Advisory Opinion conclusively establishes manufacturers' legal obligations by, for the first time, requiring manufacturers to

[19] Nothing in *Pennsylvania Department of Human Services v. United States*, 897 F.3d 497 (3d Cir. 2018), supports the government's contention that the Advisory Opinion is an interpretive rule, *see* Mot. 25–26. Unlike the Advisory Opinion, which fills a statutory gap through a rule of general applicable with the force and effect of law, the guidance in that case merely "provid[ed] an example of how the agency applies its rule in practice." *Id.* at 505. The same is true of *Shalala*, 514 U.S. at 99, where the Court concluded that an interpretive rule was not subject to notice and comment where it was consistent with regulations duly promulgated according to statutory authority.

[20] This is the case regardless of whether the Advisory Opinion is a legislative rule or an interpretive rule. *See, e.g.*, *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1021–22 (D.C. Cir. 2000) ("an agency's other pronouncements can, as a practical matter, have a binding effect" that satisfies the finality requirement).

deliver 340B-priced drugs to all contract pharmacies without any conditions. Sanofi's challenge to the Advisory Opinion is thus properly and timely before the Court.

In general, "two conditions must be satisfied for agency action to be 'final'": The action must "mark the 'consummation' of the agency's decisionmaking process," and it must be one "by which 'rights or obligations have been determined,' or from which 'legal consequences will flow.'" *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997). Courts in the Third Circuit review the following factors in determining whether agency action is final:

> 1) whether the decision represents the agency's definitive position on the question; 2) whether the decision has the status of law with the expectation of immediate compliance; 3) whether the decision has immediate impact on the day-to-day operations of the party seeking review; 4) whether the decision involved a pure question of law that does not require further factual development; and 5) whether immediate judicial review would speed enforcement of the relevant act.

Tomasi v. Twp. of Long Beach, 364 F. Supp. 3d 376, 390 (D.N.J. 2019) (quoting *Ocean Cnty. Landfill Corp. v. EPA*, 631 F.3d 652, 655 (3d Cir. 2011)). The Advisory Opinion satisfies each factor.

First, the Advisory Opinion represents HHS's "definitive position" on the questions of manufacturers' obligations to deliver 340B-priced drugs to contract pharmacies and their ability to impose reasonable conditions on these sales. *Tomasi*, 364 F. Supp. 3d at 390. With respect to both questions, the Advisory Opinion is the first time the agency addressed manufacturers' legal obligations under Section 340B.

See supra pp. 41–50. The Advisory Opinion is also the agency's final word, because there are no additional steps for the agency to take in deciding what Section 340B requires of manufacturers. *See* 85 Fed. Reg. at 54,583 (authorizing the Office of General Counsel to issue "advisory opinions to the public on questions of law"). The Advisory Opinion, in other words, "marks the 'consummation' of the agency's decision-making process." *Fang v. Dir. U.S. Imm. & Customs Enf't*, 935 F.3d 172, 180 (3d Cir. 2019).

Second, the Advisory Opinion has "the status of law with the expectation of immediate compliance." *Tomasi*, 364 F. Supp. 3d at 390. The Advisory Opinion has the status of law because it fills a statutory gap in Section 340B, *see Dia Navigation Co.*, 34 F.3d at 1265, and it contemplates immediate compliance because it contains mandatory language. *See supra* p. 42. And "legal consequences" certainly "flow" from the Advisory Opinion, including "expos[ure]" to penalties "in a future enforcement proceeding." *Sackett v. EPA*, 566 U.S. 120, 126–27 (2012); *see Del. Riverkeeper Network v. Sec'y Pa. Dep't of Env't Prot.*., 903 F.3d 65, 73 (3d Cir. 2018); *Minard Run Oil Co. v. U.S. Forest Serv.*, 670 F.3d 236, 248 (3d Cir. 2011).[21] Indeed, covered entities

[21] The government relies on *Minard* to argue that finality is a jurisdictional requirement. *See* Mot. 16. But the Third Circuit subsequently made clear that finality is only an element of an APA claim, not a jurisdictional requirement. *See Wayne Land & Min. Grp. LLC v. Del. River Basin Comm'n*, 894 F.3d 509, 525 n.10 (3d Cir. 2018); *accord Endo Pharm. Inc. v. FTC*, 345 F. Supp. 3d 554, 561 (E.D. Pa. 2018).

understand the Advisory Opinion has the status of law, as—"with [the agency's] Guidance in hand," *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1021–22, 1023 (D.C. Cir. 2000)—they have filed ADR claims alleging that Sanofi's integrity initiative violates the Advisory Opinion, *see* Del Medico Decl. Ex. 15, Petition for Declaratory and Injunctive Relief; *id.* Ex. 16, Motion for Preliminary Injunction.

Third, the Advisory Opinion has an "immediate impact on [manufacturers'] day-to-day operations." *Tomasi*, 364 F. Supp. 3d at 390. The practical effect of this new rule is not only to prohibit Sanofi's integrity initiative, but to expose Sanofi to hefty monetary penalties for refusing to acquiesce in the agency's unlawful action. *See* 42 U.S.C. § 256b(d)(1)(B)(vi). And manufacturers are immediately subject to such potential exposure. As noted above, the Advisory Opinion has already resulted in petitions filed against Sanofi under the ADR Rule. *See Tomasi*, 364 F. Supp. 3d at 390 (finding this factor satisfied where agency requirement "directly led to the … proceedings against plaintiffs' properties").

Fourth, the Advisory Opinion involves a "pure question of law that does not require further factual development." *Id.*; *see Univ. of Med. & Dentistry of N.J. v. Corrigan*, 347 F.3d 57, 69 n.7 (3d Cir. 2003) (noting final agency action expresses an agency's "definitive position" on a "pure question of law"). The Advisory Opinion asserts that its statutory interpretation is "dispositive" given "the lack of ambiguity in the plain text of the statute." ADVOP_000003. As a result, this Court's review under

the APA concerns what the Advisory Opinion calls a "straightforward textual interpretation," *id.*, another indication that the Advisory Opinion is final agency action. *See Cal. Cmtys. Against Toxics v. EPA*, 934 F.3d 627, 636 (D.C. Cir. 2019) (holding memo was final agency action because it "advance[d] what [the agency] believes is the *only permissible* interpretation of the statute").

Fifth, "immediate judicial review would speed enforcement" of Section 340B. *Tomasi*, 364 F. Supp. 3d at 390. Absent judicial review of the Advisory Opinion, manufacturers, covered entities, and the government "will continue wrangling over [its] meaning and enforceability." *Id.* The interest of the parties would be served by the Court resolving the proper interpretation of Section 340B and the legality of Sanofi's integrity initiative in this case.

The government cites a series of cases to suggest that the Advisory Opinion is not final agency action, Mot. 17, but none of these cases is on point here. All but one involved an agency merely restating a prior interpretation in an enforcement letter to a specific party. *See Menominee Indian Tribe of Wis. v. EPA*, 947 F.3d 1065, 1070 (7th Cir. 2020); *Clayton Cnty. v. FAA*, 887 F.3d 1262, 1263 (11th Cir. 2018); *Indep. Equip. Dealers Ass'n v. EPA*, 372 F.3d 420, 421 (D.C. Cir. 2004). The last case addressed an agency's publication of the *thirteenth edition* of a reference guide that had been "textually identical" for ten years. *See Golden & Zimmerman, LLC v. Domenech*, 599 F.3d 426, 429 (4th Cir. 2010). By contrast, the Advisory Opinion did not merely restate HHS's prior

interpretation of Section 340B, *see supra* pp. 44–49, but announced a new rule of general applicability to all manufacturers. *See* 5 U.S.C. § 551(4) (defining rule as "an agency statement of general … applicability and future effect designed to implement, interpret, or prescribe law or policy").

Because the Advisory Opinion is final agency action, Sanofi's challenge to the Advisory Opinion is also timely, contrary to the government's argument. *See* Mot. 19. For the first time, the Advisory Opinion requires drug manufacturers to deliver 340B-priced drugs to contract pharmacies and prohibits manufacturers from imposing reasonable conditions on these sales. *See supra* pp. 41–49. Because HHS's earlier guidance did not impose any legal obligations on drug manufacturers (or even address the permissibility of conditions), Sanofi could not have challenged HHS's interpretation of the statute any earlier. And even if Sanofi could have challenged the earlier guidance, Sanofi's challenge to HHS's interpretation of Section 340B in this case would be timely because "the agency has opened the issue up anew" in the Advisory Opinion, by offering "new justifications" for its conclusions with analysis far more detailed than any earlier statements. *CTIA-Wireless Ass'n v. FCC*, 466 F.3d 105, 110 (D.C. Cir. 2006).

* * *

In sum, the Court should set aside the Advisory Opinion because it is contrary to Section 340B, HHS acted arbitrarily and capriciously, and HHS issued the Advisory Opinion without complying with the APA's notice-and-comment requirement.

II. The Court Should Set Aside the ADR Rule.

In the ADR Rule, HHS established an unconstitutional administrative process to enforce the Advisory Opinion's new interpretation of Section 340B by authorizing unaccountable bureaucrats to resolve private disputes between manufacturers and covered entities through binding judgments, money damages, and injunctions—all without the defendants' consent. The ADR Rule should be set aside for four reasons.

First, HHS issued the ADR Rule without following the APA's notice-and-comment requirement. Although HHS gave notice of a rule regarding ADR proceedings in 2016, HHS withdrew that notice in early 2017—but then issued the ADR Rule without warning during the last month of the prior Administration, and without going through the notice-and-comment process again.

Second, the ADR Rule violates Article II of the Constitution because the members of the ADR Panels are principal officers under the Appointments Clause—which means they must be appointed by the President and confirmed by the Senate. But the ADR Rule requires neither, instead installing in this role agency employees who are not Senate-confirmed and, worse, are protected by for-cause removal

restrictions and thus not even politically accountable. Moreover, no Senate-confirmed agency employee has authority to review each ADR Panel's judgment.

Third, the ADR Rule violates Article III by granting these unaccountable bureaucrats the power to issue final judgments for money damages and equitable relief in order to resolve disputes concerning manufacturers' private rights to hold and alienate property. The Constitution reserves this authority to Article III courts.

Fourth, HHS authorized claims and remedies beyond its statutory authority and ignored several important aspects of the issue, and the ADR Rule is thus arbitrary and capricious.

A. The ADR Rule Violates the APA's Notice-and-Comment Requirement.

As another court has already held, HHS violated the APA's notice-and-comment requirement by rushing out the ADR Rule in response to political and litigation pressure at the end of the prior Administration. *See Eli Lilly*, 2021 WL 981350, at *10. The ADR Rule was thus a "surprise edict," because HHS failed to give notice and receive comments before finalizing it. *Id.*; *see* 5 U.S.C. § 553(b),(c).

In response, the government attempts to tie the ADR Rule to another proposed regulation that had received public comment—specifically, the NPRM that HHS issued in 2016. *See* ADR_000013. But as the *Eli Lilly* court held, the ADR Rule cannot rest on that NPRM, because HHS *withdrew* it in 2017—years before issuing the ADR Rule. As even HHS acknowledges, the NPRM "was removed" from the

Executive Branch's Unified Agenda of Regulatory and Deregulatory Actions, *id.*, which provides "uniform reporting" on "regulatory … activities" in the Executive Branch, *Eli Lilly*, 2021 WL 981350, at *8 n.8 (quoting the OIRA website). In fact, the Unified Agenda could not be more clear: The entry for the 2016 NPRM states "NPRM Withdrawn" as of 2017 and identifies the NPRM as a "Completed Action[]," a status reserved for "rulemakings that are being Withdrawn or ending their lifecycle with a regulatory action that completes the rulemaking." *Id.* at *8 & n.11 (quoting the Unified Agenda, *supra*).

HHS's own actions in the following years confirm that it had withdrawn the 2016 NPRM. Between 2016 and 2020, HHS took no steps to proceed with a rulemaking. On the contrary, as late as March 2020, an official speaking on behalf of HRSA informed a trade publication that HRSA "had no plans to create a binding ADR process" and "'does not plan to move forward on issuing a regulation.'" *Id.* at *8 (quoting 340B Report). Furthermore, although regulatory actions generally retain the same regulatory identification number ("RIN") throughout the rulemaking process, the ADR Rule was assigned a different RIN than the 2016 NPRM, which confirms that the 2016 NPRM "had been terminated." *Id.* at *9–10 & n.12.

No matter, the government argues, because HHS never published a "notice of withdrawal" in the Federal Register. *See* Mot. 47–48. But as the *Eli Lilly* court explained, the APA imposes no requirement that an agency publish notice of

withdrawal in the Federal Register, and "courts are not free to impose upon agencies specific procedural requirements that have no basis in the APA." 2021 WL 981350, at *9 (quoting *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 2385 (2020)).[22] Instead, "[b]ecause the 'object' of the APA is 'fair notice,' the relevant inquiry is whether, through their actions and statements, [the agency] effectively communicated a withdrawal of the proposed rule to the public." *Id.* (quoting L*ong Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 174 (2007)). Having withdrawn the 2016 NPRM, HHS could not rely on it as a shortcut around the APA for the ADR Rule. *Id.* at *10.

Even if the 2016 NPRM had not been withdrawn, the ADR Rule would still violate the APA because it not a "logical outgrowth" of the 2016 NPRM and thus cannot rest on that NPRM's notice-and-comment period. *See Council Tree Commc'ns, Inc. v. FCC*, 619 F.3d 235, 250 (3d Cir. 2010). Critical provisions of the ADR Rule were wholly absent from the NPRM. For example, the ADR Rule empowers panels to award equitable relief, issue binding judgments for money damages, and render precedential decisions, *see infra* pp.16–17, but no one would have known this was on the table because the NPRM mentions none of it. Nor did the NPRM suggest that

[22] For similar reasons, the government's suggestion that a withdrawal occurs only when the agency provides "a statement of decision" is nonsensical, and has no basis in the APA. Mot. 48.

ADR proceedings would be governed by the Federal Rules or that HHS would permit "claims that a manufacturer has limited the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price." ADR_000025.

In short, as held in *Eli Lilly*, the ADR rule is procedurally unlawful. This alone requires the Rule to be set aside, regardless of its other defects.

B. The ADR Rule Violates Article II.

Article II of the U.S. Constitution requires principal officers of the United States—but not inferior officers—to be appointed by the President with the advice and consent of the Senate. *See* U.S. Const. art. II, § 2, cl. 2; *Edmond v. United States*, 520 U.S. 651, 659–60 (1997). ADR panelists are principal officers who must be appointed by the President and confirmed by the Senate because they exercise sweeping authority with broad discretion, and their decisions are not subject to review by any superior within the Executive Branch. Under the ADR Rule, however, ADR panelists are instead appointed by the HHS Secretary and assigned to panels by the HRSA Administrator. The ADR Rule thus violates the Appointments Clause.

1. ADR Panelists Are "Officers of the United States."

The government concedes that ADR panelists are "Officers of the United States" subject to the Appointments Clause. *See* U.S. Const. art. II, § 2, cl. 2; Mot. 36.

First, ADR panelists "occupy a 'continuing' position established by law," not an "occasional or temporary" appointment, and there is no tenure limitation on the

panelists' appointment. *Lucia v. SEC*, 138 S. Ct. 2044, 2051 (2018) (quoting *United States v. Germaine*, 99 U.S. 508, 511–12 (1878)); *see* 42 U.S.C. § 256b(d)(3)(B)(i); 42 C.F.R. § 10.20.

Second, ADR panelists exercise "significant authority pursuant to the laws of the United States," *Lucia*, 138 S. Ct. at 2051 (quoting *Buckley v. Valeo*, 424 U.S. 1, 126 (1976) (per curiam)), because they have "all the authority needed to ensure fair and orderly adversarial hearings—indeed, nearly all the tools of federal trial judges," *id.* Under the ADR Rule, panelists exercise "significant discretion in determining relevant material to consider and the manner to conduct its evaluation," with "wide latitude" and "discretion in admitting evidence and testimony." 85 Fed. Reg. at 80,635, 80,636, 80,640–42 (ADR_000015, 16, 20–22). They conduct "evidentiary hearing[s] when there are material facts in dispute" and may sanction parties by "[e]xcluding evidence" or dismissing a proceeding. *Id.* at 80,645 (ADR_000025); 42 C.F.R. § 10.22(c), 10.23(a). And their decisions are precedential and binding on the parties. 85 Fed. Reg. at 80,634 (ADR_000014). Lest there be any doubt that ADR panelists are functionally equivalent to "federal trial judges," *Lucia*, 138 S. Ct. at 2051, the ADR proceedings are presumptively governed by the Federal Rules. 85 Fed. Reg. at 80,633, 80,641 (ADR_000013, 21); 42 C.F.R. § 10.23(b)–(c). Because they unquestionably exercise "significant authority" as defined by the Supreme Court, the ADR panelists are undisputedly officers of the United States.

2. ADR Panelists Are Principal Officers of the United States.

ADR panelists are also *principal* officers of the United States. Unlike inferior officers, "whose work is directed and supervised at some level by others who were appointed by Presidential nomination with the advice and consent of the Senate," principal officers answer to no superior Executive Branch officer but the President. *Edmond*, 520 U.S. at 663, 664–65. ADR panelists are principal officers because they (1) exercise final decisionmaking authority within the Executive Branch, (2) are not subject to the Secretary's supervision or oversight in reaching their decisions, and (3) can be removed only for cause.

First, the government does not dispute that ADR panelists render "final decision[s] on behalf of the United States." *Id.* at 665. The finality of their decisions follows from the plain text of Section 340B and the ADR Rule, which authorize ADR panelists to speak for the Executive Branch through "final agency decision[s]" that are "binding on the parties" and "precedential" within HHS, including for the Secretary himself. 42 U.S.C. § 256b(d)(3)(C); 42 C.F.R. § 10.24(d). Their decisions are not subject to review by the Secretary or any other agency actor. Indeed, HHS expressly declined to "incorporate an [administrative] appeals process" in the ADR Rule, 85 Fed. Reg. at 80,641 (ADR_000021), and the ADR Rule specifies that panel decisions can be invalidated only "by an order of a court," 42 C.F.R. § 10.24(d).

The finality of ADR panel decisions distinguishes this case from *Edmond*. In that case, the Supreme Court determined that Coast Guard Court of Criminal Appeals judges were inferior officers because "another Executive Branch entity, the Court of Appeals for the Armed Forces," exercised "control" over them. 520 U.S. at 664–65. The Court deemed it "significant" to inferior-officer status that officials could be "reverse[d]" by "another Executive Branch entity" and thus had "*no* power" to render a final decision. *Id.* But none of that is true here, because ADR panelists issue "final agency decisions" on behalf of HHS that cannot be reversed by the Secretary.

Many courts, including the Supreme Court, have confirmed after *Edmond*—including in cases the government invokes, Mot. 34–35—that Executive Branch review is critical to inferior officer status. In *Free Enterprise Fund v. PCAOB*, the Supreme Court held that board members were inferior officers because the Executive Branch's "oversight authority" included the power to "approv[e] and alter[]" their decisions. 561 U.S. 477, 486, 510 (2010). In *Association of American Railroads v. Department of Transportation*, the D.C. Circuit held that Surface Transportation Board arbitrators were principal officers because the relevant statute did not "provide any procedure by which the arbitrator's decision [was] reviewable by the STB." 821 F.3d 19, 39 (D.C. Cir. 2016). In *Intercollegiate Broadcasting System, Inc. v. Copyright Royalty Board*, the D.C. Circuit held that regulations made copyright royalty judges "principal officers" because, "unlike the judges in *Edmond*," their determinations were "final for

the executive branch." 684 F.3d 1332, 1340 (D.C. Cir. 2012); *see also Arthrex, Inc. v. Smith & Nephew, Inc.*, 941 F.3d 1320, 1331 (Fed. Cir. 2019), *cert. granted*, 141 S. Ct. 551 (2020) (finding patent judges to be principal officers in part because they issue final decisions "without any review by a presidentially-appointed officer"). Most recently, in *Fleming v. Department of Agriculture*, the D.C. Circuit treated ALJs as inferior officers because the Secretary of Agriculture could "step in and act as [a] final appeals officer in any case." 987 F.3d 1093, 1103 (D.C. Cir. 2021). These cases underscore the conclusion that, here, the finality of ADR panelists' decisions makes them principal officers.

Second, in exercising their duties, ADR panelists are not subject to supervision and oversight by the Secretary or any other presidentially-appointed officer. In fact, the Secretary *cannot* lawfully supervise ADR panelists because he lacks substantive rulemaking authority under Section 340B. *See Pharm. Rsch. & Mfrs. of Am.*, 43 F. Supp. 3d at 42–45. Because he cannot substantively direct ADR panelists, the Secretary has delegated "significant discretion" and "wide latitude" to ADR panelists, 85 Fed. Reg. at 80,635–36, 80,639–40, 80,642 (ADR_000015–16, 19–20, 22), including the power to decide in their own discretion how to conduct ADR proceedings, 42 C.F.R. § 10.23(a)–(b). And panel decisions are "precedential" within HHS, so they bind *even the Secretary* in all pending and future ADR disputes. 42 C.F.R. § 10.24(d).

This lack of supervision distinguishes this case from *Pennsylvania v. Department of Health & Human Services*, 80 F.3d 796 (3d Cir. 1996), which the government trumpets. *See* Mot. 34, 36–37. In *Pennsylvania*, the officials' authority (to review funding disallowances under the Child Support Enforcement Act) was "strictly limited by the statute and implementing regulations." 80 F.3d at 804 (citing 45 C.F.R. §§ 16.14, 205.40–43). Those regulations, since repealed, prescribed "the rules and procedures for calculating [relevant] error rates and for disallowing" federal payments, 45 C.F.R. § 205.43(a) (1995); procedures for reviewing cases, *id.* § 205.42(c); and substantive direction, including on the types of payments that would count as errors, *id.* § 205.42(d). And the regulations explicitly required the officials to adopt certain decisions made by a separate HHS panel or by the Secretary. *Id.* § 205.43(g)(1).[23] By contrast, ADR panelists are not subject to any comparable supervision in making their decisions. Although they are bound by the ADR Rule, that merely establishes the Board and authorizes it to entertain claims. Indeed, as noted, the ADR Rule disclaims

[23] These restrictions were so constraining that the parties in *Pennsylvania* stipulated that the officials, who were "bound by all applicable laws and regulations" of HHS and subject to the supervision of the Under Secretary, were not in "policy-making positions." *See* Appellees' Br. at 20, *Pennsylvania*, 80 F.3d 796 (No. 94-3692), 1994 WL 16166965, at *20 (citing 45 C.F.R. § 16.14); Statement of Organization, Functions, and Delegations of Authority, 53 Fed. Reg. 38,977-03, 38,977–78 (Oct. 4, 1988) (providing for the officials to be "supervised by the Under Secretary").

any intent to "strictly limit[]" ADR panelists, *cf. Pennsylvania*, 80 F.3d at 804, leaving them with nearly complete discretion over the proceedings.

Third, ADR panelists are not removable at will. The "power to remove officers" is a "powerful tool for control" that characterizes principal officers' authority over inferior officers. *Edmond*, 520 U.S. at 664; *see also Free Enter. Fund*, 561 U.S. at 510; *Pennsylvania*, 80 F.3d at 803 (holding Appeals Board members were inferior officers in part because they were removable by a superior Executive officer, including for "unacceptable performance"). But the ADR panelists are subject to no such control. Their responsibility for "finally resolving claims by covered entities" is prescribed by statute, meaning the Secretary cannot abridge their authority. 42 U.S.C. § 256b(d)(3)(B)(i); *see also id.* § 256b(d)(3)(C) (the panel decision "shall be a final agency decision."); *cf. Pennsylvania*, 80 F.3d at 803 (explaining that Appeals Board members were inferior officers because "the Secretary could altogether eliminate the powers of the Board that are at issue here"). Moreover, the ADR Rule provides that ADR panelists can be removed *only* "for cause," narrowly defined as a panelist's conflict of interest. 42 C.F.R. § 10.20(a); *see also* 85 Fed. Reg. at 80,634 (ADR_000014) ("HHS proposed that individuals serving on a 340B ADR Panel may be removed for cause. … In this final rule, if there is a conflict of interest … with respect to a claim, the 340B ADR Panel member will be removed from the 340B ADR Panel and replaced by another individual from the Board.").

The government contends that these removal restrictions do not matter because "the relevant consideration for constitutional purposes" is whether there are any constraints on removal "from the Board altogether." Mot. 38. But the government cites no authority for this proposition. And it is incorrect, because the ADR Rule limits removal in the only context in which ADR panelists exercise any authority—their service on ADR panels. The government's insistence that the Secretary may "remove an individual from a panel, or from the Board, at will—with or without a conflict of interest," *id.*, contradicts the ADR Rule and basic principles of officer removal. Any removal power that might be "incident to the power of appointment," *id.*, belongs to the individual that appointed the ADR panelists: the HRSA Administrator (not the Secretary), *see* 42 C.F.R. § 10.20(a)(1), whose power the government insists is not constitutionally relevant, *see* Mot. 38 n.6. Simply put, the regulation the government defends—one that "does not purport to place any restrictions" on removal, Mot. 37—is not the regulation the agency wrote.

The government's arguments that the Secretary can cure any Article II violation likewise imagines a different ADR Rule than the one HHS promulgated. The government contends, for example, that the Secretary could revoke the ADR panelists' authority and decide cases personally. *See* Mot. 36. But the Secretary could not remove ADR panelists from a specific assignment without cause. *See* 42 C.F.R. § 10.20(a). Nor does the ADR Rule authorize the Secretary to individually decide

cases. To make such a move, the ADR Rule's panel-membership requirements would need to be changed or revoked—which would require APA notice and comment. The government likewise argues that the Secretary could "rescind" the ADR rule to allow him to exercise supervisory authority. *See* Mot. 35. But unlike the special-counsel regulations at issue in *In re Grand Jury Investigation*, 916 F.3d 1047, 1052 (D.C. Cir. 2019), *see* Mot. 35–36, which were personnel regulations exempt from the APA's notice-and-comment requirement, *see* 916 F.3d at 1052, the ADR Rule cannot be withdrawn and replaced without "comply[ing] with the procedural requirements for new agency action." *DHS v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1908 (2020). The government's insistence that the Secretary could essentially revise the ADR Rule to cure its violation of Article II, moreover, violates the basic rule of administrative law that an agency itself, not lawyers in later litigation, must provide the justification for agency action. *See SEC v. Chenery Corp.*, 332 U.S. 194, 196 (1947); *W.R. Grace & Co. v. EPA*, 261 F.3d 330, 338 (3d Cir. 2001).

In short, the ADR Rule violates Article II because the ADR panelists are principal officers who have not been properly appointed.

C. The ADR Rule Violates Article III.

The ADR Rule also violates Article III of the U.S. Constitution, because it empowers ADR panels to exercise judicial powers in order to adjudicate disputes over private rights—which Article III reserves exclusively for the judiciary.

1. ADR Panels Exercise Judicial Powers.

A statute or regulation violates Article III if it "confer[s] the Government's 'judicial power' on entities outside Article III." *Stern v. Marshall*, 564 U.S. 462, 484 (2011). There can be little doubt that ADR panels "exercise[] the range of jurisdiction and powers normally vested only in Article III courts." *CFTC v. Schor*, 478 U.S. 833, 851 (1986).

Specifically, under the ADR Rule, covered entities may bring "an action for monetary damages or equitable relief against a manufacturer." 42 C.F.R. § 10.21(a)–(c); *Am. Hosp. Ass'n*, 2021 WL 616323, at *3, 6 (recognizing that covered entities' ADR actions bring "claims" for damages and equitable relief). And ADR panels also "make precedential and binding final agency decisions regarding [such] claims filed by covered entities." 42 C.F.R. § 10.20. Indeed, covered entities have already sought a preliminary injunction against Sanofi in the ADR process, illustrating that the panel's authority mimics the federal courts'. *See* Del Medico Decl. Ex. 16, Motion for Preliminary Injunction. The power to award such relief exceeds the scope of administrative review schemes the Supreme Court has approved. *See, e.g.*, *Schor*, 478 U.S. at 853 ("CFTC orders … are enforceable only by order of the district court."). Moreover, the ADR panels use the tools of federal courts in exercising these authorities. They take evidence, hear testimony, apply the Federal Rules, and issue

precedential decisions. *See* 42 C.F.R. § 10.23(a), (b). All of this underscores that the ADR panels exercise Article III authority. *Schor*, 478 U.S. at 851.

Disagreeing, the government downplays the authority wielded by ADR panels. According to the government, there is no Article III problem because ADR panels cannot order relief or even render "self-effectuating" decisions—the ADR Rule instead directs panels to "'submit[]'" their decisions "'to HRSA for appropriate action regarding refunds, penalties, removal, or referral to appropriate Federal authorities.'" Mot. 39–40 (quoting 42 C.F.R. § 10.24(e)). The government interprets this language to mean that an ADR panel can determine compliance and find liability under Section 340B but cannot impose any remedies. *Id.* However, the ADR Rule explicitly empowers panels to adjudicate not simply questions of compliance and liability but rather "*action[s]* for monetary damages or equitable relief."[24] 42 C.F.R. § 10.21(a) (emphasis added); *see id.* § 10.21(f); 85 Fed. Reg. at 80,635 (ADR_000015). Indeed, "[t]he ADR Rule repeatedly discusses the availability of equitable relief," *Am. Hosp. Ass'n*, 2021 WL 616323, at *6, and provides that ADR panels will resolve "proceeding[s] for damages," in which the petitioner must "introduce evidence

[24] The ADR panelists are thus unlike members of the Department of Labor's Benefits Review Board in *Kalaris v. Donovan*, 697 F.2d 376 (D.C. Cir. 1983). *See* Mot. 44–45. Those Board members lacked "essential attributes of judicial power," having only "limited powers to issue compensation orders [with] … resort to an appropriate District Court to have its orders enforced." 697 F.2d at 388.

sufficient to support its claim for damages," 42 C.F.R. § 10.21(f). These provisions would make no sense if ADR Panels were powerless to award damages or equitable relief, as the government now argues to avoid an Article III problem.

Attempting to give these provisions meaning, the government contends that the ADR Rule authorizes "equitable relief" only so a panel can "declare specified conduct to be unlawful—the equivalent of a cease-and-desist order." Mot. 40. But the ADR Rule authorizes as a remedy not "declaratory relief" but "*equitable* relief" without limitation. 42 C.F.R. § 10.20, 10.21(a)–(b) (emphasis added). By definition, "equitable relief" includes "injunction[s]." Black's Law Dictionary (11th ed. 2019); *Mertens v. Hewitt Assocs.*, 508 U.S. 248, 256 (1993). Unsurprisingly, the only court to have ruled on this question determined that the "equitable relief" "repeatedly discusse[d]" by the ADR Rule includes "forward-looking relief" (such as an injunction) and not simply "retrospective remedies" (such as a determination that a manufacturer has violated the statute), as the government now argues. *Am. Hosp. Ass'n*, 2021 WL 616323, at *6 (internal quotation marks omitted).

Moreover, the ADR panels' power to issue binding decisions is not subject to any approval by HRSA, as the government suggests. Mot. 40. Instead, the decisions are "final agency decision[s]," 42 C.F.R. §§ 10.20, 10.24(d)—which means they are "the 'consummation' of the agency's decisionmaking process" and determine the parties' "rights or obligations." *Ocean Cnty. Landfill*, 631 F.3d at 655 (quoting *Bennett*,

520 U.S. at 177–78). ADR panel decisions would not be "final" if a separate remedial phase needed to follow. *Cf. Marshak v. Treadwell*, 240 F.3d 184, 190 (3d Cir. 2001) ("A finding of liability that does not also specify damages is not a final decision.") (citation omitted).

Instead, under the ADR Rule, HRSA's role is limited to ordering additional remedies: "appropriate action regarding refunds, penalties, removal, or referral to appropriate Federal authorities," such as for civil monetary penalties. 42 C.F.R. § 10.24(e); *see* 85 Fed. Reg. at 80,642 (ADR_000022). The ADR Rule does not authorize HRSA to modify or nullify the binding and precedential final agency decisions already made by ADR panels, including decisions to award equitable relief and damages. And even if the ADR Rule gave such authority to HRSA (as the government now argues it does), that would not solve the problem—because HRSA is not an Article III court.

2. ADR Panels Adjudicate Disputes Over Private Rights.

In exercising these powers under the ADR Rule, ADR panels determine disputes over private rights, another hallmark of Article III authority. As the Supreme Court has explained, disputes "made of the stuff of the traditional actions at common law tried by the courts at Westminster in 1789" must be decided by "Article III judges in Article III courts." *Stern*, 564 U.S. at 484 (internal citations and quotation marks omitted). Such disputes include those over private rights—which are rights "between

private parties," *id.* at 491, concerning "the liability of one individual to another under the law as defined." *N. Pipeline Const. Co. v. Marathon Pipe Line Co.*, 458 U.S. 50, 70 (1982) (plurality op.) (citation omitted). These quintessential rights that "lie at the core of the historically recognized judicial power" include the freedom of contract and the right to hold and transfer private property. *Id.*; *Newland v. Marsh*, 19 Ill. 376, 383 (1857) ("The legislative power … cannot directly reach the property or vested rights of the citizen, by providing for their forfeiture or transfer to another, without trial and judgment in the courts.").

An ADR panel's judgment ordering Sanofi to convey its drugs to another private party at a discounted price adjudicates Sanofi's private rights because it determines Sanofi's "liability" to covered entities "under the law as defined" in Section 340B. *N. Pipeline*, 458 U.S. at 70. But Sanofi's rights to hold and alienate its drugs, on the terms of its choice, existed under state law before Congress enacted Section 340B and were not extinguished by Section 340B. These are private rights because they are "matter[s] which, from [their] nature, [are] the subject of a suit at the common law." *Murray's Lessee v. Hoboken Land & Improvement Co.*, 59 U.S. (18 How.) 272, 284 (1855).

The Supreme Court's decision in *Granfinanciera* confirms as much. There, the Court held that fraudulent conveyance actions under the Bankruptcy Code concern private rights that must be resolved by Article III courts, because the federal claim

"resemble[d]" a state-law contract claim concerning the amount one private party owes another, *see N. Pipeline*, 458 U.S. at 70—a "paradigmatic private right[]." *Granfinanciera S.A. v. Nordberg*, 492 U.S. 33, 56 (1989). Like the fraudulent conveyance claim in *Granfinanciera*, covered entities' claims against manufacturers in ADR proceedings are effectively state-law contract claims—with there even being a contract (the PPA) that requires offering 340B pricing to covered entities. *See* PPA Addendum, ADVOP_000055. Indeed, the pending ADR petition against Sanofi alleges that Sanofi is not offering drugs on the terms the PPA requires. *See* Del Medico Decl. Ex. 15, Petition for Declaratory and Injunctive Relief ¶¶ 30–32, 46. Just like the federal fraudulent conveyance claim in *Granfinanciera*, the ADR petition sounds in common-law breach of contract and, thus, "lie[s] at the protected core of Article III judicial power." *Granfinanciera*, 492 U.S. at 56 (internal quotation marks omitted).

The government contends that the disputes presented to ADR panels "are entirely creatures of the 340B Program" and, thus, are matters of "public right" that need not be resolved by Article III courts.[25] Mot. 43. Indeed, public rights—which are "integrally related to particular Federal Government action," *Stern*, 564 U.S. at

[25] The government asserts that private rights "sometimes" may be adjudicated by "agencies serving as adjuncts to" Article III courts. Mot. 45 n.8. But the government makes no argument that the ADR panelists qualify as such adjuncts.

491—can be adjudicated by an agency. *See Oil States Energy Servs., LLC v. Greene's Energy Grp.*, 138 S. Ct. 1365, 1374 (2018). But the government misunderstands the nature of the rights at issue. Although Section 340B creates covered entities' entitlement to drug discounts, it is *Sanofi's* private rights that are at stake in ADR proceedings, because those rights predated Section 340B and were not extinguished by the statute.

The government's reliance on *Thomas v. Union Carbide Agricultural Products Co.*, 473 U.S. 568 (1985), is therefore misplaced, because Sanofi's rights that will be adjudicated do not "derive[] from a federal regulatory scheme." *Stern*, 564 U.S. at 490. *Union Carbide* involved a public right to compensation that was created by, and existed exclusively under, a federal statute—the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"). *See* 473 U.S. at 584. Critically, as the government recognizes, Mot. 43, FIFRA created this right only after the registrant had, "[a]s a matter of state law," "extinguished" its preexisting "property rights" in the data by submitting it to the government. *Union Carbide*, 473 U.S. at 584. By contrast, Sanofi's underlying private rights to hold and alienate property on terms of its choosing exist under state law, in the absence of Section 340B or any other provision of federal law. Sanofi's preexisting rights have not been extinguished as a matter of state law. *See* PPA § VII(f), ADVOP_000052 ("Nothing in the Agreement shall be construed as a waiver or relinquishment of any legal rights of the Manufacturer … under … State

laws."). Thus, the rights at stake before ADR panels are Sanofi's private rights, and *Union Carbide* does not govern.

Disregarding that *Union Carbide* has "rather limited scope" and "should not be read too expansively," *Beard v. Braunstein*, 914 F.2d 434, 440 (3d Cir. 1990), the government contends that Congress may authorize non-Article III adjudication anytime it "creates new rights" under a federal statute or a federal regulatory scheme. Mot. 42. But that cannot be right because the claim at issue in *Granfinanciera* was created by federal statute but nevertheless involved a private right. *See* 492 U.S. at 56. The government's position would also mean that federal patent infringement claims (as creatures of statute) could be decided by a non-Article III court, even though it has long been recognized that such claims belong in Article III courts because they resemble traditional common-law actions between private parties. *See, e.g.*, *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 377 (1996); *Markman*, 52 F.3d 967, 992 (Fed. Cir. 1995) (Mayer, J., concurring in the judgment); *cf. Oil States*, 138 S. Ct. at 1378 (emphasizing that the Court's holding did not mean that infringement claims could be adjudicated outside an Article III forum). Although covered entities' ADR claims arise within a federal regulatory scheme, they must be adjudicated by an Article III court because they determine Sanofi's private rights.[26]

[26] Nor did *Astra* approve administrative adjudication of manufacturers' private rights, as the government contends. *See* Mot. 45. The *Astra* court said nothing about

Contrary to the government's suggestion, Sanofi has not consented to this scheme of administrative adjudication "in exchange for" participating in Medicaid and Medicare Part B. Mot. 43–44. Rather, Sanofi is an "objecting defendant forced to litigate involuntarily before a non-Article III court." *Wellness Int'l Network, Ltd. v. Sharif*, 575 U.S. 665, 682 (2015). Submitting to ADR panels and compliance with their orders as a condition of Medicare and Medicaid participation is hardly a voluntary choice. *See, e.g.*, *Stern*, 564 U.S. at 493 (holding consent was absent where party "had nowhere else to go if he wished to recover from [the] estate."). Moreover, Sanofi entered into the 340B Program years before the ADR Rule was promulgated.

By authorizing ADR panels to compel manufacturers like Sanofi to convey their property to contract pharmacies and empowering those panels to enforce their decisions through orders for money damages and injunctive relief, the ADR Rule confers judicial power on Executive Branch officers in violation of Article III.

D. The ADR Rule Is Contrary to Law and Arbitrary and Capricious.

In addition to these constitutional flaws, the ADR Rule contravenes Section 340B, which merely authorizes "appropriate procedures for the provision of remedies and enforcement of determinations made pursuant to such process." 42 U.S.C. § 256b(d)(3)(A). This statutory authorization does not extend to cover awards of

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Article III; it only observed that Section 340B did not create a private right of action to sue drug manufacturers. *See* 563 U.S. at 113.

money damages and equitable relief authorized by the ADR Rule. *See supra* pp. 15–17. Congress knows how to authorize these forms of relief. *See, e.g.*, *AMG Cap. Mgmt. v. FTC*, 141 S. Ct. 1341, 1343, 1348–50 (2021) (listing examples of specific forms of equitable relief authorized by statute). Its failure to do so in Section 340B speaks volumes. After all, "Congress … does not hide elephants in mouseholes." *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001).

Nor does Section 340B authorize HHS to adjudicate "claims that a manufacturer has limited the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price," as the ADR Rule provides. ADR_000025. Section 340B authorizes HHS to establish a process only for resolving "claims by covered entities that *they have been overcharged* for drugs purchased under this section." 42 U.S.C. § 256b(d)(3)(A) (emphasis added). To state an overcharge claim, a covered entity must allege that the manufacturer's charges "have exceeded the applicable ceiling price under this section." *Id.* § 256b(d)(3)(B)(iii). But a claim alleging that a drug manufacturer "has limited the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price" differs from an "overcharge[]" claim because it challenges a manufacturer's *practices* rather than its *prices*. For instance, covered entities have claimed that Sanofi's integrity initiative has limited their ability to purchase drugs, but they have not alleged that Sanofi overcharged them in any specific transactions. *See* Del Medico Decl. Ex. 15, Petition for Declaratory and

Injunctive Relief ¶¶ 30–32. The ADR Rule thus exceeds the scope of Section 340B by empowering panels to adjudicate claims by covered entities that their "ability" to purchase discounted drugs has been "limited" in some way, even if they have not been overcharged.

Finally, HHS "failed to consider … important aspect[s] of the problem." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). To begin, the ADR Rule is based on stale comments received in 2016, *see* ADR_000013. HHS entirely failed to examine key data, including factual and legal developments in the years after it withdrew the 2016 NPRM. *See Mobil Oil Corp. v. EPA*, 35 F.3d 579, 584–85 (D.C. Cir. 1994) (the "useful life" of a notice-and-comment record is "not infinite"; a record does not support rulemaking if it is not "fresh" or if new information "come[s] to light"). For example, contrary to the government's argument, Mot. 52 n.11, HHS failed to consider significant industry changes since 2016, such as the exponential increase in the use of contract pharmacies, the growing evidence of abuses in the 340B Program documented by the government itself, and the various responses of manufacturers, including the integrity initiative developed by Sanofi. *See supra* pp. 7–12. In light of the government's attempt to walk back the power of ADR panels to issue monetary and equitable relief, *see supra* pp. 69–71, the Advisory Opinion also fails reasonably to explain the scope of

ADR panels' remedial authority. None of this is consistent with the reasoned decision-making that the APA requires.

CONCLUSION

The Court should grant summary judgment to Sanofi and deny Defendants' motion to dismiss or, in the alternative, for summary judgment.

Dated: May 10, 2021

Respectfully submitted,

s/ Jennifer L. Del Medico

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SANOFI-AVENTIS U.S., LLC, *Plaintiff,* *v.* UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, *Defendants.*	Civil Action No. 3:21-cv-634

DECLARATION OF JENNIFER L. DEL MEDICO

I, Jennifer L. Del Medico, declare as follows pursuant to 28 U.S.C. § 1746:

1. I am an attorney admitted to appear before the United States District Court for the District of New Jersey. I am a partner at the law firm Jones Day and counsel for plaintiff Sanofi-Aventis U.S., LLC ("Sanofi"), in the above-captioned case. I submit this declaration in support of Sanofi's cross-motion for summary judgment and opposition to defendants' motion to dismiss or, in the alternative, for summary judgment. This declaration is based on my personal knowledge, as informed by the documents attached hereto.

2. Attached as Exhibit 1 is a true and correct copy of a communication from Gerald Gleeson, Vice President and Head, Sanofi U.S. Market Access Shared Services, distributed to concerned parties, in July 2020. This document was attached to Sanofi's amended complaint as Exhibit 1, *see* ECF 17-1, and included in the

administrative record, *see* ADVOP_002127–28.

3. Attached as Exhibit 2 is a true and correct copy of a letter from Adam Gluck, Head, U.S. and Sanofi Genzyme Corporate Affairs, to Secretary Alex M. Azar, dated August 13, 2020. This document was attached to Sanofi's amended complaint as Exhibit 2. *See* ECF 17-2.

4. Attached as Exhibit 3 is a true and correct copy of a communication from Gerald Gleeson, Vice President and Head, Sanofi U.S. Market Access Shared Services, distributed to concerned parties, in August 2020. This document was attached to Sanofi's amended complaint as Exhibit 3. *See* ECF 17-3.

5. Attached as Exhibit 4 is a true and correct copy of a communication from Gerald Gleeson, Vice President and Head, Sanofi U.S. Market Access Shared Services, distributed to concerned parties, in September 2020. This document was attached to Sanofi's amended complaint as Exhibit 4. *See* ECF 17-4.

6. Attached as Exhibit 5 is a true and correct copy of a letter from Adam Gluck, Senior Vice President and Head, U.S. and Sanofi Genzyme Corporate Affairs, et al. to concerned parties, dated September 29, 2020. This document was attached to Sanofi's amended complaint as Exhibit 5. *See* ECF 17-5.

7. Attached as Exhibit 6 is a true and correct copy of a document published by Sanofi and entitled "Sanofi's New Initiative Combats Waste and Abuse in the 340B Program." This document was attached to Sanofi's amended complaint

as Exhibit 6. *See* ECF 17-6.

8. Attached as Exhibit 7 is a true and correct copy of a document published by Sanofi and entitled "Understanding Sanofi's 340B Data Reporting Requirements." This document was attached to Sanofi's amended complaint as Exhibit 7. *See* ECF 17-7.

9. Attached as Exhibit 8 is a true and correct copy of a Program Announcement published by Gerald Gleeson, Vice President and Head, Sanofi U.S. Market Access Shared Services, to concerned parties on February 1, 2021. This document was attached to Sanofi's amended complaint as Exhibit 8. *See* ECF 17-8.

10. Attached as Exhibit 9 is a true and correct copy of a letter from Xavier Becerra, Attorney General of California, et al. to Secretary Alex M. Azar, et al. dated December 14, 2020. This document was attached to Sanofi's amended complaint as Exhibit 9. *See* ECF 17-9.

11. Attached as Exhibit 10 is a true and correct copy of a letter from Adam Gluck, Senior Vice President and Head, U.S. and Sanofi Genzyme Corporate Affairs, to Richard J. Pollack, President and CEO, American Hospital Association, dated August 28, 2020. This document was attached to Sanofi's amended complaint as Exhibit 10. *See* ECF 17-10.

12. Attached as Exhibit 11 is a true and correct copy of a letter from the American Hospital Association, et al. to Secretary Alex M. Azar, dated August 26,

2020. This document was attached to Sanofi's amended complaint as Exhibit 11. *See* ECF 17-11.

13. Attached as Exhibit 12 is a true and correct copy of a letter from Todd A. Nova on behalf of Advocate Christ Medical Center, et al. to Jeannie Jehnke, Government Pricing, Sanofi-Aventis U.S., LLC, dated October 6, 2020. This document was attached to Sanofi's amended complaint as Exhibit 12. *See* ECF 17-12.

14. Attached as Exhibit 13 is a true and correct copy of a letter from William B. Schultz, et al. on behalf of the American Hospital Association, et al. to Chan Lee, North America General Counsel Sanofi-Aventis U.S., LLC, et al. dated January 7, 2021. This document was attached to Sanofi's amended complaint as Exhibit 13. *See* ECF 17-13.

15. Attached as Exhibit 14 is a true and correct copy of a letter from W. Ron Allen, Chairman and CEO, Jamestown S'Klallam Tribe, to Adam Gluck, Senior Vice President and Head, U.S. and Sanofi Genzyme Corporate Affairs, dated January 19, 2021. This document was attached to Sanofi's amended complaint as Exhibit 14. *See* ECF 17-14.

16. Attached as Exhibit 15 is a true and correct copy of the Petition for Declaratory and Injunctive Relief dated January 13, 2021 and filed by the National Association of Community Health Centers as Petition No. 210112-2 before the U.S. Department of Health and Human Services Administrative Dispute Resolution Panel.

This document was attached to Sanofi's amended complaint as Exhibit 15. *See* ECF 17-15.

17. Attached as Exhibit 16 is a true and correct copy of the Motion for Preliminary Injunction dated January 14, 2021 and filed by the National Association of Community Health Centers under Petition No. 210112-2 before the U.S. Department of Health and Human Services Administrative Dispute Resolution Panel. This document was attached to Sanofi's amended complaint as Exhibit 16. *See* ECF 17-16.

18. I declare under penalty of perjury that the foregoing is true and correct.

Date: May 10, 2021

s/ Jennifer L. Del Medico
Jennifer L. Del Medico

EXHIBIT 1

To Whom It May Concern:

I am writing to inform you that Sanofi is implementing a new 340B program integrity initiative to address duplicate discounts. Sanofi supports the 340B Program's core objective of increasing access to outpatient drugs among uninsured and vulnerable patients and is committed to maintaining and strengthening its mission. However, we are concerned about the rate of duplicate discounting on Medicaid prescriptions filled with 340B-purchased drugs. Similarly, manufacturers pay ineligible rebates on Medicare Part D and commercial utilization due to the lack of transparency in the 340B program.

To resolve these issues, Sanofi will require 340B covered entities to submit claims data for 340B prescriptions of Sanofi products filled through its contract pharmacies. Sanofi will use this data to match against rebate claims it receives to ensure it isn't paying ineligible discounts. This initiative is enabled through 340B ESP™, a Second Sight Solutions technology. Sanofi is requiring 340B covered entities to register at www.340BESP.com by October 1, 2020.

Sanofi has maintained a strong commitment to the 340B program since its inception. We also recognize that for the 340B program to continue in its mission, serious program integrity and transparency challenges must be addressed. That is why we are adopting the 340B ESP™ platform and we look forward to working with 340B covered entities to further strengthen the 340B program.

Best regards,

Gerald Gleeson
VP & Head, Sanofi US Market Access Shared Services

NEXT STEPS AND FREQUENTLY ASKED QUESTIONS

To get started with Second Sight Solutions' 340B ESP™ platform, follow these three simple steps:

1. Go to www.340BESP.com to register your account. Upon initial registration you will be prompted with an onboarding tutorial that will walk you through the account set up process step by step. This process takes ~15 minutes.
2. Once your account is activated, you will be able to securely upload data to 340B ESP™. You will receive periodic notifications of pending data submissions and new contract pharmacy set up activities.
3. Login to 340B ESP and submit your 340B contract pharmacy claims data on a bi-weekly basis. Once your account is set up, the claims upload process takes ~ 5 minutes.

In addition to the frequently asked questions below, you can visit www.340BESP.com/FAQs to learn more about 340B ESP™. For further help with the registration, account setup, and data submission process please call Second Sight Solutions at 888-398-5520. To learn more about how Sanofi is working to improve program integrity through 340B ESP™, please contact Sanofi directly at Sanofi340BOperations@sanofi.com.

Q: How will Sanofi use the 340B claims data that we provide through 340B ESP™?

A: Data uploaded by 340B covered entities will be used to identify and resolve duplicate Medicaid and commercial rebates.

Q: How does 340B ESP™ protect the privacy of my patients?

A: Data uploaded to 340B ESP™ is de-identified and meets the definition of a De-identified Data Set under HIPAA. This means no actual protected health information (PHI) is collected and the data cannot be combined with other data sets to reveal the identity of a patient. Additional security controls are embedded throughout the platform.

Q: Is Sanofi requesting data for all Sanofi products?

A: No. Sanofi is only requesting data for Sanofi drugs commonly dispensed through retail, specialty and outpatient pharmacies registered on the HRSA database as a contract pharmacy. Physician-administered drugs are not part of this program. 340B ESP™ automatically limits the data in your upload file to the applicable NDCs.

Q: What happens if my organization does not provide 340B contract pharmacy claims data?

A: Sanofi is requiring 340B covered entities to register with 340B ESP™ and begin providing 340B claims data by October 1, 2020. 340B covered entities that elect not to provide 340B claims data will no longer be eligible to place Bill To / Ship To replenishment orders for Sanofi products dispensed through a contract pharmacy. All 340B covered entities will continue to be able to purchase Sanofi products at the 340B price when shipped to an address registered on the 340B covered entity database as a parent or child site.

Q: Is Sanofi requesting data for pharmacies that are registered with HRSA as a covered entity?

A: No. Sanofi is only requesting data for 340B claims that originates from contract pharmacies. Covered entities do not need to provide 340B claims for prescriptions filled in their own outpatient pharmacies.

Q: What benefit does the 340B covered entity realize by using 340B ESP™?

A: By providing 340B claims data that originate from contract pharmacies, you will enable Sanofi to definitively identify duplicate Medicaid rebates. Covered entities will then be informed which pharmacies are dispensing 340B purchased drugs to Medicaid patients. This information can be used to further strengthen the audit processes and compliance controls of the covered entity.

Q: Does HRSA and/or Apexus support this initiative?

A: HRSA encourages 340B covered entities to work with pharmaceutical manufacturers in good faith to resolve issues of non-compliance in the 340B program. Although neither HRSA nor Apexus has commented publicly on this specific initiative, Sanofi believes 340B ESP™ provides a simple platform for Sanofi and 340B covered entities to engage collaboratively and in good faith to address duplicate discounts.

Q: How often will I need to upload 340B contract pharmacy claims data to 340B ESP™?

A: The 340B ESP™ platform requires claims uploads every two weeks. The actual upload process takes ~5 minutes and should not place significant burden on 340B covered entity operations. Email reminders are automatically generated from 340B ESP™ and covered entities can monitor claims submission status when logged in to the platform.

Q: What technology requirements exist to successfully upload data to 340B ESP™?

A: 340B ESP™ is compatible with most internet browsers including Microsoft Edge, Google Chrome, Safari, FireFox and others. However, we strongly recommend using Google Chrome for the best user experience. Users will need an internet connection and access to a supported browser to successfully upload data.

EXHIBIT 2

August 13, 2020

The Honorable Alex M. Azar II
Secretary
U.S. Dept. of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Azar,

I write on behalf of Sanofi to address the concerns raised by the American Hospital Association (AHA) regarding Sanofi's new 340B Program integrity initiative. Sanofi supports the 340B Program's core objective of increasing access to outpatient drugs among uninsured and vulnerable patients and is committed to strengthening its mission. Under our initiative, 340B covered entities will upload de-identified claims data to a secure system so that Sanofi can identify and prevent duplicate discounts in compliance with applicable law. This initiative will allow us to continue meeting our commitment to the 340B program while improving program integrity.

I. Duplicate Discounts Pose a Widespread Compliance Threat

The 340B statute prohibits duplicate discounts, meaning that manufacturers cannot be compelled to double pay a Medicaid rebate and 340B discount on the same drug.[1] Moreover, duplicate discounting in Medicare Part D and commercial insurance is counterproductive for program sustainability.

Notwithstanding this prohibition, duplicate discounts pose a widespread threat. In 2018 and 2019, HRSA identified Medicaid fee-for-service duplicate discounting in over 30% of its covered entity audits. Duplicate discounts likely are even more prevalent in Medicaid managed care because HRSA does not audit covered entities regarding their ability to prevent Medicaid managed care duplicate discounts and because HRSA has not created any mechanism to prevent them.[2] The growth of Medicaid managed care -- 35 states reported providing Medicaid

[1] 42 U.S.C. § 256b(a)(5)(A)(i) ("A covered entity shall not request payment under [Medicaid] . . . with respect to a drug that is subject to an agreement under this section [a 340B-priced drug] if the drug is subject to the payment of a [Medicaid] rebate to the State . . . .").

[2] GAO, 340B Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement, GAO-18-480 at 39, 45 (June 2018), https://www.gao.gov/assets/700/692697.pdf.

prescription drug benefits through Medicaid managed care in a 2018 survey[3] -- exacerbates this problem. Moreover, 340B "contract pharmacy" arrangements, i.e., arrangements where a drug is shipped to a third party pharmacy and billed at the 340B ceiling price to a 340B covered entity, "create complications in preventing duplicate discounts" according to HHS OIG.[4] The GAO has reported "weaknesses in HRSA's oversight that impede its ability to ensure compliance with 340B Program requirements at contract pharmacies,"[5] and CMS has recognized that "some states face challenges with avoiding duplicate discounts on 340B drugs dispensed by 340B contract pharmacies."[6] Contract pharmacies likewise contribute to duplicate discounting outside the Medicaid context as well. Accordingly, the rapid growth in contract pharmacy arrangements compounds the duplicate discounting problem. Between 2010 and 2019, the number of 340B contract pharmacies has grown 1,700 percent to about 23,000 in 2019.[7]

II. Sanofi's Compliance Initiative Will Not Burden Covered Entities and Will Comply with Applicable Law

To address these concerns, Sanofi is launching a new program integrity effort. Under this initiative, Covered Entities will register and submit data every two weeks regarding dispenses of certain Sanofi drug products through contract pharmacy arrangements, using a secure online portal (340BESP.com). The uploaded data will be de-identified (HIPAA-compliant) and will consist of data that contract pharmacies already collect and submit to third party payors when seeking insurance reimbursement. (Likewise, Sanofi collects similar claims-level data when validating payor price concessions.) Sanofi will collect 340B claims data only for contract pharmacy dispenses, and Sanofi will omit physician-administered drugs from this initiative. Data uploaded by 340B covered entities will be used by Sanofi to identify and resolve duplicate Medicaid and commercial rebates, by comparing these data against Medicaid and commercial payor data. Prior to October 1, 2020, covered entities will need to register with 340B ESP™ and submit claims level-detail on all 340B contract pharmacy utilization in order to be eligible for 340B Bill To / Ship To replenishment orders for Sanofi products dispensed

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[3] Kaiser Family Foundation, Medicaid's Prescription Drug Benefit: Key Facts (May 1, 2019), https://www.kff.org/medicaid/fact-sheet/medicaids-prescription-drug-benefit-key-facts/.

[4] Memorandum Report: Contract Pharmacy Arrangements in the

340B Program, OEI-05-13-00431 at 2 (February 4, 2014), https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf.

[5] 340B Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement, at 35.

[6] CMS, Best Practices for Avoiding 340B Duplicate Discounts in Medicaid at 3 (January 8, 2020), https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/cib010820.pdf.

[7] GAO, 340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement, GAO-20-212 at 2 (Jan. 2020), https://www.gao.gov/assets/710/703966.pdf.

through a contract pharmacy. However, all 340B covered entities will remain able to purchase Sanofi products at the 340B price for shipment to their own facilities.

Thus, although AHA mischaracterizes our initiative as intended to limit distribution of 340B-priced drugs, instead our program solely seeks the information needed to protect our company from duplicate discounts. Further, Sanofi plans to inform participating covered entities of the pharmacies that are dispensing 340B purchased drugs to Medicaid patients. This information can be used by covered entities to further strengthen their audit processes and compliance controls.

Our initiative complies with the 340B statute and Pharmaceutical Pricing Agreement (PPA), which require that Sanofi "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."[8] Simply put, Sanofi will continue to offer all of its drugs to all 340B covered entities. At most, if a covered entity refuses to provide the claims data described above, we will restrict the entity's use of contract pharmacy arrangements, but these entities will remain eligible to purchase at 340B prices for shipment to their own facilities.

AHA's letter argues that Sanofi is out-of-compliance with HRSA's guidance regarding contract pharmacy arrangements. Specifically, AHA references a passage of this guidance that provides that "if a covered entity using contract pharmacy services requests to purchase a covered outpatient drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at a price not to exceed the statutory 340B discount price."[9] Contrary to what AHA asserts, Sanofi will continue to sell its drugs at the 340B price. Even covered entities that do not provide the required data will remain able to purchase 340B drugs for shipment to the covered entity itself. The 340B statute supports this approach. Because the statute includes detailed eligibility requirements for 340B covered entities and a prohibition on duplicate discounts, the 340B statute supports manufacturers' right to require covered entities to provide the data necessary to ensure compliance with these limitations, especially because duplicate discounts otherwise will continue unchecked. Moreover, the 340B statute does not address contract pharmacy arrangements, nor does it grant HRSA authority to issue binding rules in this area.[10] These considerations give manufacturers discretion to adopt their own reasonable approaches.

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[8] 42 U.S.C. § 256b(a)(1); Pharmaceutical Pricing Agreement Addendum, https://www.hrsa.gov/sites/default/files/opa/manufacturers/ppa_addendum.pdf.

[9] 75 Fed. Reg. 10272, 10278 (March 5, 2010).

[10] PhRMA v. United States Dep't of Health & Human Servs., 43 F. Supp. 3d 28, 42 (D.D.C. 2014) (explaining that HHS has only "specifically delineated" rulemaking authorities, none of which apply here).

SANOFI

We agree with AHA that HRSA guidance provides that covered entities remain responsible for ensuring the compliance of their contract pharmacies. We read this guidance, however, as expressing HRSA's expectation that covered entities will not offload this responsibility to their contract pharmacies. It does not, nor could it, bar manufacturers from reasonably collecting information to protect themselves from duplicate discounts that, as noted, remain a significant problem under the 340B Program.

Finally, AHA's letter expresses concern that our compliance initiative will launch during the COVID-19 pandemic. Please know that Sanofi understands well the challenges posed by this pandemic as we carry out multiple research and development initiatives to fight the disease, and as we engage in the daily business of making and delivering medicines for patients. We want to assure HHS that we would not implement our initiative if we believed it would hamper the fight against COVID-19. However, because our initiative will create only a minor data sharing obligation for 340B covered entities and strengthen the 340B Program, this initiative will not impair our common fight against the pandemic.

Thank you for your leadership in national public health during this critical time. Please contact me at 202-585-3085 with any questions you may have. At your request, we would be pleased to discuss this issue with you further.

Sincerely,

Adam Gluck
Head, U.S. and Sanofi Genzyme Corporate Affairs
Sanofi U.S.

CC: Deputy Director Herzog, Office of Pharmacy Affairs, HRSA

EXHIBIT 3

To Whom It May Concern:

I am following up on my email dated July 31st regarding Sanofi's 340B program integrity initiative, enabled by Second Sight Solutions' 340B ESP™ platform. As I discussed in the previous email, this platform will enable us to strengthen the integrity of the 340B program by eliminating duplicate discounts that originate from 340B contract pharmacy utilization.

Instances of duplicate Medicaid rebates remain a serious issue in the 340B program. In 2018 and 2019, over 30 percent of audits identified instances of duplicate Medicaid rebates. The actual prevalence of duplicate Medicaid rebates is likely much higher because, as the Government Accountability Office reported in January 2020, HRSA does not audit for duplicate Medicaid rebates originating from managed Medicaid utilization. This rate of non-compliance is not sustainable and 340B covered entities and manufacturers must do more to address this issue.

This is why Sanofi has adopted 340B ESP™. Through this platform, 340B covered entities submit 340B claims to Sanofi that are used to identify and eliminate all instances of duplicate Medicaid and commercial discounts. To date, you have not registered on 340B ESP™. Therefore, we ask that you take the time to do so now. 340B covered entities must register their account and begin providing 340B claims data by October 1, 2020 in order to place Bill To / Ship To replenishment orders for Sanofi products for 340B contract pharmacy arrangements.

By working together to address the ongoing issue of duplicate discounts, we can ensure that the 340B program will continue to support our shared mission of improving the health of our patients.

Best regards,

Gerald Gleeson
VP & Head, Sanofi US Market Access Shared Services

NEXT STEPS AND FREQUENTLY ASKED QUESTIONS

To get started with Second Sight Solutions' 340B ESP™ platform, follow these three simple steps:

1. Go to www.340BESP.com to register your account. You will receive a two-factor verification code that is sent directly to your cell phone. As part of your initial registration, you will also receive a one-time authentication code via email. You can enter the code provided in the email or enter the unique authentication code provided in this email.
2. Once your account is activated, you will be able to securely upload data to 340B ESP™. You will receive periodic notifications of pending data submissions and new contract pharmacy set up activities.
3. Login to 340B ESP and submit your 340B contract pharmacy claims data on a bi-weekly basis. Once your account is set up, the claims upload process takes ~ 5 minutes.

In addition to the frequently asked questions below, you can visit www.340BESP.com/FAQs to learn more about 340B ESP™. For further help with the registration, account setup, and data submission process please call Second Sight Solutions at 888-398-5520. To learn more about how Sanofi is working to improve program integrity through 340B ESP™, please contact Sanofi directly at Sanofi340BOperations@sanofi.com.

Q: How will Sanofi use the 340B claims data that we provide through 340B ESP™?

A: Data uploaded by 340B covered entities will be used to identify and resolve duplicate Medicaid and commercial rebates.

Q: How does 340B ESP™ protect the privacy of my patients?

A: Data uploaded to 340B ESP™ is de-identified and meets the definition of a De-identified Data Set under HIPAA. This means no actual protected health information (PHI) is collected and the data cannot be combined with other data sets to reveal the identity of a patient. Additional security controls are embedded throughout the platform.

Q: Is Sanofi requesting data for all Sanofi products?

A: No. Sanofi is only requesting data for Sanofi drugs commonly dispensed through retail, specialty and outpatient pharmacies registered on the HRSA database as a contract pharmacy. Physician-administered drugs are not part of this program. 340B ESP™ automatically limits the data in your upload file to the applicable NDCs.

Q: What happens if my organization does not provide 340B contract pharmacy claims data?

A: Sanofi is requiring 340B covered entities to register with 340B ESP™ and begin providing 340B claims data by October 1, 2020. 340B covered entities that elect not to provide 340B claims data will no longer be eligible to place 340B Bill To / Ship To replenishment orders for Sanofi products dispensed through a contract pharmacy. All 340B covered entities will continue to be able to purchase Sanofi products at the 340B price when shipped to an address registered on the 340B covered entity database as a parent or child site.

Q: Is Sanofi requesting data for pharmacies that are registered with HRSA as a covered entity?

A: No. Sanofi is only requesting data for 340B claims that originates from contract pharmacies. Covered entities do not need to provide 340B claims for prescriptions filled in their own outpatient pharmacies.

Q: What benefit does the 340B covered entity realize by using 340B ESP™?

A: By providing 340B claims data that originate from contract pharmacies, you will enable Sanofi to definitively identify duplicate Medicaid rebates. Covered entities will then be informed which pharmacies are dispensing 340B purchased drugs to Medicaid patients. This information can be used to further strengthen the audit processes and compliance controls of the covered entity.

Q: Does HRSA and/or Apexus support this initiative?

A: HRSA encourages 340B covered entities to work with pharmaceutical manufacturers in good faith to resolve issues of non-compliance in the 340B program. Although neither HRSA nor Apexus has commented publicly on this specific initiative, Sanofi believes 340B ESP™ provides a simple platform for Sanofi and 340B covered entities to engage collaboratively and in good faith to address duplicate discounts.

Q: How often will I need to upload 340B contract pharmacy claims data to 340B ESP™?

A: The 340B ESP™ platform requires claims uploads every two weeks. The actual upload process takes ~5 minutes and should not place significant burden on 340B covered entity operations. Email reminders are automatically generated from 340B ESP™ and covered entities can monitor claims submission status when logged in to the platform.

Q: What technology requirements exist to successfully upload data to 340B ESP™?

A: 340B ESP™ is compatible with most internet browsers including Microsoft Edge, Google Chrome, Safari, FireFox and others. However, we strongly recommend using Google Chrome for the best user experience. Users will need an internet connection and access to a supported browser to successfully upload data.

EXHIBIT 4

To Whom It May Concern:

I am following up on my emails dated July 30th and August 17th regarding Sanofi's adoption of 340B ESP™, Second Sight Solutions' 340B compliance platform. As I discussed in the previous emails, this platform will enable Sanofi to work collaboratively to strengthen the integrity of the 340B program by eliminating duplicate discounts that originate from 340B contract pharmacy utilization. Sanofi is making 340B ESP™ available to 340B covered entities at no cost and we are requiring all 340B covered entities to visit www.340BESP.com to register their account by October 1, 2020. If you have already registered and will be submitting claims data for Sanofi products, please disregard this notice.

340B covered entities that have not registered their account and begun providing 340B claims data by October 1, 2020 will no longer be eligible to place 340B Bill To / Ship To replenishment orders for Sanofi products for 340B contract pharmacy arrangements. All 340B covered entities will continue to be able to purchase Sanofi products at the 340B price when shipped to an address registered on the 340B covered entity database as a parent or child site.

Program integrity is critical to the success of the 340B program and can be achieved through collaboration between covered entities and pharmaceutical manufacturers. Use of 340B ESP™ by the covered entity community will allow Sanofi to resolve duplicate discounts and improve program integrity for all 340B stakeholders. By working together to address the ongoing issue of duplicate discounts, we can ensure that the 340B program will continue to support our shared mission of improving the health of our patients.

Sincerely,

Gerald Gleeson
VP & Head, Sanofi US Market Access Shared Services

NEXT STEPS AND FREQUENTLY ASKED QUESTIONS (UPDATED)

To get started with Second Sight Solutions' 340B ESP™ platform, follow these three simple steps:

1. Go to www.340BESP.com to register your account. You will receive a two-factor verification code that is sent directly to your cell phone. As part of your initial registration, you will also receive a one-time authentication code via email. You can enter the code provided in the email or enter the unique authentication code provided in this email.
2. Once your account is activated, you will be able to securely upload data to 340B ESP™. You will receive periodic notifications of pending data submissions and new contract pharmacy set up activities.
3. Login to 340B ESP and submit your 340B contract pharmacy claims data on a bi-weekly basis. Once your account is set up, the claims upload process takes ~ 5 minutes.

In addition to the frequently asked questions below, you can visit www.340BESP.com/FAQs to learn more about 340B ESP™. For further help with the registration, account setup, and data submission process please call Second Sight Solutions at 888-398-5520. To learn more about how Sanofi is working to improve program integrity through 340B ESP™, please contact Sanofi directly at Sanofi340BOperations@sanofi.com.

Q: How will Sanofi use the 340B claims data that we provide through 340B ESP™?

A: Data uploaded by 340B covered entities will be used to identify and resolve duplicate Medicaid and commercial rebates.

Q. My covered entity excludes Medicaid patients from our contract pharmacy utilization and/or my state has a Medicaid carve out that excludes these patients from 340B. Do I still need to submit data to Sanofi through 340B ESP?

A: Yes. This initiative is to address duplicate Medicaid rebates as well as ineligible rebates paid to commercial and Medicare Part D payers. Sanofi utilizes the claims data provided by 340B covered entities to address these duplicate discounts. All forms of duplicate discounts impair the sustainability of the 340B Program, so all must be addressed. The 340B statute permits this approach because Sanofi will continue to offer 340B pricing to covered entities outside contract pharmacy arrangements, regardless of whether data is provided.

Q: How does 340B ESP™ protect the privacy of my patients?

A: Data uploaded to 340B ESP™ is de-identified and meets the definition of a De-identified Data Set under HIPAA. This means no actual protected health information (PHI) is collected and the data cannot be combined with other data sets to reveal the identity of a patient. Additional security controls are embedded throughout the platform.

Q: The required claims data elements include prescription number, prescribed date and date of service (fill date). Aren't those data elements considered PHI?

The prescription number, prescribed date and date of service (or fill date) are de-identified through a HIPAA compliant hashing process known as SHA-3 hashing. An additional layer of security called a "salt" is applied prior to any data being uploaded to 340B ESP™. This process was granted an Expert Determination by Dr. Brad Malin, a professor at Vanderbilt University Medical Center, indicating that it meets the definition of a De-Identified Data Set under HIPAA and does not contain PHI. Additional information on this expert determination may be requested by contacting Second Sight Solutions at 888-398-5520.

Q. My covered entity requires that we enter into a Business Associate Agreement (BAA) with Second Sight Solutions prior to submitting data. How do I initiate that process?

Second Sight Solutions does make a standard BAA available to 340B covered entities that require a BAA to be in place prior to submitting data. To request a BAA, you can email support@340besp.com or complete the BAA request form at www.340Besp.com/BAA.

Q: Is Sanofi requesting data for all Sanofi products?

A: No. Sanofi is only requesting data for Sanofi drugs commonly dispensed through retail, specialty and outpatient pharmacies registered on the HRSA database as a contract pharmacy. Physician-administered drugs are not part of this program. 340B ESP™ automatically limits the data in your upload file to the applicable NDCs.

Q: How do I know which NDCs to submit into the 340B ESP™ platform?

A: At a minimum, covered entities must upload data for all Sanofi NDCs that are not physician-administered drugs. Sanofi NDCs have the following NDC "labeler code" values at the beginning of their NDC numbers: 00024, 00039, 00068, 00075, 00088, 00310, 00597, 00955, 58468 and 72733. Alternatively, a covered entity could upload a broader set of data, and the system will share with Sanofi only data on Sanofi's NDCs..

Q: What happens if my organization does not provide 340B contract pharmacy claims data?

A: Sanofi is requiring 340B covered entities to register with 340B ESP™ and begin providing 340B claims data by October 1, 2020. 340B covered entities that elect not to provide 340B claims data will no longer be eligible to place 340B Bill To / Ship To replenishment orders for Sanofi products dispensed through a contract pharmacy. All 340B covered entities will continue to be able to purchase Sanofi products at the 340B price when shipped to an address registered on the 340B covered entity database as a parent or child site.

Q: Is Sanofi requesting data for pharmacies that are registered with HRSA as a covered entity?

A: No. Sanofi is only requesting data for 340B claims that originates from contract pharmacies. Covered entities do not need to provide 340B claims for prescriptions filled in their own outpatient pharmacies.

Q: What benefit does the 340B covered entity realize by using 340B ESP™?

A: By providing 340B claims data that originate from contract pharmacies, you will enable Sanofi to definitively identify duplicate Medicaid rebates. Covered entities will then be informed which pharmacies are dispensing 340B purchased drugs to Medicaid patients. This information can be used to further strengthen the audit processes and compliance controls of the covered entity.

Q: Does HRSA and/or Apexus support this initiative?

A: HRSA encourages 340B covered entities to work with pharmaceutical manufacturers in good faith to resolve issues of non-compliance in the 340B program. Although neither HRSA nor Apexus has commented publicly on this specific initiative, Sanofi believes 340B ESP™ provides a simple platform for Sanofi and 340B covered entities to engage collaboratively and in good faith to address duplicate discounts.

Q: How often will I need to upload 340B contract pharmacy claims data to 340B ESP™?

A: The 340B ESP™ platform requires claims uploads every two weeks. The actual upload process takes ~5 minutes and should not place significant burden on 340B covered entity operations. Email reminders are automatically generated from 340B ESP™ and covered entities can monitor claims submission status when logged in to the platform.

Q: What technology requirements exist to successfully upload data to 340B ESP™?

A: 340B ESP™ is compatible with most internet browsers including Microsoft Edge, Google Chrome, Safari, FireFox and others. However, we strongly recommend using Google Chrome for the best user experience. Users will need an internet connection and access to a supported browser to successfully upload data.

EXHIBIT 5

September 29, 2020

Dear xxx,

We wanted to follow up on Sanofi's previous emails regarding our new 340B Program integrity initiative. As you know, the intent of our initiative is to collect data in an effort to reduce waste in the 340B Program by preventing Medicaid, Part D, and commercial duplicate discounts. Sanofi designed this initiative in full compliance with applicable law and so as not to burden 340B covered entities or patients. Sanofi supports the 340B Program's core objective of increasing access to outpatient drugs among uninsured and vulnerable patients and is committed to strengthening the 340B Program's mission, a goal that is supported and advanced through our initiative to prevent duplicate discounts.

Government reports and our own experience show that our duplicate discount concerns are well-founded. Despite the legal ban on forcing pharmaceutical manufacturers to double pay Medicaid rebates and 340B discounts on the same drug,[1] duplicate discounting on Medicaid claims has continued to occur. Over 30% of Health Resources and Services Administration (HRSA) audits of covered entities in 2018 and 2019 found Medicaid duplicate discounting, and government reports have repeatedly documented this ongoing concern.[2] Likewise, in a limited scope test that analyzed three years of Medicaid rebates from five states for three Sanofi products, we identified over $16M in 340B duplicate discounts. Further, government reports have found that contract pharmacies have unfortunately hindered efforts to prevent duplicate discounts.[3] Between 2010 and 2019, the number of 340B contract pharmacies has grown 1,700 percent to about 23,000.[4] This rapid growth in contract pharmacy arrangements has only reinforced the need for our initiative.

Our initiative complies with the 340B statute and our agreement with the Department of Health and Human Services, which require that Sanofi "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."[5] Sanofi will continue to offer all of its drugs to all 340B covered entities. At most, if a covered entity refuses to provide the requested data, we will restrict the entity's use of contract pharmacy arrangements, but these entities will remain eligible to purchase at 340B prices for shipment

[1] 42 U.S.C. § 256b(a)(5)(A)(i).
[2] *See, e.g.*, GAO, Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement, GAO-18-480 (June 2018), https://www.gao.gov/assets/700/692697.pdf (hereinafter, "Oversight of Contract Pharmacies Needs Improvement"); GAO, 340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement, GAO-20-212 (January 2020), https://www.gao.gov/assets/710/703966.pdf (hereinafter, "Oversight of MDRP Intersection Needs Improvement"); OIG, Memorandum Report: Contract Pharmacy Arrangements in the 340B Program, OEI-05-13-00431 (February 4, 2014), https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf.
[3] *Id*.
[4] GAO, Oversight of MDRP Intersection Needs Improvement, at 2.
[5] 42 U.S.C. § 256b(a)(1).

to their own facilities. Sanofi will offer 340B pricing on a non-discriminatory basis through contract pharmacy arrangements if a covered entity provides the modest data Sanofi requests, which are identical to data already submitted by contact pharmacies to other third parties and by insurers to manufacturers for rebate purposes, to prevent duplicate discounts.

Please understand that we have designed our initiative so as not to burden covered entities. Our data submission portal is user-friendly, and as noted above, the required information is no different than what manufacturers require of insurance companies when paying rebates. The required information is the NCPDP standard for prescription claims. These data are generated by the pharmacy and submitted to insurance companies and, in the case of 340B contract pharmacies, to the third-party administrators that identify 340B eligible claims. Moreover, we do not request data on physician-administered drugs or drugs dispensed by covered entities' own facilities. Our approach also avoids burdensome and ineffective manual data exchanges.

Even more importantly, patients will not be affected by our initiative. Government Accountability Office reports have found that contract pharmacies often do not give discounts to patients and that in-house pharmacies (to which we in all circumstances will continue to sell 340B drugs) are significantly more likely to pass along drug cost savings to patients.[6] Given these findings and the ubiquity of duplicate discounts, we are hopeful that all stakeholders invested in the success and purpose of the 340B Program will work together on what we believe is a shared goal of improving 340B Program integrity. Eliminating duplicate discounts ultimately will free resources to be focused where they belong: on reducing patients' out-of-pocket costs.

We appreciate your cooperation in this initiative and value our relationship with you very much. Please do not hesitate to reach out to Sanofi340BOperations@Sanofi.com if you have any further questions about this matter.

Sincerely,

Adam Gluck
Senior Vice President and Head, U.S. and Sanofi Genzyme Corporate Affairs
Sanofi U.S.

Gerry Gleeson
Vice President and Head, U.S. Market Access Shared Services
Sanofi U.S.

Enclosure

[6] GAO, Oversight of Contract Pharmacies Needs Improvement, at 30 and n. 46.

EXHIBIT 6

SANOFI'S NEW INITIATIVE COMBATS WASTE AND ABUSE IN THE 340B PROGRAM

Sanofi supports the 340B Program and its core objective of increasing access to outpatient drugs for uninsured and vulnerable populations, and we remain committed to strengthening this mission.

However, for-profit intermediaries, especially 340B contract pharmacies, have distorted the 340B Program in recent years to serve their own profit making goals, hurting patients and driving waste and abuse in the process.

Contract pharmacies are multi-billion dollar commercial pharmacy chains that dispense 340B drugs under contract with covered entities. These for-profit pharmacies bill insurance -- and low-income uninsured patients -- at their normal rates, but take a large cut of the deep 340B discounts available to covered entities.

Big pharmacy chains dominate this space. According to a recent analysis, two national pharmacy chains account for nearly half of all contract pharmacy locations.[1]

Sadly, and contrary to recent public statements by other program stakeholders, patients do not benefit from contract pharmacy arrangements. Often patients receive no discount at all on contract pharmacy-dispensed drugs, and 340B covered entities' own in-house pharmacies are much more likely to provide discounts to patients than these pharmacy chains.[2] Worse, the financial conflicts created by the 340B program seriously risk skewing prescribing decisions, undercutting care quality, and increasing patient out-of-pocket costs.[3]

Given the profit potential, it is little wonder that the number of contract pharmacies has exploded in recent years, growing from under 1,300 in 2010 to almost 28,000 this year. This meteoric growth has led to waste and abuse. For example, because of the lack of transparency, manufacturers are unable to determine in real time whether Medicaid or other insurers are seeking rebates on 340B drugs.

Therefore, if insurers seek rebates on sales that are subject to the 340B discount as well, the manufacturer ultimately pays two discounts on the same drug. The 340B statute prohibits this type of duplicate discounting.

Given the amounts of money at stake for the pharmacy chains and insurers, it is little surprise that duplicate discounting happens all the time. Government reports have cautioned that duplicate discounts are hard to prevent in contract pharmacy arrangements, and that HRSA's oversight in this respect has been insufficient. To this point, over 30% of HRSA audits of covered entities in 2018 and 2019 found Medicaid duplicate discounting.

1. Drug Channels, Walgreens and CVS Top the 28,000 Pharmacies Profiting from the 340B Program. Will the Unregulated Party End?, at https://www.drugchannels.net/2020/07/walgreens-and-cvs-top-28000-pharmacies.html.
2. See GAO, Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement, GAO-18-480, at 30 (June 2019).
3. See GAO, Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals, GAO-15-442, at GAO Highlights (June 2015).

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SANOFI'S NEW INITIATIVE COMBATS WASTE AND ABUSE IN THE 340B PROGRAM

This context is important to understand what Sanofi is doing as there has been some misinformation in the marketplace. To combat the real concern about duplicate discounting, Sanofi is launching a limited scope initiative starting on October 1.

Beginning on that date, Sanofi will collect de-identified claims data on 340B-priced drugs dispensed by contract pharmacies. This data will allow Sanofi to identify 340B-priced drugs and to pay Medicaid and other insurers' rebate invoices accurately.

If a covered entity does not provide these data, then it will be ineligible for 340B pricing through contract pharmacy arrangements, but will remain able to purchase 340B-priced drugs for shipment to its own facilities.

This initiative complies in full with the 340B statute. To be clear, Sanofi will continue to offer all of its drugs to all 340B covered entities. If a covered entity provides the data, Sanofi will offer 340B pricing through contract pharmacy arrangements.

If a covered entity refuses to provide the requested data, Sanofi will restrict the entity's use of contract pharmacy arrangements, but these entities will remain eligible to purchase at 340B prices for shipment to their own facilities.

SANOFI'S INITIATIVE WILL NOT HARM PATIENTS

Patients -- even the low-income uninsured -- often pay full price at contract pharmacies, and government reports have observed that 340B financial conflicts can skew prescribing decisions, undercut care quality, and increase patient out-of-pocket costs.

Under Sanofi's initiative, covered entities will remain able to purchase at 340B prices for dispensing at their own sites of care -- where patients are significantly more likely to receive discounts.

Sanofi's data submission portal will be user-friendly and the data elements required will be limited in scope and of the type commonly included in insurance reimbursement claims.

Sanofi understands well the challenges posed by the COVID-19 pandemic as we carry out multiple research and development initiatives to fight this disease and continue making and delivering medicines for patients. This effort will ultimately strengthen the 340B program and will not impair our common fight against COVID-19.

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SANOFI'S NEW INITIATIVE COMBATS WASTE AND ABUSE IN THE 340B PROGRAM

Hospital trade groups have circulated misinformation about our initiative. Here are the Myths versus the Facts:

MYTH Requiring disclosure of contract pharmacy data is "illegal."

FACT The law allows manufacturers to collect data to validate their 340B discounts and Medicaid rebates. Sanofi will continue to offer its drugs at 340B prices for shipment to covered entity facilities, regardless of whether the covered entity provides the requested data. This is fully consistent with the 340B statute.

MYTH HRSA's 2010 guidance on contract pharmacies requires manufacturers to ship product at 340B prices to any contract pharmacy of a covered entity, including when the covered entity uses multiple contract pharmacies.

FACT As HRSA has acknowledged, the 2010 contract pharmacy guidance is not legally binding. The 340B statute does not mention contract pharmacy arrangements, let alone require manufacturers to sell into any particular version of these arrangements. Sanofi's plan to follow HRSA's 2010 guidance, so long as covered entities provide the limited data Sanofi needs to protect itself against duplicate discounts, fully complies with the 340B statute.,

MYTH Sanofi is refusing to provide 340B pricing to covered entities.

FACT Sanofi will continue to offer all of its drugs at 340B pricing to all 340B covered entities. The only thing that will change is that, in order to use a contract pharmacy, covered entities will have to provide data that allows Sanofi to detect and prevent duplicate discounts. Even those entities that do not provide data will continue to be able to purchase Sanofi products at 340B prices for shipment directly to their facilities.

MYTH Patient drug access will suffer under Sanofi's initiative.

FACT Sanofi's initiative will not harm patients. Contract pharmacies often do not give discounts to patients, and government reports have observed that 340B financial conflicts skew prescribing decisions, undercut care quality, and increase patient out-of-pocket costs. Under Sanofi's initiative, covered entities will remain able to purchase at 340B prices for dispensing at their own sites of care -- where patients are significantly more likely to receive discounts. Patients will remain able to fill prescriptions at their local pharmacies, regardless of whether data is shared.

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EXHIBIT 7

UNDERSTANDING SANOFI'S 340B DATA REPORTING REQUIREMENTS

A New Simple Process That Combats Abuse

THE PROBLEM

The 340B program's core objective is to increase access to outpatient drugs for uninsured and vulnerable populations. However, duplicate discounts have become increasingly prevalent, and GAO reports found contract pharmacies often do not give discounts to patients.

OUR SOLUTION

Sanofi will now collect de-identified claims data* on 340B-priced drugs dispensed by contract pharmacies. This will enable a collaborative process of identifying and resolving duplicated discounts to strengthen the 340B program for uninsured and vulnerable populations.

Our user-friendly data submission portal avoids burdensome, ineffective manual data exchanges and is in line with existing processes. Pharmacies submit data to the insurance companies who, in turn, invoice the manufacturer for rebate payments. Pharmacies also submit data to third party administrators if the pharmacy is a 340B contract pharmacy. We are requesting a subset of that data in this process.

THE REQUIRED DATA FIELDS

- Rx Number - Hashed*: An identifier applied to a prescription by a pharmacy
- National Drug Code: A unique identifier of a drug dispensed to a patient according to a prescription
- Date of Service - Hashed*: The date on which the prescription was filled at the pharmacy
- Prescriber ID: The National Provider Identifier ("NPI") of the physician who wrote the prescription
- Prescribed Date - Hashed*: The date on which the prescription was written by the physician
- Service Provider ID: The unique identifier of the pharmacy that filled the prescription
- Contracted Entity ID: The HRSA ID of the covered entity that designated the prescription 340B and has a contract pharmacy arrangement with the dispensing pharmacy
- Quantity: The number of units dispensed to the patient

**This process was granted an Expert Determination by Dr. Brad Malin, a professor at Vanderbilt University Medical Center, indicating that it meets the definition of a De-Identified Data Set under HIPAA and does not contain PHI.*

SANOFI

EXHIBIT 8

SANOFI

To Whom It May Concern:

As discussed in Sanofi's previous communications regarding our 340B Program integrity initiative, Sanofi collects limited, de-identified claims data through 340B ESP™, Second Sight Solutions' 340B compliance platform, for 340B-priced drugs dispensed by contract pharmacies. The minimal data sought allows Sanofi to identify 340B-priced claims and to eliminate duplicate discounts that originate from 340B contract pharmacy utilization. We write to confirm that Sanofi continues to operate our integrity initiative, which complies with applicable law, and to provide updates on our initiative's scope and implementation.

First, we note that our integrity initiative includes only the following categories of covered entities that have historically accounted for a significant share of contract pharmacy dispensing, and therefore duplicate discount risk, for Sanofi's products:

- Consolidated Health Center Programs (CH)
- Critical Access Hospitals (CAH)
- Disproportionate Share Hospitals (DSH)
- Rural Referral Centers (RRC)
- Sole Community Hospitals (SCH)

Other covered entity types need not register or provide the data we request.

Second, beginning on March 1, 2021, any 340B-covered entity that falls within one of the five (5) included covered entity categories listed above that does not have an in-house pharmacy location registered on the covered entity database as a shipping address or child site of the covered entity may designate a single contract pharmacy for this purpose. A qualifying covered entity may choose a single contract pharmacy for the covered entity and its child sites and Sanofi will provide 340B pricing in this circumstance, irrespective of whether the covered entity provides the data Sanofi requests.

In order to designate a contract pharmacy, a covered entity must first register at https://www.340besp.com/. After registering and logging in to its account, the covered entity may designate its single contract pharmacy in the Entity Profile tab. This designation will be made for the parent 340B ID and will apply to any child sites. Please note that a contract pharmacy must have an assigned HIN for the wholesaler to process 340B transactions for Sanofi drug products. Covered entities that designate a contract pharmacy without a HIN will be notified of this requirement and provided additional information on how to assign a HIN for their contract pharmacy.

For a covered entity's contract pharmacy designation to take effect on March 1, its contract pharmacy selection needs to be made by Monday, February 22. After February 22, please allow 10 business days for the designation to take effect. A covered entity may change its contract pharmacy designation once every twelve (12) months, or more often if the designated contract pharmacy is terminated from the HRSA OPAIS database.

Finally, we remind covered entities that they need not provide any information on physician-administered drugs.

We appreciate your cooperation in this initiative and value our relationship with you very much. Please contact Sanofi340BOperations@Sanofi.com if you have any questions about these matters.

Sincerely,

Gerald Gleeson
VP & Head, Sanofi US Market Access Shared Services

EXHIBIT 9

Xavier Becerra
Attorney General

William Tong
Attorney General

Derek Schmidt
Attorney General

Doug Peterson
Attorney General

December 14, 2020

Secretary Alex M. Azar
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201
Secretary@HHS.gov
Via Email and U.S. Mail

Administrator Thomas J. Engels
Health Resources and Services Administration
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857
Via Email and U.S. Mail

Re: Drug Manufacturers' Actions Violating 340B Drug Pricing Program Requirements

Dear Secretary Azar and Administrator Engels:

We, the undersigned State Attorneys General of California, Connecticut, Kansas, Nebraska, Colorado, Delaware, Hawaii, Illinois, Iowa, Maine, Maryland, Massachusetts, Michigan, Minnesota, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Dakota, Vermont, Virginia, Washington, Wisconsin, and the District of Columbia, write to urge the U.S. Department of Health and Human Services (HHS) and the Health Resources and Services Administration (HRSA) (collectively HHS), to address drug manufacturers' unlawful refusal to provide critical drug discounts to covered entities, such as community health centers, under the 340B Drug Pricing Program. The 340B statute requires manufacturers that want to participate in Medicare Part B and Medicaid to "offer each covered entity covered outpatient drugs for purchase at or below the

applicable ceiling price."[1] Yet,—amid the ongoing COVID-19 pandemic—drug manufacturers Eli Lilly & Company, AstraZeneca PLC, Sanofi SA, Novartis Pharmaceuticals, Merck & Co., and United Therapeutics Corp. have threatened the loss of or have already refused to provide drug discounts for drugs shipped to contract pharmacies that administer 340B drugs on behalf of some of our nation's most impactful safety-net providers. We applaud HHS's recent promulgation of regulations establishing the required Alternative Dispute Resolution (ADR) process, but urge HHS to provide immediate relief to the health centers and hospitals that have already lost significant cost savings, by making immediate determinations that manufacturers' actions violate the terms of their participation in the Medicare Part B and Medicaid Programs.

HHS has the authority to address these ongoing violations of § 340B of the Public Health Service Act, 42 U.S.C. § 256b. Specifically, HHS has the authority to issue civil monetary penalties, and to issue guidance articulating the statutory responsibilities of drug manufacturers. The illegal actions of drug manufacturers during this time of urgent need compel HHS to utilize its authority to maintain and support the purpose and execution of the 340B Drug Pricing Program.

We understand that HHS has now issued a final rule to create a binding administrative dispute resolution process under which 340B health centers could seek to remedy some of this unlawful conduct.[2] Still, because the ADR process will not become effective until January 14, 2021, we urge the department to seriously consider the vital role played by contract pharmacies and to prohibit drug manufacturers from dictating whether and how a covered entity can access 340B pricing for their contract pharmacies.

Each day that drug manufacturers violate their statutory obligations, vulnerable patients and their healthcare centers are deprived of the essential healthcare resources that Congress intended to provide. Drug manufacturers are, without justification, flouting discounted pricing requirements for low-income patients and/or unreasonably conditioning 340B pricing on data demands, depriving such patients of affordable medications to the detriment of the health centers and hospitals that serve these vulnerable communities. During a national public health crisis, these actions are especially egregious and cannot be ignored.

A. The States and 340B Covered Entities Share a Common Purpose

The partnership between the States and 340B covered entities is not only a matter of public policy but enshrined in federal law. To ensure that public hospitals, community health centers, and others serving indigent patients, including state-run hospitals, have necessary resources, Congress directed the Secretary to enter into agreements with drug manufacturers to limit the amount required to be paid for drugs purchased by such covered entities. The Medicaid statute requires that drug manufacturers participate in the 340B pricing program as a condition of

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[1] 42 U.S.C. § 256b(1).

[2] *See* 340B Drug Pricing Program; Administrative Dispute Resolution Regulation, RIN 0906-AB26 (Dec. 12, 2020), https://public-inspection.federalregister.gov/2020-27440.pdf (to be published in the Federal Register on Dec. 14, 2020.

having their drugs covered under Medicaid and Medicare Part B.[3] The statute requires drug manufacturers to enter into Pharmaceutical Pricing Agreements (PPAs) with HHS regarding outpatient medications covered by the Medicaid program.[4] The PPAs "*shall require* that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price."[5]

As Congress explained, 340B "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."[6] The purpose of the statute is "to enable" 340B entities "to obtain lower prices on the drugs that they provide to their patients," thus "reaching more eligible patients and providing more comprehensive services."[7] To that end, covered entities treating vulnerable patient populations can "stretch scarce federal resources as far as possible, reaching more eligible patients.''[8] Without these lower prices, community health centers may be forced to restrict healthcare services provided to at-risk patients in a time of great need.

Thus, the States and the 340B covered entities work in partnership to provide individuals access to affordable healthcare, including prescription drugs. Both the States and the 340B entities benefit when covered entities receive the price discounts to which they are entitled. In addition to discounted drugs, 340B enables covered entities to stretch resources to support underserved patients and provide comprehensive services beyond the reach of state Medicaid programs. In this way, 340B entities provide additional services to low-income communities.

The more medical care 340B covered entities can provide with their limited resources and state reimbursement, the further state-Medicaid budgets will go in serving the States' uninsured and underinsured residents. 340B prices are a vital lifeline for safety-net providers across the country. These savings ensure that medication and primary care are affordable for low-income patients, making care accessible to persons below 100% of the poverty level for no more than a nominal fee, and ensure that patients between 101-200% of the poverty level are charged on a sliding fee scale. These critical benefits allow covered entities to expand access to medication and other services, such as supporting in-house pharmacies, including extending pharmacy hours and pharmacy staff, providing automated systems that electronically dispense prescribed medication to patients in remote areas, mail-order prescription delivery programs, and

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[3] 42 U.S.C. § 256b(a)(1); 42 U.S.C. § 1396r-8(a)(2018).

[4] 42 U.S.C. §§ 256b(a)(1);1396r-8(a)(5).

[5] 42 U.S.C. § 256b(1)(emphasis added). The ceiling price is defined as being "equal to the average manufacturer price for the drug under title XIX of the Social Security Act in the preceding calendar quarter," which is then reduced by a rebate percentage calculated by Medicaid. 42 U.S.C. § 256b(a)(1)-(2).

[6] H.R. Rep. No. 102-384(II), at 12 (1992).

[7] H.R. Rep. *supra*, note 4 at 7, 12.

[8] *Id.*

funding behavioral health, OBGYN, and dental services that are co-located to help create a continuum of care for patients.

Moreover, 340B helps support non-billable services by covered entities that lead to improved public health outcomes. For example, many 340B covered entities provide robust care coordination for HIV and Hepatitis C patients, as well as STI prevention, and play a key role in expanding access to preventive services for men and women's reproductive health. Among many other benefits, the 340B pricing helps health centers, already stretched thin, to develop infrastructure necessary to care for underserved populations. This means the ability to modernize their IT infrastructure, improve electronic health records, expand their service capacity by building additional exam rooms, and train employees to use data that improve clinical and operational measures.

B. Congress Required HHS to Regulate and Oversee Compliance with the 340B Program

As you know, the 340B Drug Pricing Program, enacted by Congress as part of the Public Health Service Act, and signed into law by President George H. W. Bush in 1992, has provided low-income patients access to reduced-price prescription drugs for decades. The 340B "covered entities"[9] include crucial community health providers such as children's hospitals, rural hospitals, federally qualified health centers, Ryan White HIV/AIDS Program funded-recipients, and other hospitals and health centers that have served vulnerable patients for years.[10]

HHS should use the enforcement mechanisms Congress has provided to immediately address flagrant and clear statutory violations by the drug manufacturers. For example, if a manufacturer overcharges a covered entity, HHS may require the manufacturer to reimburse the covered entity, and HHS may also terminate the manufacturer's PPA,[11] which also terminates the drug manufacturer's eligibility for Medicaid coverage of its drugs.[12]

In 2010, Congress also underscored the requirement of drug manufacturer compliance, adding the imposition of civil monetary penalties for any instance in which a manufacturer overcharges a 340B covered entity for a 340B drug.[13] Congress provided that the HHS's regulatory authority over the 340B Program includes the ability to impose civil monetary

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[9] *See* 42 U.S.C. § 256b(a).

[10] There are over 12,000 covered entities nationwide. U.S. House of Representatives, Committee on Energy & Commerce, Subcommittee on Oversight & Investigations, 115th Congress, email from U.S. Dept. of HHS to Committee Staff (Dec. 21, 2017).

[11] § 1396r–8(b)(4)(B)(i), (v). *See also* Dep't. of Health and Human Servs., Health Resources and Servs. Admin., Healthcare Systems Bureau, *Pharmaceutical Pricing Agreement*, OMB No. 0915-0327, § IV(c), https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/pharmaceutical-pricing-agreement-example.pdf.

[12] 42 U.S.C. § 1396r–8(a)(1), (5).

[13] 42 U.S.C. § 256b(d)(1).

penalties, with HHS issuing a Civil Monetary Penalties Regulation in 2017.[14] Both Congress and HHS have made clear that civil monetary penalties are available when participating manufacturers overcharge covered entities, with a separate penalty of up to $5,000.00 for each individual medication order.[15]

In addition, throughout the years, HRSA has repeatedly issued guidance regarding the 340B Program. Since 1996, HRSA has stated that the law expressly allows covered entities to contract with outpatient pharmacies to fill prescriptions for 340B eligible patients.[16] In 2010, HRSA released additional guidance making clear that covered entities can use multiple external contract pharmacies as they work to fulfill the mission of providing healthcare to underserved populations.[17] HRSA's guidance specifically allows contract pharmacies to receive 340B drugs under a "bill to/ship to" model, whereby the drug manufacturer sends invoices to the covered entity, but ships drugs to the contract pharmacy.[18] The actions of some drug manufacturers both violate the law and abruptly disavow longstanding HRSA policy and well-established practice for carrying out the vital mission of the program.

Notwithstanding clear legal requirements, some drug manufacturers have brazenly ceased providing 340B pricing to covered entities using contract pharmacies and others have unilaterally imposed conditions on 340B pricing.[19] HRSA recently expressed "significant concerns" with this unilateral conduct on the part of at least one manufacturer.[20] Similar concerns have been expressed by at least one state Attorney General directly to Eli Lilly, Astra Zeneca, Merck, Novartis and Sanofi.[21] Some drug manufacturers have stated that they will provide 340B pricing to covered

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[14] *See* 42 C.F.R. § 10.11 and 42 C.F.R. Part 1003. S*ee also Pharm. Research & Manufacturers of America v United States Dept. of Health & Human Services,* 43 F. Supp.3d 28, 41 (D.D.C. 2014).

[15] 42 U.S.C. § 256b(d)(1); 42 C.F.R. § 10.11(b).

[16] *See* 61 Fed. Reg. 43,549 (Aug. 23, 1996).

[17] *See* 75 Fed. Reg. 10,272 (March 5, 2010).

[18] *See* 61 Fed. Reg. 43,549 (Aug. 23, 1996).

[19] This conduct by drug manufacturers is not a just recent problem. As early as 2015, Celgene, now owned by Bristol Myers Squibb, implemented a policy that limited the distribution network for Revlimid®, Pomalyst®, and Thalomid®, such that 340B pricing was not available to all 340B covered entities. Celgene provided notice to covered entities of this policy implementation in 2015 through HRSA. *See* http://www.hrsa.gov/opa/programrequirements/manufacturerletters/2015/celgeneletter.pdf.

[20] September 21, 2020 letter from Robert Charrow, General Counsel to the Secretary of Health and Human Services, to Eli Lilly and Company. https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hhs-eli-lilly-letter.pdf.

[21] https://portal.ct.gov/AG/Press-Releases/2020-Press-Releases/AG-Tong-Demands-Drug-Makers-Abandon-Unlawful-Actions-Imperiling-Access-to-Affordable-Prescriptions.

entities using contract pharmacies but are conditioning such pricing on unacceptable terms.[22] The imposition of these additional requirements has no basis in the text of the Public Health Service Act, is untethered to maintaining 340B Program integrity, and serves only to increase costs for covered entities. Moreover, these actions are disrupting an essential method used by many covered entities to dispense 340B drugs to underserved and vulnerable patient populations who rely on these pharmacies in their communities to fill their prescriptions. These actions also deprive or threaten to deprive 340B pricing necessary to enable covered entities to continue serving low-income patients who may otherwise do without necessary healthcare.

C. The 340B Program Enjoys Strong Bipartisan Support, Confirming the Importance of Access to Affordable Prescription Drugs for All Americans

Congress has expressed bipartisan support for the 340B Program as it has operated for years. The House of Representatives Committee on Energy and Commerce noted in 2018 that the 340B Program "is an important program that enjoys strong bipartisan support in Congress. . . On numerous occasions, the committee has emphasized the importance of the 340B program in providing care to vulnerable Americans."[23]

Most recently, Congress has issued letters decrying the conduct of drug manufacturers who unilaterally seek to impose conditions without legal basis and take other steps to undermine the 340B Program. In September, a bipartisan group of 246 U.S. Representatives urged HHS to continue to comply with 340B Program requirements without imposing baseless restrictions regarding the use of contract pharmacies.[24] On November 13, 2020, a bipartisan group of 217 members of the U.S. House of Representatives issued a letter to HHS expressing "grave concern" regarding measures being considered by drug manufacturers which "threaten 'safety net providers' lawful access to discounted drugs through the 340B Program."[25, 26]

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[22] For example, some manufacturers are illegally conditioning 340B pricing on the provision of claims data to an agent of the manufacturer with insufficient assurance of compliance under the Health Insurance Portability and Accountability Act. In addition, some manufacturers are requiring covered entities to sign documents stating that they are not entitled to receive 340B pricing through a contract pharmacy in order to receive 340B pricing.

[23] https://republicans-energycommerce.house.gov/wp-content/uploads/2018/01/20180110Review_of_the_340B_Drug_Pricing_Program.pdf.

[24]https://mckinley.house.gov/uploadedfiles/congressional_member_340b_letter_to_azar_9.14.20.pdf.

[25] https://spanberger.house.gov/uploadedfiles/201113_final_340b_hhs_letter.pdf (addressing recent actions to shift the 340B Program from a discount to a rebate formula).

[26] A smaller group of senators similarly urged that HHS not ignore noncompliance by drug manufacturing companies which harms underserved patients. https://www.blumenthal.senate.gov/imo/media/doc/2020.09.15_Letter%20to%20PhRMA%20on%20340B%20Contract%20Pharmacies%20FINAL%20SIGNED.pdf.

Such strong bipartisan support, even decades after its inception, confirms Congress' unwavering commitment to protect the purpose of the 340B Program and underscores the importance of providing access to affordable prescription drugs to all Americans.

D. Drug Manufacturers' Actions Exacerbate the Harms Brought On by the COVID-19 Pandemic and Undermine HHS's Efforts to Support 340B Covered Entities

These recent actions by the drug manufacturers are deeply troubling, particularly given the ongoing COVID-19 health crisis. Not only are the manufacturers' actions an attempt to disrupt long-settled expectations and existing contractual arrangements for dispensing 340B drugs, but they have been taken when millions of Americans in our respective States are already reeling from the grave health and financial consequences caused by a historic pandemic and unprecedented economic crisis. Indeed, HHS has called the timing of such unfortunate recent actions "*at the very least*, insensitive to the recent state of the economy."[27] We urge HHS to do more than decry these unlawful practices and provide immediate relief, beyond the new ADR process, to halt these actions now.

Safety-net healthcare institutions are struggling to meet the dual challenges of responding to COVID-19 while maintaining financial stability. As you know, this unprecedented effort requires providing covered entities with flexibility and additional resources to combat the virus. HRSA recently issued a number of COVID-19 resources aimed at assisting 340B covered entities in maintaining 340B Program compliance throughout the COVID-19 outbreak.[28] Allowing 340B entities regulatory flexibility, such as the use of abbreviated health records, the expansion of 340B-eligible child sites, the relaxation of the prohibition on acquiring covered outpatient drugs through group purchasing organizations due to shortages, and the encouraged use of telemedicine platforms as a critical way of treating COVID-19 patients, confirm that your office understands the serious challenges many healthcare centers are facing. The States applaud these actions, as there is a critical need for the expansion of healthcare coverage to help those who have lost their jobs and those in need of care in response to COVID-19.

However, drug manufacturers' concerted efforts to cut off, threaten, or belabor discounted drug distribution to contract pharmacies utilized by covered entities undermines HRSA's efforts to support these safety-net providers. We urge you to provide immediate relief, not only because it is critical to the community providers that serve low-income patients, but also because it is more necessary than ever now as many of these Americans are also the hardest hit by the COVID-19 pandemic.

The drug manufacturers' combined actions directly thwart the essence of the 340B Program—ensuring that medicine and healthcare are provided to the underserved patients who

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[27] September 21, 2020 letter from Robert Charrow, General Counsel to the Secretary of Health and Human Services, to Eli Lilly and Company. https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hhs-eli-lilly-letter.pdf.

[28] Health Res. and Servs. Admin., *COVID-19 Resources*, https://www.hrsa.gov/opa/COVID-19-resources (last visited Nov. 20, 2020).

need it most—and it is the duty of HHS, not the drug manufacturers, to ensure the integrity of the 340B Program.

* *

While we were pleased to learn that HHS has finalized the long-delayed ADR rule and we continue to review it in its entirety, we urge you to provide clarity to all 340B stakeholders regarding these important issues as soon as possible. In addition, it is our hope that your final rule will provide a substantive enforcement mechanism for covered entities and that implementation is undertaken with haste. The landscape has altered considerably in the last several years, and the events of 2020 have sharpened the need for discounted pricing afforded by the 340B Program. The undersigned Attorneys General welcome any opportunity to provide input, either formally or informally, with regard to the final rule or the content of this letter. In the meantime, HHS should use its authority and any available measures, including imposition of civil penalties where appropriate, to hold those drug manufacturers in violation of the law directly accountable. The vulnerable and underserved patients of 340B covered entities of our States and nationwide deserve no less.

Sincerely,

Attorney General of California

DEREK SCHMIDT
Attorney General of Kansas

Attorney General of Connecticut

DOUG PETERSON
Attorney General of Nebraska

cc: Robert P. Charrow
General Counsel
Office of the Secretary
U.S. Department of Health & Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

PHIL WEISER
Attorney General of Colorado

Attorney General of Maine

KATHY JENNINGS
Attorney General of Delaware

BRIAN FROSH
Attorney General of Maryland

KARL A. RACINE
Attorney General of the District of Columbia

MAURA HEALEY
Attorney General of Massachusetts

CLARE E. CONNORS
Attorney General of Hawaii

DANA NESSEL
Attorney General of Michigan

Attorney General of Illinois

KEITH ELLISON
Attorney General of Minnesota

TOM MILLER
Attorney General of Iowa

AARON D. FORD
Attorney General of Nevada

GURBIR S. GREWAL
Attorney General of New Jersey

JOSH SHAPIRO
Attorney General of Pennsylvania

HECTOR BALDERAS
Attorney General of New Mexico

PETER F. NERONHA
Attorney General of Rhode Island

LETITIA A. JAMES
Attorney General of New York

Attorney General of South Dakota

Attorney General of North Carolina

THOMAS J. DONOVAN, JR.
Attorney General of Vermont

MIKE HUNTER
Attorney General of Oklahoma

Attorney General of Virginia

ELLEN F. ROSENBLUM
Attorney General of Oregon

BOB FERGUSON
Attorney General of Washington

Joshua L. Kaul

Attorney General of Wisconsin

EXHIBIT 10

August 28, 2020

Richard J. Pollack
President & Chief Executive Officer
American Hospital Association
800 10th Street, NW
Two CityCenter, Suite 400
Washington, DC 20001

Dear Mr. Pollack,

I write on behalf of Sanofi to answer your letter of August 21, 2020 regarding our new 340B Program integrity initiative. Our initiative will collect data to prevent duplicate discounts, will comply with applicable law, and will not burden 340B covered entities or patients. Given the benefits of our initiative, I am both surprised and disappointed by your letter's unfounded claims and incendiary tone. Sanofi supports the 340B Program's core objective of increasing access to outpatient drugs among uninsured and vulnerable patients and is committed to strengthening the Program's mission, a goal that is only supported and advanced through our initiative to prevent illegal and/or inappropriate duplicate discounts.

Our duplicate discount concerns are well-founded. Despite the legal ban on forcing pharmaceutical manufacturers to double pay Medicaid rebates and 340B discounts on the same drug,[1] duplicate discounting on Medicaid claims runs rampant. Likewise, duplicate discounting in Medicare Part D and commercial insurance is counterproductive for program sustainability. Over 30% of Health Resources and Services Administration (HRSA) audits of covered entities in 2018 and 2019 found Medicaid duplicate discounting, and government reports have repeatedly documented this ongoing problem.[2] Likewise, in a limited project that analyzed three years of Medicaid rebates from five states for three Sanofi products, we identified over $16 MM in 340B duplicate discounts. Further, government reports have found that contract pharmacies complicate efforts to prevent duplicate discounts and that HRSA's contract pharmacy and duplicate discount oversight has been inadequate.[3] The rapid growth in contract pharmacy arrangements compounds this problem and necessitates our initiative. Between 2010 and 2019, the number of 340B contract pharmacies has grown 1,700 percent to about 23,000.[4]

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[1] 42 U.S.C. § 256b(a)(5)(A)(i).
[2] *See, e.g.*, GAO, Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement, GAO-18-480 (June 2018), https://www.gao.gov/assets/700/692697.pdf (hereinafter, "Oversight of Contract Pharmacies Needs Improvement"); GAO, 340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement, GAO-20-212 (January 2020), https://www.gao.gov/assets/710/703966.pdf (hereinafter, "Oversight of MDRP Intersection Needs Improvement"); OIG, Memorandum Report: Contract Pharmacy Arrangements in the 340B Program, OEI-05-13-00431 (February 4, 2014), https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf.
[3] *Id*.
[4] GAO, Oversight of MDRP Intersection Needs Improvement, at 2.

Our initiative complies with the 340B statute and our agreement with the Department of Health and Human Services, which require that Sanofi "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."[5] Simply put, Sanofi will continue to offer all of its drugs to all 340B covered entities. At most, if a covered entity refuses to provide the requested data, we will restrict the entity's use of contract pharmacy arrangements, but these entities will remain eligible to purchase at 340B prices for shipment to their own facilities. Sanofi will voluntarily offer 340B pricing through contract pharmacy arrangements, consistent with the HRSA guidance you reference, if a covered entity provides the data Sanofi requests to prevent the duplicate discounts that otherwise would continue unchecked.

Contrary to your hyperbolic language, our initiative will not burden covered entities. Our data submission portal will be user-friendly and the data elements submitted will be limited and of the type commonly included in insurance reimbursement claims. Moreover, we do not request data on physician-administered drugs or drugs dispensed by covered entities' own facilities. Our approach avoids burdensome and ineffective manual data exchanges.

Even more importantly, patients will not be adversely impacted by our initiative. Unfortunately, even though 340B Program purchasing has tripled since 2014,[6] Government Accountability Office reports have found that contract pharmacies often do not give discounts to patients and that 340B hospitals provide similar median levels of charity care (as a percentage of revenue) as non-340B hospitals.[7] Given these findings and the ubiquity of duplicate discounts, I am disappointed that you would attack our initiative as unethical and defend a broken system, instead of acknowledging covered entities' shortcomings and partnering on what should be a shared goal of improving 340B Program integrity. Eliminating duplicate discounts ultimately will free resources to be focused where they belong: on reducing patients' out-of-pocket costs.

Finally, Sanofi understands well the challenges posed by the COVID-19 pandemic as we carry out multiple research and development initiatives to fight the disease and continue making and delivering medicines for patients. Because our initiative will create only a minor data sharing obligation for 340B covered entities and will strengthen the 340B Program, this initiative will not impair our common fight.

At your request, we would be pleased to discuss these issues with you further.

Sincerely,

Adam Gluck
Senior Vice President and Head, U.S. and Sanofi Genzyme Corporate Affairs
Sanofi U.S.

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[5] 42 U.S.C. § 256b(a)(1).

[6] Drug Channels, New HRSA Data: 340B Program Reached $29.9 Billion in 2019; Now Over 8% of Drug Sales (June 9, 2020), https://www.drugchannels.net/2020/06/new-hrsa-data-340b-program-reached-299.html.

[7] GAO, Oversight of Contract Pharmacies Needs Improvement, at 30; GAO, Drug Discount Program: Characteristics of Hospitals Participating and Not Participating in the 340B Program (GAO-18-521R), at 13 (June 18, 2018), https://www.gao.gov/assets/700/692587.pdf.

EXHIBIT 11

August 26, 2020

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

Dear Secretary Azar:

On behalf of the nation's 340B hospitals, we urge you to protect vulnerable communities from actions taken by five of the nation's largest pharmaceutical manufacturers that undermine access to critical drugs and other health care services. We ask the Department of Health and Human Services (HHS) to use its authority to require that these and other pharmaceutical manufacturers comply with the law. This is particularly critical now as these hospitals need every resource available to care for their patients in vulnerable communities during the COVID-19 public health crisis.

So far, a number of companies are complicit with these unlawful tactics:

Eli Lilly

Last month, Eli Lilly announced that effective July 1, 2020, the company will no longer provide 340B pricing on three of its products when purchased by 340B hospitals to be dispensed by 340B contract pharmacies.[1] This refusal to sell a drug at a 340B price is a violation of the statute's requirement that manufacturers offer 340B prices to eligible covered entities. Eli Lilly has left open the possibility that it will extend this policy to other drugs, which include several high-priced drugs to treat diabetes.

AstraZeneca

The drug manufacturer AstraZeneca recently announced that, starting October 1, 2020, it will no longer offer 340B pricing to covered entities for any drugs that will be dispensed through contract pharmacies. AstraZeneca sells a wide range of products eligible for 340B pricing, including many costly cancer and diabetes drugs that do not have lower-priced generic alternatives. Cutting off access to 340B pricing for these expensive products would significantly reduce hospital access to program savings, affecting their ability to provide services to patients.

[1] Limited Distribution Plan Notice for Cialis® (tadalafil) Erectile Dysfunction NDCs, https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/limited-distribution-plan-notice-cialis.pdf.

Section 340B(a)(1) of the Public Health Services Act requires manufacturers to sell covered outpatient drugs to covered entities at or below the 340B ceiling price if such drug is made available to any other purchaser at any price.[2] There is no provision under the statute that allows these companies to deny 340B pricing to a covered entity for any drug. Therefore, these policies are a clear violation of the law, and HHS is compelled to take action to stop it from being carried out.

Merck

On June 29, Merck sent letters to 340B covered entities asking them to submit contract pharmacy claims data for "commonly dispensed" Merck drugs to allow the company to prevent duplicate discounts related to contract pharmacies. Without "significant cooperation" from covered entities, Merck says it "may take further action to address 340B Program integrity." While Merck did not state that such action would include no longer offering 340B pricing to covered entities for drugs dispensed by contract pharmacies, we are concerned the company appears poised to do so.

Sanofi

The drug manufacturer Sanofi sent letters last month similar to those sent by Merck threatening to deprive 340B covered entities' access to discounted drugs for dispensing through contract pharmacies if the claims data demanded are not supplied to the company by October 1.

Novartis

In a similar manner, Novartis recently sent letters to 340B covered entities requiring them to submit all 340B claims data originating from contract pharmacies beginning October 1, stating that 340B discounts will be unavailable to entities that fail to do so.

As you are aware, Congress created the 340B drug pricing program to allow hospitals and other covered entities serving vulnerable populations "to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[3] Covered entities use the savings from the high prices of prescription drugs enabled under the 340B drug program to support care for vulnerable communities in a variety of ways, including supporting clinic and medical services that would otherwise be unavailable.

If left unaddressed, these actions will open the way for other drug manufacturers to deny discounts for other products. This is clearly contrary to the intent of the 340B program

[2] 42 U.S.C. § 256b(a)(1).
[3] H.R. Rep. 102-384(II) at 12 (1992).

and will result in significant harm to the millions of patients and communities who rely on providers that participate in the program for their care.

At a time when our nation and our hospitals are focused on confronting the global pandemic of COVID-19 and dealing with the continuing increase in prescription drug costs, we urge the Department to use its authority to address these troubling actions and assure that the pharmaceutical industry does not prioritize excess profits over care for vulnerable communities. We thank you for your continued leadership.

Sincerely,

340B Health
America's Essential Hospitals
American Hospital Association
American Society of Health-System Pharmacists
Association of American Medical Colleges
Catholic Health Association
Children's Hospital Association

cc: Eric D. Hargan, Deputy Secretary, Department of Health and Human Services
Thomas J. Engels, Administrator, Health Resources and Services Administration
Krista Pedley, Director, Office of Pharmacy Affairs, Health Resources and Services Administration

EXHIBIT 12

HALL RENDER
KILLIAN HEATH & LYMAN

Hall, Render, Killian, Heath & Lyman, P.C.
330 East Kilbourn Avenue, Suite 1250
Milwaukee, WI 53202
https://www.hallrender.com

Todd A. Nova
(414) 721-0464
tnova@hallrender.com

October 6, 2020

Via Certified Mail and E-Mail to Sanofi340BOperations@Sanofi.com:

Ms. Jeannie Jehnke
Government Pricing
Sanofi-Aventis U.S., LLC
Sanofi Pharmaceuticals, Inc.
Sanofi Pasteur, Inc.
Sanofi U.S. Corporation
55 Corporate Drive
Mail Slot: 55B-300 US Market Access - Commercial
Bridgewater, NJ 08807

RE: Illegal and Discriminatory 340B Limited Distribution Model

Dear Ms. Jehnke:

We represent the 340B drug discount program ("340B Program") participating covered entities listed in the attached Exhibit A ("Clients" or "Covered Entities"). Together, these organizations utilize 340B Program savings to make available vital safety-net care directly affecting the lives of millions of our country's most vulnerable patients. As you are aware, the United States Health Resources and Services Administration ("HRSA") Office of Pharmacy Affairs ("OPA") has a longstanding process for resolving disputes between 340B Program covered entities and manufacturers.[1] This letter represents our Clients' good-faith effort to engage in dialogue to reach a mutually acceptable resolution pursuant to that process. We note that this dispute may also implicate administrative and private rights of action, and our Clients reserve all rights to pursue such actions.

Since at least October 1, 2020 Sanofi U.S. ("Sanofi") has refused to make required 340B pricing available to our Clients for prescriptions dispensed to their eligible patients at contracted pharmacy locations. Sanofi has improperly conditioned our Clients' ability to purchase drugs at 340B prices on their entering into a unilateral agreement with a third-party software company that requires, among other things, the disclosure of confidential information pursuant to binding, unreasonable and non-negotiable terms and conditions. As described in detail in our September 28, 2020 letter to you and your apparent agent Second Sight Solutions, LLC ("Second Sight"), the structure of Second Sight's operations and its required terms are unreasonable and result in impermissible discriminatory covered outpatient drug pricing. Sanofi has stated publicly that it is engaging in an

[1] *See* 61 Fed. Reg. 65,406, 65,412 (Dec. 12, 1996).

initiative "to collect data in an effort to reduce waste in the 340B program by preventing Medicaid, Part D, and commercial duplicate discounts."[2] Sanofi states its belief that it has "designed this initiative in full compliance with all applicable law and so as not to burden 340B covered entities or patients."[3]

As a bipartisan majority of the U.S. House of Representatives communicated to HHS Secretary Azar, "[t]hese actions are in violation of the statutory requirement that drug companies charge no more than the 340B ceiling price when selling their products to 340B providers."[4] As such, on behalf of each Client, we are writing to demand that Sanofi make available 340B pricing for all Sanofi NDCs dispensed to Covered Entity 340B eligible patients through their contracted pharmacies, beginning from the date that Sanofi unilaterally refused to offer such required pricing, which we believe to be October 1, 2020.

Sanofi has taken this action unilaterally, without explanation, and without identifying any suspected violation on the part of any Client. Sanofi caused direct and immediate harm to our Clients and their patients when it refused to ship 340B-eligible drugs to properly enrolled contract pharmacies providing services to Covered Entity patients.

Of course, if and to the extent Sanofi has any reasonable allegations of noncompliance associated with a Covered Entity's contract pharmacy patients, we would welcome the opportunity to engage in a dialogue to reach a mutually acceptable resolution. Absent any such allegation, we note that we agree with the statement from HHS that False Claims Act liability is "a potential consequence in the event that [a manufacturer] knowingly violates a material condition of the program that results in over-charges[.]"[5] As noted above, we reserve the right to take any additional actions available to our Clients in order to enable them to access the 340B Program pricing to which they are entitled and which Sanofi has unilaterally, and unreasonably, refused to make available.

More generally, we note that the 340B Program is available only to safety-net providers who, by definition, care for the most medically vulnerable patients and are either non-profit or government-operated providers. Our Clients use the savings from 340B drug sales to expand access to health care in underserved communities, consistent with Congress's intent in establishing the 340B Program. Congress's explicit goal in creating the 340B Program was to protect covered entities against manufacturer price increases, "enabl[ing] these entities to stretch scarce Federal resources

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[2] Email from Sanofi (A. Gluck and G. Gleeson) to mass email list of 340B covered entities (Oct. 1, 2020, 12:00 PM).

[3] *Id.*

[4] Letter from Rep. David B. McKinley et al. to Sec. Azar, Sept. 14, 2020 (hereinafter "Letter from 243 Members of Congress").

[5] Letter to Eli Sanofi and Company (Ms. Anat Hakim) from HHS General Counsel Mr. Robert P. Charrow (September 21, 2020) (hereinafter "HHS General Counsel Letter.").

as far as possible, reaching more eligible patients and providing more comprehensive services."[6] The 340B Program establishes, as a matter of law, a privileged place for safety-net providers where they are protected from unreasonable manufacturer price hikes.

In the wake of Sanofi's refusal to provide 340B pricing to Covered Entities, our Clients have been forced to reassess the viability of crucial safety-net programs. As a direct result of Sanofi's unilateral and unlawful action, our Clients may be required to limit hours, close service lines, and otherwise limit the availability of health care services during a pandemic that has wrought havoc on underserved communities. This immediate impact shows just how crucial the 340B Program is to ensuring that our nation's most vulnerable patients receive adequate medical care.

Under its Pharmaceutical Pricing Agreement ("PPA"), Sanofi is prohibited from charging Covered Entities a price that exceeds the 340B ceiling prices. Sanofi's discriminatory distribution model violates this requirement. To be clear, Sanofi was not obligated to execute the PPA. It did so voluntarily in order to make available Medicaid and Medicare Part B reimbursement for its drugs.[7]

In its email to covered entities, Sanofi states that it is taking these steps because it objects to covered entities serving their patients through contract pharmacies. Contract pharmacy arrangements are a legitimate mechanism used by Covered Entities to treat their patients, and their use is founded on soundly reasoned, longstanding agency guidance. As HRSA OPA noted in 1996, "[i]t would defeat the purpose of the 340B program if these covered entities could not use their affiliated pharmacies in order to participate in the 340B program."[8] In 2016, Sanofi signed an addendum to its PPA which restated the statutory requirement that a manufacturer must "offer each 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."[9] Sanofi was aware of HRSA's position with respect to contract pharmacy arrangements when it made this commitment. If Sanofi determines that the costs of participating in the 340B Program outweigh the benefits, it may terminate its PPA at any time upon 60 days' notice.[10]

Neither the 340B Statute nor the PPA permit Sanofi to take precautionary measures against speculative harms. If Sanofi believes that a covered entity has engaged in wrongful conduct, its recourse is through HRSA's audit and dispute resolution process. This audit process, like the 340B Program generally, is designed to protect both covered entities and manufacturers. Manufacturers are not allowed to engage in the kind of self-help that Sanofi has implemented. Even where the

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[6] H.R. Rep. No. 102-384, *12.

[7] 42 U.S.C. § 1396r-8(a)(1).

[8] 61 Fed. Reg. 43,550 (Aug. 23, 1996).

[9] HRSA OPA, 340B OPAIS Entry for Astra Pharmaceuticals, L. P. (Sept. 28, 2020) (available at https://340bopais.hrsa.gov/manufacturerdetails/56870) (last accessed Sept. 28, 2020); 42 U.S.C. § 256b(a)(1); HRSA Pharmaceutical Pricing Agreement, Addendum (2019)

[10] HRSA Pharmaceutical Pricing Agreement, § VI(b) (2019).

manufacturer has evidence showing that an identified covered entity has violated the statute, it must continue to sell the entity drugs at 340B prices. "Not until the entity is found guilty of prohibited activity and a decision is made to remove the entity from the covered entity list, will the manufacturers no longer be required to extend the discount."[11] At that time, HRSA can require the covered entity to repay the manufacturer for noncompliant discounts, and may impose civil monetary penalties for egregious conduct.

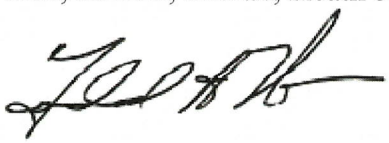
The power and responsibility to enforce the 340B Statute rest with HRSA, by delegation of the Secretary. As recognized by a bipartisan majority of the U.S. House of Representatives, "[t]here are no provisions in the statute that allow manufacturers to set conditions or otherwise impede a provider's ability to access 340B discounts."[12] Sanofi cannot engage a third-party vendor to bully covered entities into handing over data to which Sanofi itself is not entitled. As such, we believe Sanofi's unilateral limitation on 340B Covered Entity contracted pharmacy patient dispensing to be discriminatory and in violation of Sanofi's legal obligations.

As a next step, we again request that Sanofi reverse its position relative to our Clients and make them whole for any 340B discounts due for prescriptions dispensed to eligible patients beginning as of the date that 340B pricing was terminated, which we believe to be October 1, 2020. If Sanofi is unwilling to engage in good-faith efforts with us to resolve these issues, we intend to request that HRSA OPA impose the maximum civil monetary penalty, $5,883, for each instance of overcharging a Covered Entity for 340B drugs.[13] We also reserve the right to pursue all other remedies available to our Clients.

Please reach out to me at tnova@hallrender.com or (414) 721-0464 to respond to our good-faith request to discuss and resolve this issue or with any questions.

Very truly yours,

Hall, Render, Killian, Heath & Lyman, P.C.



Todd A. Nova

cc: RADM Krista Pedley
Elizabeth Elias, Esq.
Daniel Miller, Esq.

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[11] HRSA Manufacturer Audit Guidelines, 61 Fed. Reg. at 65,408 (Dec. 12, 1996).

[12] Letter from 243 Members of Congress.

[13] 45 C.F.R. § 102.3; 42 U.S.C. § 256b(d)(1)(B)(vi).

EXHIBIT A

Covered Entities

Advocate Christ Medical Center
DSH140208

Advocate Lutheran General Hospital
RRC140223-00

Advocate North Side Health Network
DSH140182

Advocate Trinity Hospital
DSH140048

Alamance Regional Medical Center
DSH340070

Aria Health Jefferson Northeast
DSH390115

Aurora Health Care Central Inc. d/b/a
Aurora Sheboygan Memorial Medical
Center
DSH520035

Aurora Health Care Metro, Inc.
DSH520138

Baraga County Memorial Hospital
CAH231307

Bixby Medical Center n/k/a Charles and
Virginia Hickman Hospital
DSH230005

Bon Secours Maryview Medical Center
DSH490017

Bon Secours Richmond Community
Hospital
DSH490094

Centura Health - Avista Adventist Hospital
DSH060103

Children's Hospital of San Antonio
PED453315

Children's Hospital of Wisconsin
PED523300

Children's National Medical Center
PED093300-00

CHRISTUS Health Central Louisiana d/b/a
CHRISTUS Coushatta Health Center
CAH191312

CHRISTUS Hospital
RRC450034

CHRISTUS Jasper Memorial Hospital
DSH450573

CHRISTUS Lake Area Hospital
DSH190201

CHRISTUS Mother Frances Hospital –
Tyler
RRC450102

CHRISTUS Santa Rosa Hospital - San
Marcos
DSH450272

CHRISTUS Santa Rosa Health System –
Santa Rosa Hospital Medical Center
RRC450237

CHRISTUS Spohn Hospital Alice
DSH450828

CHRISTUS Spohn Hospital Beeville
DSH450082

CHRISTUS Spohn Hospital Corpus Christi
Memorial
DSH450046

CHRISTUS Spohn Hospital Kleberg
DSH450163

CHRISTUS St. Frances Cabrini Hospital
DSH190019

CHRISTUS St. Michael
DSH450801

CHRISTUS Health Shreveport - Bossier
DSH190041

Clara Maass Medical Center
DSH310009

Clermont Mercy Hospital
DSH360236

Community Health Center of Branch County n/k/a Coldwater Regional Hospital
DSH230022

Cookeville Regional Medical Center
RRC440059-00

Cottage Grove Community Hospital
CAH381301-00

D.W. McMillan Memorial Hospital
DSH010099

Defiance Regional Hospital
CAH361328-00

Dickenson Community Hospital
CAH491303-00

Dickinson County Healthcare System
SCH230055-00

Eaton Rapids Medical Center
CAH231324-00

Ephraim McDowell Regional Medical Center, Inc.
DSH180048

Fisher-Titus Medical Center
RRC360065

Fort Logan Hospital
CAH181315-00

Fostoria Community Hospital
CAH361318-00

Franklin Woods Community Hospital
DSH440184

Good Samaritan Hospital Corvallis
RRC380014-00

Good Samaritan Regional Health Center
RRC140046-00

Good Shepherd Medical Center - Marshall
DSH450032

Greeneville Community Hospital
DSH440050

Gundersen Lutheran Medical Center, Inc.
DSH520087

Hancock County Hospital
CAH441313

Harbor Beach Community Hospital, Inc.
CAH231313-00

Helen Newberry Joy Hospital
CAH231304-00

Herrick Memorial Hospital
CAH231334-00

Holston Valley Medical Center
RRC440017

Holy Rosary Healthcare
CAH271347

HSHS Holy Family Hospital, Inc.
DSH140137

Indian Path Community Hospital
DSH440176

James B. Haggin Memorial Hospital
CAH181302-00

Jersey City Medical Center, Inc.
DSH310074

Johnson City Medical Center
DSH440063

Johnson County Community Hospital
CAH441304-00

Kennedy University Hospital - New Jersey
DSH310086

Lake View Memorial Hospital Inc.
CAH241308-00

Lee Memorial Health System d/b/a Lee Memorial Hospital
DSH100012

Lonesome Pine Hospital
DSH490114

Lutheran Medical Center
DSH060009

Longmont United Hospital
DSH060003

McKenzie Memorial Hospital
CAH231314-00

Memorial Hospital of Boscobel
CAH521344-00

Mercy Allen Hospital
CAH361306-00

Mercy Health - St. Charles Hospital
DSH360081

Mercy Health - St. Vincent Medical Center
DSH360112

Mercy Health Lourdes Hospital LLC
RRC180102-00

Mercy Health-Love County
CAH371306-00

Mercy Health-Marcum & Wallace Hospital, LLC
CAH181301-00

Mercy Hospital - St. Louis
DSH260020

Mercy Hospital ADA Inc.
DSH370020

Mercy Hospital Ardmore Inc.
SCH370047-00

Mercy Hospital Aurora
CAH261316-00

Mercy Hospital Berryville
CAH041329-00

Mercy Hospital Booneville
CAH041318-00

Mercy Hospital Carthage
CAH261338-00

Mercy Hospital Cassville
CAH261317-00

Mercy Hospital Columbus
CAH171308-00

Mercy Hospital Fort Smith
DSH040062

Mercy Hospital Healdton Inc.
CAH371310-00

Mercy Hospital Joplin
DSH260001

Mercy Hospital Kingfisher Inc.
CAH371313-00

Mercy Hospital Lebanon
DSH260059

Mercy Hospital Lincoln
CAH261319-00

Mercy Hospital Logan County
CAH371317-00

Mercy Hospital OKC
RRC370013-00

Mercy Hospital Springfield
DSH260065

Mercy Hospital Tishomingo Inc.
CAH371304-00

Mercy Hospital Watonga Inc.
CAH371302-00

Mercy Memorial Hospital
CAH361312-00

Mercy Regional Medical Center
DSH060013

Mercy St. Francis Hospital
CAH261335-00

Mercy Willard Hospital
CAH361310-00

MidMichigan Medical Center
SCH230222-00

MidMichigan Medical Center - Alpena
DSH230036

MidMichigan Medical Center - Gladwin
CAH231325-00

MidMichigan Medical Center - Gratiot
DSH230030

Molokai General Hospital
CAH121303-00

Monmouth Medical Center, Inc.
DSH310075

Monmouth Medical Center, Inc. d/b/a Monmouth Medical Center Southern Campus
DSH310084

Monument Health Custer Hospital
CAH431323-00

Monument Health Lead - Deadwood Hospital
CAH431320-00

Monument Health Rapid City Hospital
DSH430077

Monument Health Spearfish Hospital
SCH430048

Monument Health Sturgis Hospital
CAH431321-00

Mother Frances Hospital – Jacksonville
CAH451319

Mother Frances Hospital – Sulphur Springs – CHRISTUS Hopkins Health Alliance
DSH450236

Mother Frances Hospital – Winnsboro
CAH451381

Moundview Memorial Hospital and Clinics, Inc.
CAH521309-00

New Hanover Regional Medical Center
DSH340141

Newark Beth Israel Medical Center, Inc.
DSH310002

Niagara Falls Memorial Medical Center
DSH330065

North Hawaii Community Hospital
DSH120028

Northeast Alabama Regional Medical Center
DSH010078

Northwest Ohio Hemophilia Treatment Center
HM11574

Norton Community Hospital
DSH490001

Palmer Lutheran Health Center
CAH161316-00

PeaceHealth d/b/a Ketchikan Medical Center
CAH021311-00

PeaceHealth d/b/a Peace Harbor Medical Center
CAH381316-00

PeaceHealth d/b/a Peace Island Medical Center
CAH501340-00

PeaceHealth Southwest Medical Center
DSH500050

PeaceHealth St. John Medical Center
DSH500041

Penn State –Milton S. Hershey Medical Center
DSH390256

Penrose/St. Francis Healthcare
DSH060031

ProMedica Memorial Hospital
DSH360156

Platte Valley Medical Center
DSH060004

Raphael Health Center, Inc.
CH0514720

Rappahannock General Hospital
CAH491308-00

Regional One Health
DSH440152

Ripon Medical Center, Inc.
CAH521321-00

Robert Wood Johnson University Hospital, Inc.
DSH310038

Russell County Hospital
DSH490002

St. Mary's Hospital and Medical Center
HV00593

Sanford Bagley Medical Center
CAH241328-00

Sanford Bemidji Medical Center
DSH240100

Sanford Bismarck
DSH350015

Sanford Canton - Inwood Medical Center
CAH431333-00

Sanford Clinic Brookings
FP572012

Jeannie Jehnke
October 6, 2020
Exhibit A

Sanford Clinic Watertown
FP572011

Sanford Health Network d/b/a Sanford Canby Medical Center
CAH241347-00

Sanford Health Network d/b/a Sanford Chamberlain Medical Center
CAH431329-00

Sanford Health Network d/b/a Sanford Medical Center Clear Lake
CAH431307-00

Sanford Health Physicians Partners
FP571057

Sanford Health Westbrook Medical Center
CAH241302-00

Sanford Hillsboro
CAH351329-00

Sanford Hospital Webster
CAH431311-00

Sanford Jackson Medical Center
CAH241315-00

Sanford Medical Center Fargo
DSH350011 + HM10193

Sanford Medical Center Luverne
CAH241371-00

Sanford Medical Center Mayville
CAH351309-00

Sanford Medical Center Wheaton
CAH241304-00

Sanford Sheldon Medical Center
CAH161381-00

Sanford Thief River Falls
CAH241381-00

Sanford Tracy Medical Center
CAH241303-00

Sanford USB Medical Center Sioux Falls
HM57117

Sanford USD Medical Center
DSH430027

Sanford Vermillion Medical Center
CAH431336-00

Sanford Worthington Medical Center
DSH240022

Schneck Medical Center
DSH150065

Sedgwick County Hospital & Nursing Home
CAH061310-00

Shawnee Health Service and Development Corporation
CH050040

St. James Healthcare
SCH270017

Saint Joseph Hospital
DSH060028

St. Mary's Hospital and Medical Center Inc.
DSH060023

South Suburban Hospital
RRC140250-00

Spectrum Health Big Rapids Hospital
SCH230093-00

Spectrum Health Gerber
CAH231338-00

Spectrum Health Hospitals
HM935

Spectrum Health Hospitals
DSH230038

Spectrum Health Ludington
SCH230110-00

Spectrum Health Pennock Hospital
CAH231339-00

Spectrum Health Reed City Hospital
CAH231323-00

Spectrum Health United Hospital
DSH230035

Springfield Regional Medical Center
DSH360086

SSM Cardinal Glennon Children's Medical Center
HM13100

SSM DePaul Health Center
DSH260104

SSM Health Saint Louis University Hospital
DSH260105

SSM St. Anthony Hospital
DSH370037

SSM St. Joseph Health Center
DSH260005

SSM St. Mary's Health Center
DSH260091

St. Anthony North Health Campus
DSH060104

St. Anthony Shawnee Hospital
DSH370149

St. Anthony Summit Medical Center
DSH060118

St. Catherine Hospital
SCH170023-00

St. Elizabeth Boardman Health Center
DSH360276

St. Elizabeth Health Center
RRC360064-00

St. Elizabeth's Hospital of Wabasha, Inc.
CAH241335-00

St. Joseph Health Center
DSH360161

St. Joseph Medical Center
RRC390096

St. Joseph's Health Services, Inc. dba St. Joseph's Health Services-Gundersen
CAH521304-00

St. Luke's Hospital of Duluth
DSH240047

St. Mary-Corwin Medical Center
DSH060012

St. Mary's Hospital, Centralia, Illinois
RRC140034-00

St. Ritas Medical Center LLC
DSH360066

St. Thomas More Hospital
CAH061344-00

St. Vincent Hospital of the Hospital Sisters of the Third Order of St. Francis
DSH520075

St. Vincent Hospital
DSH320002

St. Vincent Healthcare
DSH270049

The Moses H. Cone Memorial Hospital
Operating Corporation
DSH340091

The Queen's Medical Center
DSH120001

The Toledo Hospital
DSH360068

Thomas Jefferson University Hospitals
DSH390174

Tri-County Memorial Hospital, Inc.
CAH521316-00

Twin Lakes Regional Medical Center
DSH180070

United General Medical Center
CAH501329-00

University of Connecticut Health Center
RWI06030

University of Connecticut Hemophilia
Treatment Center
HM06030

University of Toledo Medical Center
DSH360048

Waupun Memorial Hospital
CAH521327-00

Wayne County Hospital, Inc.
CAH181321-00

West Allis Memorial Hospital Inc. d/b/a
Aurora West Allis Medical Center
DSH520139

EXHIBIT 13

William B. Schultz
PARTNER
Zuckerman Spaeder LLP
wschultz@zuckerman.com
202-778-1820

ZUCKERMAN SPAEDER

January 7, 2021

VIA EMAIL

Chan Lee
North America General Counsel Sanofi-Aventis U.S. LLC
55 Corporate Drive
Bridgewater, NJ 08807
United States
chan.lee@sanofi.com

David H. Seidel
Jones Day
555 California Street, 26th Floor
San Francisco, CA 94104
dseidel@jonesday.com

Dear Mr. Lee and Mr. Siedel:

We represent the American Hospital Association, 340B Health, the Association of American Medical Colleges, America's Essential Hospitals, National Association of Children's Hospitals d/b/a the Children's Hospital Association, American Society of Health-System Pharmacists, Avera St. Mary's Hospital, Riverside Hospital, Inc., d/b/a Riverside Regional Medical Center, and Dignity Health d/b/a St. Mary's Medical Center in a lawsuit filed in the Northern District of California against Secretary Alex Azar and the Department of Health and Human Services (HHS) challenging the Department's failure to enforce the statutory requirement that Sanofi-Aventis U.S. LLC (Sanofi) and five other drugs companies provide 340B covered entities covered outpatient drugs at or below the 340B ceiling price when 340B drugs are dispensed from a contract pharmacy. *American Hospital Association et al v. Department of Health & Human Services et al.*, No. 3:20-cv-08806-YGR.

After the lawsuit was filed, the General Counsel of HHS issued an advisory opinion on December 30, 2020, in which the Department agrees with us that the 340B statute requires drug companies to provide 340B entities covered outpatient drugs at or below the 340B ceiling price when those covered entities use contract pharmacies to dispense the drugs. *See* Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program. The Department further explained that "neither the agency nor a private actor is authorized by section 340B to add requirements to the statute." *Id.* at 2. Accordingly, Sanofi's policy of requiring 340B covered entities to submit

claims data for 340B prescriptions of Sanofi products filled through contract pharmacies and refusing covered entities that do not provide such claims data 340B prices on products filled through contract pharmacies is in clear violation of the statute, and Sanofi should immediately discontinue its illegal practice. In addition, Sanofi should reimburse 340B entities for the damages they have incurred due to Sanofi's policy.

If Sanofi continues its illegal practice, we will continue to seek to require that HHS enforce the 340B statute, covered entities are reimbursed for damages caused by the illegal policy, and the matter is referred to the HHS Inspector General for the imposition of civil money penalties.

We look forward to your response.

Sincerely,

William B. Schultz

William B. Schultz
Margaret M. Dotzel

EXHIBIT 14

JAMESTOWN S'KLALLAM TRIBE
1033 Old Blyn Highway, Sequim, WA 98382 360/683-1109 FAX 360/681-4643

January 19, 2021

Adam Gluck
Senior Vice President and Head
US and Sanofi Genzyme Corporate Affairs
Sanofi US

Gerry Gleeson
Vice President and Head
US Market Access Shared Services
Sanofi US Sanofi340BOperations@Sanofi.com

Re: Jamestown S'Klallam Tribe Demand Letter Regarding 340B Access and Repayment

To Whom It May Concern:

On behalf of the Jamestown S'Klallam Tribe (Tribe), I write to request that Sanofi immediately resume providing 340B Program pricing at the Tribe's contract pharmacies and repay amounts that Sanofi has overcharged the Tribe. Since October 1, 2020, Sanofi has restricted access to the 340B Program by charging higher than the ceiling price at the Tribe's contract pharmacies. This restriction of 340B access is illegal, as recognized by the Department of Health and Human Services (HHS) Office of General Counsel (OGC) Advisory Opinion 20-06.[1] Additionally, Sanofi has an obligation to repay all amounts it has overcharged the Tribe as a result of this illegal restriction.

Importance of 340B Access and Contract Pharmacies to the Tribe

The Tribe and the patients it serves depend on the 340B Program for access to important medications. As you may be aware, despite treaty and trust obligations to provide for Indian health care, the federal government only funds the Indian health system at approximately 60 percent of need, making it the most underfunded federal health care program. Because of this reality, we depend on various protections in law that assist us in maximizing limited resources in order to serve our patients. One such important protection is access to the 340B Program, which Congress created with the intent "to stretch scarce Federal resources as far as possible."[2] Every dollar we save due to 340B discount pricing is put toward meeting the Tribe's patient care needs.

The Tribe relies on contract pharmacies to deliver 340B drugs to its patients. Each pharmacy that the Tribe contracts with is an agent of the Tribe for the purposes of the 340B Program,[3] and these contract pharmacies are essential to getting much-needed medications into the hands of the Tribe's patients.

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[1] HHS OGC, Advisory Op. 20-06, *On Contract Pharmacies Under the 340B Program* (Dec. 30, 2020) [hereinafter "Advisory Op. 20-06"], https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/340B-AO-FINAL-12-30-2020_0.pdf.

[2] H.R. Rep. No. 102-384, Pt. 2 at 12 (1992).

[3] See Advisory Op. 20-06 at 6.

Illegal Restriction of 340B Access

Sanofi's restriction of 340B access violates the company's statutory obligations and leaves it vulnerable to civil and monetary penalties as well as other legal action.

The 340B program is governed by section 340B of the Public Health Service Act, 42 U.S.C. § 256b, and it requires drug manufacturers to participate in the 340B drug discount program for the manufacturers to receive payment for their outpatient drugs from Medicaid or Part B of Medicare. The statute requires the Secretary of Health and Human Services (HHS) to enter into a rebate agreement with each manufacturer of covered outpatient drugs. The rebate agreement must require the manufacturer to offer each covered entity covered outpatient drugs for purchase at or below the applicable discount ceiling price.

Since its inception, the 340B Program has relied on the existence of contract pharmacy arrangements to achieve its objectives,[4] and the Health Resources and Services Administration (HRSA) long ago published guidelines in the Federal Register approving the purchase of drugs by covered entities for shipment to a contract pharmacy. See, 61 Fed. Reg. 43549 (Aug. 23, 1996). HRSA issued final guidance in 2010 allowing covered entities to use multiple contract pharmacies. 75 Fed. Reg. 10272, 10274–10278 (Mar. 5, 2010).

HHS OGC concluded in Advisory Opinion 20-06, "covered entities under the 340B Program are entitled to purchase covered outpatient drugs at no more than the 340B ceiling price—and manufacturers are required to offer covered outpatient drugs at no more than the 340B ceiling price—even if those covered entities use contract pharmacies to aid in distributing those drugs to their patients."[5] HHS OGC based this conclusion on the plain language of Section 340B, which requires 340B pricing to be provided for covered drugs "purchased by a covered entity" and places no restriction on where such drugs may be delivered.[6] HHS OGC specifically found that "the situs of delivery … is irrelevant."[7]

Sanofi's Reporting Platform Requirements are Impermissible

Sanofi's justification for cutting off 340B access at the Tribe's contract pharmacies is that the Tribe did not submit to demands to participate in the 340B ESP platform. Sanofi is not permitted to require the Tribe participate in a burdensome reporting process that is not required by statute. Sanofi is obligated under law to immediately resume shipment of 340B drugs to all of the Tribe's contract pharmacies. Failure to do so could subject Sanofi to civil and monetary penalties and other legal action.

HHS OGC stated in Advisory Opinion 20-06 that "neither the agency nor a private actor is authorized by section 340B to add requirements to the statute."[8] Thus, manufacturers may not add to the statute a requirement that covered entities participate in the 340B ESP platform.

Subsection 256b(a)(5)(A) of Title 42 prohibits covered entities from obtaining duplicate discounts by billing Medicaid for more than the actual cost of acquisition of a covered drug

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[4] Advisory Op. 20-06 at 3–4.

[5] *Id.* at 8.

[6] *Id.* at 2 ("This fundamental requirement is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs.").

[7] *Id.* at 3.

[8] *Id.* at 2.

subject to the payment of a rebate to the State plan. Section 256b, however, does not authorize drug manufacturers to impose on covered entities compliance requirements such as requiring all claims data be submitted to a manufacturer. Nor does it permit drug manufacturers from imposing burdensome requirements on covered entities if they do not comply with such a request. Seeking data on 340B program billing of commercial payers is outside the scope of the 340B program.

Further, a mechanism already exists for ensuring that covered entities do not obtain duplicate Medicaid discounts. That mechanism is to initiate a compliance audit, as prescribed by section 256b(a)(5) and as governed by guidelines established by the Health Resources and Services Administration. Drug manufacturers are not authorized by statute or by HRSA to initiate new and burdensome compliance programs for covered entities as a condition of fulfilling their obligations under the 340B program.

Repayment of Overcharges

Sanofi is additionally required to repay the Tribe for the amounts it has overcharged the Tribe by refusing to provide 340B pricing to the Tribe's contract pharmacies since October 1, 2020. The Tribe requests that Sanofi immediately remit the amount of these illegal overcharges to the Tribe.

HRSA has previously stated that "manufacturers are required to issue refunds if it is determined that a covered entity paid a price higher than the 340B ceiling price."[9] Further, "[i]f a manufacturer refuses to refund covered entities after it has been determined covered entities were overcharged … that could meet the knowingly and intentionally standard to apply a civil monetary penalty."[10]

Conclusion

The Tribe requests that Sanofi immediately resume providing 340B access to all of the Tribe's contract pharmacies and repay the Tribe the amounts the company has overcharged the Tribe for 340B covered drugs since October 1, 2020.

Sincerely,

W. Ron Allen, Chairman/CEO

Cc: National Congress of American Indians (NCAI)
National Indian Health Board (NIHB)
Portland Area Indian Health Board (PAIHB)
American Indian Health Commission (AIHC)

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[9] 83 Fed. Reg. 1210, 1219 (Jan. 5, 2017).
[10] *Id.* at 1218.

EXHIBIT 15

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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EXHIBIT 16

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

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS *Petitioner,* v. ELI LILLY AND COMPANY and SANOFI-AVENTIS U.S. LLC and ASTRAZENECA PLC *Respondents.*	Petition No: 210112-2

PETITIONER'S MOTION FOR PRELIMINARY INJUNCTION

Petitioner National Association of Community Health Centers ("NACHC"), on behalf of its joint claimant Federally-qualified health center ("FQHC") covered entity members, hereby moves the Administrative Dispute Resolution Panel ("Panel") to employ its equitable authority under 42 C.F.R. § 10.21(a) to compel drug manufacturers Eli Lilly and Company ("Lilly"), Sanofi-Aventis U.S. LLC ("Sanofi"), and AstraZeneca PLLC ("AstraZeneca") (collectively, the "drug manufacturers") to immediately make their covered outpatient drugs available to FQHC covered entities at or below 340B ceiling prices when shipped to a contract pharmacy, pending the Panel's final resolution of this claim.

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MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

The joint claimants—FQHC covered entities who are required by statute to care for some of the country's most vulnerable and medically underserved patients—participate in the 340B Program as Congress intended. NACHC Pet. ¶¶ 6, 24 (Jan. 13, 2021).

In recent months, pharmaceutical manufacturers Lilly, Sanofi, and AstraZeneca (the "drug manufacturers" or "manufacturers") have unlawfully restricted the joint claimants' ability to purchase covered outpatient drugs at 340B discount pricing by ceasing such sales to covered entities where the drugs at issue will be dispensed to covered entity patients via contract pharmacies. *See* Pet.. ¶¶ 1, 26–28, 30–32, 34–35. As alleged in the joint claimants' Petition, such limitations on access are unlawful overcharges in violation of 42 U.S.C. § 256b(a)(1) and 42 C.F.R. § 10.21(c)(1).

The factual record is clear and no material facts are in dispute. In addition to the public notices and correspondence the joint claimants cite in their Petition, several federal district court filings document and describe the drug manufacturers' unlawful actions in the manufacturers' own words. *See, e.g.,* Mem. in Supp. of Eli Lilly and Co's Mot. to Intervene, ECF No. 12-1 at 19–21, *Ryan White Clinics for 340B Access v. Azar*, Case No. 1:20-cv-02906 (D.D.C. filed Oct. 9, 2020); Mem. in Supp. Of Sanofi-Aventis U.S. LLC's Mot. to Intervene, ECF No. 13-1 at 3, *Ryan White Clinics v. Azar*, Case No. 1:20-cv-02906; Mem. in Supp. of AstraZeneca's Mot. to Intervene, ECF No. 29-1 at 15, *Ryan White Clinics*, No. 1:20-cv-02906-KBJ (Nov. 24, 2020); Compl. at 16–20, *AstraZeneca Pharmaceuticals v. Azar*, Case No. 1:21-cv-00027 (D. Del. Jan. 12, 2021); Compl. at 2, 15–17, *Sanofi-Aventis U.S. v. Azar*, Case No. 3:21-cv-00634 (D. N.J. Jan. 12, 2021); Compl. at 27–28, *Eli Lilly and Co. v. Azar*, Case No. 1:21-cv-00081 (S.D. Ind. Jan.

12, 2021); *see also* Pet. ¶¶26–36. The drug manufacturers' federal court filings cited in this paragraph are attached as Exhibits A, B, C, D, E, and F, respectively.

The manufacturers' public justifications for their unlawful actions are meritless. The 340B statute imposes a clear duty on the drug manufacturers to offer covered outpatient drugs at 340B discount pricing for covered entities to purchase regardless of a particular covered entity's chosen dispensing mechanism. Equally clear is the unwavering interpretation given to that statute by the U.S. Department of Health and Human Services (HHS), the agency entrusted with overseeing the 340B Program, including by adjudicating disputes like this one.

Preliminary injunctive relief is not only appropriate here, where the joint claimants are all but guaranteed to prevail on the merits of their overcharging claims, but also necessary to prevent further irreparable harm to the joint claimants and their patients while the Panel adjudicates this matter. The 340B statute guarantees "that claims shall be resolved fairly, efficiently, and expeditiously" through the ADR process. 42 U.S.C. § 256b(d)(3)(B)(ii). Because of the absence—until yesterday—of an ADR process, the joint claimants have already been detrimentally delayed in obtaining relief. *See* Compl. ¶¶ 75–86, *Nat'l Ass'n of Cmty. Health Ctrs. v. Azar,* No. 1:20-cv-03032-KBJ (D.D.C. Oct. 21, 2020), attached as Exhibit G. Now, having successfully secured the regulatory implementation of that process through litigation in federal court, the joint claimants implore the Panel to use its equitable authority to compel a return to status quo 340B sales and purchasing through a grant of preliminary injunctive relief.[1]

[1] Before its district court litigation was stayed, Petitioner was poised to seek preliminary injunctive relief to alleviate the harm caused by the drug manufacturers' refusal to allow the joint claimants to purchase covered outpatient drugs at 340B pricing for dispensing through contract pharmacies. Indeed, the declarations attached to this filing—originally prepared and executed for filing in the D.C. District Court—demonstrate the urgent need for equitable relief.

II. BACKGROUND

The 340B Program, *codified at* 42 U.S.C. § 256b *et seq*., requires drug manufacturers, as a condition of having their drugs covered by Medicare and Medicaid, to enter into pharmaceutical pricing agreements (PPAs) with HHS, under the terms of which they must make certain outpatient drugs available to covered entities at prices that do not exceed a statutorily-set ceiling price. 42 U.S.C. § 256b(a)(1). By reducing drug costs to covered entities—which are predominantly safety-net providers serving poor, underserved, and either uninsured or underinsured populations—the 340B Program furthers its legislative objective to enable covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II), 12 (1992).

Petitioner's FQHC covered entity members receive, or are deemed eligible to receive, federal grant funds under Section 330 of the Public Health Service ("PHS") Act to provide certain required health care and related services to medically underserved populations regardless of patient insurance status or ability to pay for such services. 42 U.S.C. §§ 254b(a), (e), (k); Pet. ¶ 6. As alleged in the Petition, these statutorily required services include pharmacy services, and FQHCs are permitted to meet their patients' pharmaceutical needs either directly or through contracts or similar arrangements. Pet. ¶¶ 3, 19 (citing 42 U.S.C. § 254b(a), (b)(1)(A)(i)(V)).

Although FQHC covered entities have flexibility in determining how best to meet the needs of their patient population and communities, any operational savings or revenue an FQHC generates—through 340B Program participation or otherwise—must be used to further the health center's project. *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). As Congress intended, FQHC covered entities use 340B Program savings and revenue to provide additional services within their federally-designated service areas. *See* H.R. Rep. No. 102-384(II), at 12 (1992). For example, FQHCs use their 340B savings to cover the cost of medication for uninsured or underinsured patients who could not otherwise afford such costs. *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43549-01, 43549 (Aug. 23, 1996) (noting that covered entities can use 340B savings to subsidize patients' prescriptions). FQHC covered entities also use these funds to expand and increase access to necessary medical and crucial enabling services. *See id.* at 43549, 43551 (noting that covered entities can also use 340B savings to increase the number of patients they serve, increase the number of services they provide, and offer more comprehensive services).

As alleged in the Petition and reflected in the drug manufacturers' own public statements and legal filings, the drug manufacturers recently threatened—and then imposed—significant (unlawful) limitations on the FQHC covered entities' ability to purchase covered outpatient drugs at or below applicable 340B ceiling prices. *See* Pet. ¶¶ 27, 30, 34.

On October 21, 2020, Petitioner, on behalf of the joint claimants, brought suit in federal court to compel the implementation of the statutorily-required ADR process of which Petitioner now avails itself. *See* Ex. G (NACHC Compl.) at 1–2. The final rule establishing that process was published on December 14, 2020, with an effective date of January 13, 2021. Given the publication of the final rule, Petitioner and HHS Secretary jointly moved to stay that matter pending the establishment of this Panel and its adjudication of Petitioner's joint claim. *See* Joint Mot. for Stay, ECF No. 12, *Nat'l Ass'n of Cmty. Health Ctrs.*, No. 1:20-cv-03032, (D.D.C. Dec. 17, 2020) (stay granted Jan. 7, 2021), attached as Exhibit H.

III. ARGUMENT

This Panel should grant Petitioner's request for immediate equitable relief pending final adjudication of the joint claim asserted in its Petition. The joint claimants are almost certain to succeed on the merits of this joint claim, and such interim equitable relief will prevent further irreparable harm to the joint claimants and their patients while their first-of-its-kind claim is pending in this newly established process. Additionally, the delay in the ADR rulemaking and implementation of this process—for which Petitioner bears no blame—renders Petitioner's request for relief all the more pressing.

Preliminary injunctive relief is appropriate where the movant shows it "is likely to succeed on the merits, that [it] is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in [its] favor, and that an injunction is in the public interest." *Winter v. Natural Resources Defense Council, Inc.*, 555 U.S. 7, 20 (2008). In the D.C. Circuit—where Petitioner, on behalf of its covered entity members, filed suit seeking the creation of this ADR process—a preliminary injunction is warranted where a movant demonstrates (1) a substantial likelihood of success on the merits, (2) that they will suffer irreparable injury if injunctive relief is not granted, (3) that the injunction would not substantially injure other interested parties, and (4) that the public interest is furthered by the injunction. *See Chaplaincy of Full Gospel Churches v. England*, 454 F.3d 290, 297 (D.C. Cir. 2006); *see also Sherley v. Sebelius*, 644 F.3d 388, 393 (D.C. Cir. 2011) (indicating likelihood of success on the merits is key factor).

A. Petitioner is Substantially Likely to Succeed on the Merits.

Petitioner is all but guaranteed to succeed on the merits of its joint claim. The drug manufacturers' refusal to allow the joint claimants to purchase covered outpatient drugs at or

below the drugs' applicable ceiling prices is not only an abrupt departure from decades of past practice and a repudiation of previously accepted agency policies, but also amounts to a prohibited overcharge as defined in 42 C.F.R. § 10.21(c)(1) (defining prohibited overcharging activity to include any "limit[ation on] the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price").

In longstanding, well-reasoned, and persuasive agency issuances—that are squarely on point and date back nearly twenty-five years—HHS has consistently and repeatedly stated that covered entities may contract with third parties to provide pharmaceutical services to their patients. For instance, in an August 23, 2006 final notice published in the Federal Register, HHS wrote: "[e]ach covered entity should conduct its own business review and patient assessment to determine what level of pharmacy services is needed, and the appropriate delivery mechanism for those services." Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. at 43549–50. (Aug. 23, 1996). The Agency also provided, in its "Contract Pharmacy Services Revised Final Mechanism" included in that Notice that "[u]nder section 340B, we believe that if a covered entity using contract pharmacy services requests to purchase a covered drug from a participating manufacturer, the statute directs the manufacturer to sell the drugs at the discounted price." *Id.* At that time, HHS, considering a situation in which a covered entity directs a drug shipment to its contract pharmacy, saw "no basis on which to conclude that section 340B precludes this type of transaction or otherwise exempts the manufacturer from statutory compliance." *Id.*

HHS reiterated its unwavering interpretation of the 340B statute in a March 2010 final notice published to "inform interested parties of final guidelines regarding the utilization of multiple contract pharmacies" without individualized Agency approval. Notice Regarding 340B

Drug Pricing Program-Contract Pharmacy Services, 75 Fed. Reg. 10272-01, 10272–73 (Mar. 5, 2010) (replacing all previous 340B Program guidance, including 61 Fed. Reg. 43549). The notice informed all stakeholders that covered entities were free to use contract pharmacies for dispensing "as long as they comply with guidance developed to help ensure against diversion and duplicate discounts and the policies set forth regarding patient definition." *Id.* at 10273.

Roughly a decade after the March 2010 final notice was published, on September 21, 2020, HHS General Counsel Robert P. Charrow responded to a September 8, 2020 request from Lilly for an advisory opinion as to whether Lilly's "new unilateral policy" on 340B contract pharmacies "would subject Lilly to sanctions." *See* Pet. Exhibit E (Sept. 21, 2020 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.). In that letter, General Counsel Charrow indicated that HHS "ha[d] significant initial concerns" with Lilly's limitations on covered entities' ability to purchase Lilly drugs at 340B discount pricing, advised Lilly that it could not and should not "view the absence of any questions from the government as somehow endorsing Lilly's policy," and warned Lilly that "a [False Claims Act] suit against Lilly is a potential consequence in the event that Lilly knowingly violates a material condition of the [340B] program that results in over-charges to grantees and contractors." *Id.* at 1–2; *Cf.* 42 C.F.R § 10.11(a) (providing that a manufacturers' "knowing[] and intentional[]" refusal to offer covered outpatient drugs at 340B pricing is an example of prohibited overcharging subject to civil monetary penalties); *see also* Letter from Krista M. Pedley, Director, Office of Pharmacy Affairs, Health Res. & Servs. Admin., to Derek L. Asay, Senior Director, Government Strategy, Eli Lilly & Co. (Aug. 26, 2020) at 1 (noting "[u]nder 42 U.S.C. 256b(a)(1), manufacturers must offer covered entities outpatient drugs at specified prices"), attached as Exhibit I; Letter from

Krista Pedley to Christie Bloomquist (Sept. 2, 2020) at 1-2 (asserting AstraZeneca's actions "could have the effect of severely limiting access" to 340B drugs during the COVID-19 pandemic, which "would undermine the 340B Program and the Congressional intent behind enactment of the 340B statute"), attached as Exhibit J. The manufacturer-imposed limitations on purchasing considered in the cited letters from HHS are the same as those at the heart of the joint claimants' Petition.

Finally, as the joint claimants explain in their Petition, a December 30, 2020 HHS Office of General Counsel Advisory Opinion, also written to address the very conduct at issue here, is a particularly persuasive and forceful reiteration of HHS' prior interpretive guidance:

> to the extent contract pharmacies are acting as agents of a covered entity, a drug manufacturer in the 340B Program is obligated to deliver its covered outpatient drugs to those contract pharmacies and to charge the covered entity no more than the 340B ceiling price for those drugs.

Pet. Exhibit B (HHS Office of General Counsel, *Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program* at 1 (Dec. 30, 2020)). As HHS further notes in that Advisory Opinion, the 340B statute, in plain language, requires manufacturers to offer covered outpatient drugs at or below the ceiling price for "purchase by" covered entities and neither qualifies, restricts, nor otherwise conditions this requirement on the mechanism through which a covered entity *distributes* its covered outpatient drugs so long as the covered entity *purchases* the drugs. *Id.* at 2.

The Panel is not only bound by the plain language of the 340B statute, there is no legally justifiable reason for it to depart from HHS's longstanding interpretation of that statute as permitting covered entities to purchase covered outpatient drugs at 340B discount pricing for dispensing to covered entity patients either directly or through contract pharmacies. *See Fed. Commc'ns Comm'n v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009) (agency generally

may not depart from prior policies without reasoned basis, including acknowledgment of changed position); *Barnhart v. Walton*, 535 U.S. 212, 220 (2002) (noting courts "normally accord particular deference to an agency interpretation of 'longstanding' duration") (*quoting North Haven Bd. of Ed. v. Bell*, 456 U.S. 512, 522 n.12 (1982)); *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 213 (1988) (deference inappropriate for agency interpretation initially adopted in litigation, particularly where interpretation departs from prior agency position). The drug manufacturers effectively conceded that the Panel must adhere to its prior interpretive guidance in three separate—but strikingly similar— lawsuits, each filed just the day before the ADR process became available. One of those suits, initiated by Lilly, characterizes HHS's December 30, 2020 Advisory Opinion as a "binding decision under which manufacturers like Lilly must offer full 340B discounts to contract pharmacies on all covered drugs." Ex. F (Eli Lilly Compl.) at 4–5; *see also* Ex. D (AstraZeneca Compl.); Ex. E (Sanofi Compl.).

B. <u>The Joint Claimants Will Continue to Suffer Irreparable Harm Absent Preliminary Injunctive Relief</u>

The joint claimants will be irreparably harmed if the Panel does not grant preliminary injunctive relief. A movant seeking a preliminary injunction demonstrates irreparable harm by showing two things: (1) the harm that will result in the absence of injunctive relief "must be 'certain and great,' 'actual and not theoretical,' and so 'imminen[t] that there is a clear and present need for equitable relief to prevent irreparable harm;'" and (2) that harm cannot be remediated. *See League of Women Voters of the United States v. Newby*, 838 F.3d 1, 7–8 (D.C. Cir. 2016) (*quoting Chaplaincy of Full Gospel Churches*, 454 F.3d at 297).

FQHCs currently provide numerous non-reimbursable services in part through 340B savings and program income. These services include, for example, medication therapy management, behavioral health care, dental services, case management and care coordination

services, translation/interpretation services for patients with limited English language ability, and transportation assistance. *See, e.g.,* Declaration of J.R. Richards ¶ 14 (indicating covered entity's "behavioral health, dental, mobile van services, patient assistance program, and free prescription delivery" are funded in part through 340B savings and revenue), attached as Exhibit K; Declaration of Donald A. Simila ¶¶ 15, 16, 17, and 19 (indicating substance abuse, dental, and OB/GYN services supported by 340B funds), attached as Exhibit L; Declaration of Patricia DeShields ¶ 16 (indicating uninsured patients' prescription drug costs, transportation, medical supplies, lab fees, and vaccinations supported by 340B funds), attached as Exhibit M.

If drug manufacturers continue to refuse to provide 340B discounts for contract pharmacies, FQHCs will be forced to drastically reduce or even eliminate these services. Ex. K (Richards Decl.) ¶¶ 24, 25 (estimating that covered entity will lose approximately $350,000 annually—41 percent of its annual budget—as result of 340B restrictions, forcing reduction in services); Declaration of Heather Rickertsen ¶¶ 34, 36 (estimating annual loss of approximately $1 million in revenue and $500,000 to $2 million increase in cost of goods sold, forcing reduction in coverage of patient copays, clinical pharmacy programs, enabling services, care coordination, and Pacific Islander health program), attached as Exhibit N; Ex. L (Simila Decl.) ¶¶ 28–30 (estimating annual revenue loss of approximately $600,000 from Lilly's actions alone, resulting in "major reductions in services" and "significant reduction in access to comprehensive care for an elderly, impoverished, and underserved rural community"); *see also* Declaration of Lee Francis ¶ 30 ("We already know that critical patient programs will need to be reduced or eliminated because of the decline in 340B savings and revenue."), attached as Exhibit O.

Reductions in 340B savings and revenue resulting from the drug manufacturer's unlawful overcharging will also result in many covered entities needing to reduce the size of their clinical

staffs, further restricting the amount and scope of care they provide to patients. For example, Upper Great Lakes Family Health Center, an FQHC covered entity which serves approximately 25,000 patients annually in Michigan's remote Upper Peninsula, reports that 340B reductions have already forced it to reduce staffing for OB/GYN services and that it is currently planning other major reductions in services—including closure of service delivery sites, termination of employees, reductions in health care providers, and likely closure of OB/GYN, dental, and mental health services. Ex. L (Simila Decl.) ¶ 29; *see also* Ex. K (Richards Decl.) ¶ 25; Declaration of Kiame Jackson Mahaniah ¶ 20 (currently preparing to permanently layoff 5 percent of its employees due to loss of 340B revenue), attached as Exhibit P; Declaration of Kimberly Christine Chen ¶ 42 (indicating likely elimination of clinical pharmacists and closure of one or more rural clinic locations due to manufacturers' restrictions), attached as Exhibit Q.

These harms are also incapable of remediation, especially given the 340B program's purpose. Covered entities cannot retroactively provide, and their patients cannot retroactively benefit from, critical health care and enabling services that must be reduced or eliminated due to manufacturers' noncompliance with 340B pricing requirements.

C. Other Interested Parties Will Not be Substantially Harmed by the Preliminary Injunction

The drug manufacturers will not be substantially harmed by a preliminary injunction that, in effect, restores the status quo ante. First, as a threshold matter, enforcement of a pre-existing federal obligation causes no cognizable harm at all. *See Newsom v. Albemarle Cnty. School Bd.*, 354 F.3d 259, 261 (4th Cir. 2003).

Second, the requested relief would restore the 340B program's status quo as it existed for decades—*i.e.*, drug manufacturer compliance with both the 340B statute's plain language and HHS interpretive rules recognizing the propriety of the contract pharmacy model to dispense

drugs to patients of FQHC covered entities. That longstanding state of affairs changed mere months ago by virtue of the drug manufacturers' own unilateral actions.

From 1996 to late 2020, drug manufacturers honored covered entity's purchases at 340B discount pricing where the purchased drugs are shipped to and dispensed by covered entities' contract pharmacies. While covered entities (and their patients) will suffer irreparable harm in the absence of injunctive relief, *see* Section III.B, *supra*, there is no reason to believe that the drug manufacturers will be substantially, much less irreparably, harmed by continuing to do what they did for more than 20 years during the period it takes the ADR panel to "expeditiously" resolve this dispute. *See*, *e.g.*, Pet. Ex. E at 2 (noting "[t]he price of Lilly's stock has increased by more than 11 percent since January 1, 2020" reflecting jump in comprehensive income "from $1.414 billion during the second quarter of 2019 to $1.615 billion for the second quarter of 2020"). Further, given the substantial public equities at stake in providing affordable medications and health care services to vulnerable communities, any private interest asserted by the drug manufacturers should be given little weight. Unlike the deprivation of medical care or the restriction of services to an underserved population, drug manufacturers could only conceivably complain of economic harm, for which they would have a damages remedy in this ADR process. 42 U.S.C. § 256b(d)(3)(A).

D. <u>The Requested Relief is in the Public Interest</u>

Requiring the drug manufacturers to provide 340B-priced drugs to covered entities' contract pharmacies pending the resolution of the ADR proceedings is in the public interest. First, the public interest is not served by the drug manufacturer's continued violation of their statutory obligations. *See Washington Post Guild Majority v. Washington-Baltimore Newspaper Guild, Local 35 (ANG)*, No. 76-0009, 1976 WL 1547 at *4 (D.D.C. 1976) ("the public interest is

served by preventing the violation of a federal statute"); *Laborers' Int'l Union of N. Am. v. Nat'l Post Office Mail Handlers, Watchmen, Messengers & Grp. Leaders Div. of Laborers Int'l Union of N. Am.*, Case No. 88-1731-OG, 1989 WL 251211, at *12 (D.D.C. Jan. 17, 1989) ("The public interest lies in seeing that the statute is complied with.").

Second, the public interest favors a preliminary injunction because it will prevent the substantial direct and indirect harm to covered entities patients' currently resulting from the drug manufacturers' violations of the 340B statute. Due to the drug manufacturers' practical elimination of the joint claimants' ability to purchase the manufacturers' drugs at or below applicable ceiling prices for dispensing through contract pharmacies, the joint complainants' patients have experienced dramatic increases in the price of life-sustaining medications used to treat common, chronic conditions such as diabetes, cardiovascular disease, and respiratory diseases. *See, e.g.,* Declaration of Ludwig M. Spinelli ¶ 21 (asthma and diabetes medication), attached as Exhibit R; Ex. N (Rickertsen Decl.) ¶ 30 (medications treating diabetes, heart disease, hypertension, and asthma/COPD). For instance, a joint claimant FQHC health center located in Connecticut and serving approximately 50,000 patients in the Bridgeport and Stamford regions reports that uninsured health center patients receiving insulin or asthma medication through their health center's contract pharmacy now have to either pay up to $1800 for medication which previously cost them less than $16 for the same amount or, if a substitution is possible, coordinate with and wait for their providers to approve the substitution of a cheaper alternative medication. *See* Ex. R (Spinelli Decl.) ¶ 21 (noting change to $300–600 for a month's supply of medication which previously cost $12–15 per three months' supply); *see also* Declaration of Daniel Fulwiler ¶ 14a (noting change in price for month's supply of insulin from less than $17 to $700), attached as Exhibit S.

Other joint claimants, including those with existing in-house pharmacy capabilities that could theoretically be leveraged to provide discounted medications to needy patients, report that patients would have to travel prohibitive distances to reach such a pharmacy. For example, North Country HealthCare, located in Flagstaff, Arizona, indicates that some of its patients previously served by its contract pharmacies would have to travel up to 180 miles to reach the FQHC's nearest in-house pharmacy. *See* Ex. Q (Chen Decl.) ¶ 21; *see also* Declaration of Ronald E. Castle ¶ 15 (declaring that health center's single in-house pharmacy is located roughly at mid-point of 110-mile service area), attached as Exhibit T. A delay in obtaining life-sustaining and health maintenance medications caused by these sorts of practical barriers to access can result in significant adverse health effects for the joint claimants' patients—including death. Great Salt Plains Health Center, located in northwestern Oklahoma, reports that its "patients will be denied access to medications that are critical to their survival, such as rescue inhalers, blood pressure medications, and insulin." Declaration of Timothy E. Starkey ¶ 16, attached as Exhibit U; *see also* (Declaration of David Steven Taylor ¶ 18 (reporting that numerous patients are already forgoing insulin treatments because of increased cost and/or difficulty in traveling to the FQHC's in-house pharmacy), attached as Exhibit V; Ex. R (Spinelli Decl.) ¶¶ 23–25 (reporting that diabetic and asthmatic patients have been forced to forego medication and/or switch to less effective substitute medication).

A shift to clinical alternative medications—when such alternatives exist—may result in reduced health outcomes due to lower efficacy, serious side effects, or decreased medication compliance as a result of patient confusion or difficulty in adapting to a new regimen. *See e.g.* Ex. Q (Chen Decl.) ¶ 38 (reporting that switching stable diabetic patients to substitute medications reduces adherence to medication regimens and increases weight gain and the risk of

hypoglycemia "which can lead to seizures, coma, and even death"); Ex. K (Richards Decl.) ¶ 23 (reporting that patients whose diabetes is controlled with one medication may develop uncontrolled diabetes or suffer other adverse effects when switching to a substitute medication).

The public interest is served by ensuring the continued viability of the nation's health care safety-net and the health of its most vulnerable patients. *See Lopez v. Heckler*, 713 F.2d 1432, 1437 (9th Cir. 1983) ("Our society as a whole suffers when we neglect the poor, the hungry, the disabled, or when we deprive them of their rights or privileges."). Indeed, the existence of the PHS Act programs at issue here evidences a significant public interest in safeguarding access to health care for those who are medically underserved.

IV. CONCLUSION

For the foregoing reasons a preliminary injunction should issue compelling the drug manufacturers to comply with their statutory obligation to offer the joint claimants' covered outpatient drugs at or below 340B ceiling prices, regardless of whether those drugs are to be dispensed in-house or through a contract pharmacy, until the Panel resolves the merits of Petitioner's joint claim.

Dated: January 14, 2021

Respectfully submitted,

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SANOFI-AVENTIS U.S., LLC, *Plaintiff,* *v.* UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, *Defendants.*	Civil Action No. 3:21-cv-634

[PROPOSED] ORDER

Upon consideration of Defendants' Motion to Dismiss or, in the Alternative, for Summary Judgment and Plaintiff Sanofi-Aventis U.S., LLC's Cross-Motion for Summary Judgment, it is ORDERED that the Defendants' Motion is DENIED and Plaintiff's Motion is GRANTED.

It is further ORDERED, pursuant to 5 U.S.C. § 706, that the 340B Drug Pricing Program Administrative Dispute Resolution Regulation, 85 Fed. Reg. 80,632 (Dec. 14, 2020) (codified at 42 C.F.R. pt. 10), is VACATED.

It is further ORDERED, pursuant to 5 U.S.C. § 706, that U.S. Department of Health and Human Services Office of General Counsel Advisory Opinion 20-06, On Contract Pharmacies Under the 340B Program (Dec. 30, 2020), is VACATED.

The Court further enters a DECLARATORY JUDGMENT that Section 340B of the Public Health Service Act ("Section 340B"), 42 U.S.C. § 256b, does not require

drug manufacturers to provide discounted covered outpatient drugs to contract pharmacies; that Section 340B does not prohibit drug manufacturers from imposing conditions on the provision of discounted covered outpatient drugs to contract pharmacies; and that Plaintiff Sanofi-Aventis U.S., LLC's integrity initiative complies with the requirements of Section 340B.

SO ORDERED.

Date: _____

_____
Hon. Freda L. Wolfson
United States District Judge

CERTIFICATE OF SERVICE

I hereby certify that on May 10, 2021, a copy of Plaintiff's Notice of Cross-Motion for Summary Judgment, Plaintiff's Memorandum of Law in Support of Cross-Motion for Summary Judgment and in Opposition to Defendants' Motion to Dismiss or, in the Alternative, for Summary Judgment, and the Declaration of Jennifer L. Del Medico, together with its supporting exhibits, was filed with the Clerk of the Court by using the CM/ECF system. I certify that all participants in this case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

May 10, 2021 *s/ Jennifer L. Del Medico*