IN THE 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,

ALEX M. AZAR II, in his official capacity as Secretary of Health and Human Services,

ROBERT P. CHARROW, in his official capacity as General Counsel of the United States Department of Health and Human Services,

HEALTH RESOURCES AND SERVICES ADMINISTRATION,

THOMAS J. ENGELS, in his official capacity as Administrator of the Health Resources and Services Administration,

Defendants.

Civil Action No. 3:21-cv-634

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff Sanofi-Aventis U.S. LLC ("Sanofi"), by and through its undersigned attorneys, alleges as follows:

INTRODUCTION

1. This Administrative Procedure Act ("APA") case challenges a new rule governing the 340B drug-discounting program (the "340B Program") issued by the U.S. Department of Health and Human Services ("HHS") without statutory authority and without complying with the requirements for issuing rules having the force and effect of law.

2. Section 340B of the Public Health Service Act requires pharmaceutical manufacturers to discount their drugs (often quite significantly) for fifteen types of "covered entities" that are enumerated in the statute—governmental and non-profit entities that mostly provide care for underserved areas or populations. Manufacturers that overcharge covered entities can face enforcement actions, significant civil monetary penalties, and revocation of their ability to participate in the Medicare and Medicaid programs.

3. Instead of dispensing 340B-priced drugs themselves, many covered entities have entered into agreements with for-profit contract pharmacies (such as commercial chain pharmacies like Walgreens and CVS), under which contract pharmacies acquire and dispense the discounted drugs to the covered entities' patients, with the covered entities writing the underlying prescriptions.

4. These contract pharmacy arrangements have made it much harder for drug manufacturers to detect "duplicate discounting," which occurs when the same prescription is subject to both a 340B discount and a Medicaid rebate. Section 340B expressly prohibits duplicate discounting, which—if unaddressed—can result in manufacturers being forced to sell their drugs for below cost. As the use of contract pharmacies has exploded in recent years, duplicate discounting has also increased.

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

better identify and prevent duplicate discounts. To be clear, Sanofi still offers 340B discounts on all of its drugs to all covered entities without this condition. But Sanofi currently offers 340B pricing through contract pharmacy arrangements only if a covered entity provides the data requested (unless an exception applies).

6. In a new rule entitled Advisory Opinion 20-06 (the "Advisory Opinion"), however, HHS imposed new legal obligations on drug manufacturers that effectively outlaw Sanofi's integrity initiative. HHS's new rule expands the list of entities entitled to acquire 340B-priced drugs—now to include for-profit contract pharmacies—and limits manufacturers' ability to detect waste and abuse in the 340B Program (such as through the integrity initiative adopted by Sanofi). In particular, the Advisory Opinion interprets Section 340B to require drug manufacturers to provide 340B discounts to contract pharmacies and to prohibit manufacturers from imposing conditions on such sales. As a result, the Advisory Opinion exposes Sanofi to enforcement actions, severe monetary penalties, and revocation of its ability to participate in the Medicare and Medicaid programs for operating its integrity initiative.

7. The Court should hold unlawful and set aside the Advisory Opinion for at least the following four reasons.

8. *First*, HHS failed to comply with the APA's notice-and-comment requirement before issuing the Advisory Opinion. The APA requires agencies to provide advance notice and an opportunity to comment on legislative rules having the force and effect of law. The Advisory Opinion contains a legislative rule having the force and effect of law—namely, that manufacturers *shall* provide 340B discounts to contract pharmacies and *shall not* impose

conditions on these sales—that effectively dooms Sanofi's integrity initiative. HHS's failure to comply with the APA's notice-and-comment requirement means the Advisory Opinion is procedurally unlawful and must be vacated.

9. *Second*, HHS also failed to comply with its own procedural regulations when issuing the Advisory Opinion. In addition to the APA's notice-and-comment requirement, HHS has adopted regulations governing the issuance of guidance documents such as the Advisory Opinion, yet the agency skirted these procedural requirements, too. The Advisory Opinion is contrary to law and arbitrary and capricious as a result.

10. *Third*, the Advisory Opinion's interpretation of Section 340B is wrong. Section 340B does not require 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. Even if manufacturers must provide 340B-priced drugs to contract pharmacies, Sanofi's integrity initiative complies with Section 340B because Sanofi ships discounted drugs to contract pharmacies—and, moreover, will do so for all covered entities under reasonable conditions that are not burdensome and that do not discriminate against covered entities as compared to commercial customers. The Advisory Opinion thus exceeds HHS's statutory authority, and Sanofi's integrity initiative is fully consistent with Section 340B.

11. *Fourth*, both of the Advisory Opinion's key conclusions—that Section 340B requires manufacturers to provide discounted drugs to contract pharmacies, and that

manufacturers may not impose conditions on doing so—are arbitrary and capricious because the agency failed to reasonably explain its interpretation of the statute.

12. For these reasons, the Court should set aside the Advisory Opinion, declare that Section 340B does not require manufacturers to provide discounted covered outpatient drugs to contract pharmacies or prohibit manufacturers from imposing conditions on doing so, confirm that Sanofi's integrity initiative comports with the statute, and enjoin HHS from enforcing the Advisory Opinion in any administrative proceeding.

JURISDICTION AND VENUE

13. This Court has jurisdiction over this case under 28 U.S.C. § 1331 because Sanofi's claims arise under the APA. *See* 5 U.S.C. § 702.

14. This Court has the authority to grant declaratory relief and to vacate and set aside the Advisory Opinion under the Declaratory Judgment Act, the APA, and this Court's inherent equitable powers. *See* 28 U.S.C. §§ 2201, 2202; 5 U.S.C. §§ 702, 706.

15. Venue is proper in this district under 28 U.S.C. § 1391(e)(1)(C) and 5 U.S.C. § 703.

PARTIES

16. Plaintiff Sanofi-Aventis U.S. LLC ("Sanofi") is a global healthcare leader that produces extensive lines of prescription medicines, vaccines, and other consumer health products. Sanofi's headquarters are located in Bridgewater, New Jersey.

17. Defendant HHS is an agency of the United States government.

18. Defendant Alex M. Azar II is the Secretary of HHS (the "Secretary") and is sued in his official capacity.

19. Defendant Robert P. Charrow is General Counsel of HHS and is sued in his official capacity.

20. Defendant Health Resources and Services Administration ("HRSA") is an HHS agency.

21. Defendant Thomas J. Engels is Administrator of HRSA and is sued in his official capacity.

STATEMENT OF FACTS

I. The 340B Program

22. Congress established the 340B Program in 1992 to reduce pharmaceutical costs for "public hospitals and community health centers, many of which provide safety-net services to the poor." HHS Office of the General Counsel, Advisory Opinion 20-06: On Contract Pharmacies Under the 340B Program ("Advisory Opinion"), at 1 (Dec. 30, 2020), https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/340B-AO-FINAL-12-30-2020_0.pdf.

23. Section 340B of the Public Health Service Act, 42 U.S.C. § 256b, requires drug manufacturers participating in the 340B Program to offer certain drugs at a significant discount to a list of entities (known as "covered entities") defined by statute. While manufacturers are not formally required to participate in the 340B Program, they have little practical choice but to do so. Their participation in Medicare and Medicaid, which together contribute a significant portion of manufacturers' annual revenues, "is conditioned on their entry into [Pharmaceutical Pricing Agreements] for covered drugs purchased by 340B entities." *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 113 (2011).

24. In particular, Section 340B requires that the Secretary "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" a discounted price calculated according to a prescribed statutory formula. 42 U.S.C. § 256b(a)(1). This agreement is known as the Pharmaceutical Pricing Agreement ("PPA"). Section 340B further provides that "[e]ach such agreement . . . shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below" the discounted price. *Id.*

25. Failure to comply with the 340B statute exposes a manufacturer to termination of the PPA (and, correspondingly, the manufacturer's ability to participate in Medicare and Medicaid) as well as enforcement actions and civil monetary penalties.

26. Section 340B defines "covered entities" in an enumerated list of 15 discrete types of entities, such as children's hospitals and rural hospitals. *Id.* § 256b(a)(4)(A)–(O). In full, that list is:

> (A) A Federally-qualified health center (as defined in section 1905(l)(2)(B) of the Social Security Act).
>
> (B) An entity receiving a grant under section 256a of this title.
>
> (C) A family planning project receiving a grant or contract under section 300 of this title.
>
> (D) An entity receiving a grant under subpart II of part C of subchapter XXIV (relating to categorical grants for outpatient early intervention services for HIV disease).
>
> (E) A State-operated AIDS drug purchasing assistance program receiving financial assistance under subchapter XXIV.

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

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

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

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

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

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

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

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

> (M) A children's hospital excluded from the Medicare prospective payment system pursuant to section 1886(d)(1)(B)(iii) of the Social Security Act, or a free-standing cancer hospital excluded from the Medicare prospective payment system pursuant to section 1886(d)(1)(B)(v) of the Social Security Act, that would meet the requirements of subparagraph (L), including the disproportionate share adjustment percentage requirement under clause (ii) of such subparagraph, if the hospital were a subsection (d) hospital as defined by section 1886(d)(1)(B) of the Social Security Act.
>
> (N) An entity that is a critical access hospital (as determined under section 1820(c)(2) of the Social Security Act), and that meets the requirements of subparagraph (L)(i).
>
> (O) An entity that is a rural referral center, as defined by section 1886(d)(5)(C)(i) of the Social Security Act, or a sole community hospital, as defined by section 1886(d)(5)(C)(iii) of such Act, and that both meets the requirements of subparagraph (L)(i) and has a disproportionate share adjustment percentage equal to or greater than 8 percent.

27. Notably, the list of covered entities does not include contract pharmacies, which are for-profit third-party pharmacies that fill prescriptions written by other healthcare providers.

28. In order to prevent waste and abuse, Section 340B prohibits "duplicate discounts or rebates," which occur when the same prescription receives both a 340B discount and a Medicaid rebate. *Id.* § 256b(a)(5)(A).

29. Section 340B also prohibits "diversion," by barring covered entities from reselling or otherwise transferring discounted drugs to persons other than their patients. *See id.* § 256b(a)(5)(B).

30. Section 340B authorizes not just the Secretary but also manufacturers themselves to audit a covered entity's compliance with these twin requirements. *See id.*

§ 256b(a)(5)(C). The Secretary can sanction covered entities that fail to comply with these requirements. *See id.* § 256b(a)(5)(D).

31. Section 340B directs the Secretary to promulgate regulations establishing an administrative process for resolving (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. *See id.* § 256b(d)(3)(A).

32. The Secretary promulgated such regulations on December 14, 2020, and they are scheduled to take effect on January 13, 2021. *See* 340B Drug Pricing Program: Administrative Dispute Resolution Regulation, 85 Fed. Reg. 80,632, 80,632 (Dec. 14, 2020) (to be codified at 42 C.F.R. pt. 10) (the "ADR Rule").

33. Claims brought under the ADR Rule are to be adjudicated by a panel (the "ADR Panel") consisting of representatives in equal numbers from the HHS Office of General Counsel, HRSA, and the Centers for Medicare & Medicaid Services ("CMS"). *Id.* at 80,634.

34. CMS, like HRSA, is an HHS agency. The HHS Office of General Counsel "supervises all legal activities of the Department and its operating agencies," including HRSA and CMS, and furnishes "all legal services and advice to the Secretary, Deputy Secretary, and all offices, branches, or units of the Department in connection with the operations and administration of the Department and its programs." Statement of Organization, Functions, and Delegations of Authority ("Statement of Organization"), 85 Fed. Reg. 47,228, 47,230 (Aug. 4, 2020).

35. Under the ADR Rule, the ADR Panel is charged with reviewing "[c]laims by a covered entity that it has been overcharged by a manufacturer for a covered outpatient drug, including claims that a manufacturer has limited the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price." 85 Fed. Reg. at 80,645; 42 C.F.R. § 10.21(c)(1).

II. Covered Entities' Use of Contract Pharmacies

36. Even though Congress did not include contract pharmacies as covered entities, define a role for contract pharmacies in the 340B Program, or otherwise mention them in the 340B statute, HHS and its agency HRSA have issued guidance on whether covered entities can use contract pharmacies.

37. In 1996, four years after the 340B Program was created, HRSA issued guidance purporting to allow contract pharmacies to dispense 340B-priced drugs by signing agreements with covered entities. *See* 61 Fed. Reg. 43,549 (Aug. 23, 1996). HRSA provided in this guidance that a covered entity could enter into such an arrangement with a maximum of one contract pharmacy. *Id.* at 43,555. But HRSA recognized that it lacked authority to expand the list of covered entities. *Id.* at 43,549. It also maintained that this guidance was merely an interpretive rule that created "no new law" and "no new rights or duties." *Id.* at 43,550. This guidance did not address whether manufacturers could impose conditions on the provision of 340B-priced drugs to contract pharmacies.

38. In 2010, HRSA issued guidance that sought to expand the participation of contract pharmacies in the 340B Program. *See* 75 Fed. Reg. 10,272 (Mar. 5, 2010). This guidance purported to allow covered entities to contract with an *unlimited* number of

pharmacies, without any geographical restrictions. *See id.* at 10,272–73. But HRSA once more denied that it was creating any new rights or obligations, characterizing the 2010 guidance as "interpretive guidance." *Id.* at 10,273. And again, this guidance did not address whether manufacturers could impose conditions on providing 340B-priced drugs to contract pharmacies.

39. Since HRSA issued its 2010 guidance, covered entities' use of contract pharmacies has exploded. For-profit contract pharmacies participating in the 340B Program increased in number from 1,300 in 2010, to nearly 20,000 by 2017. *See* U.S. Government Accountability Office ("GAO"), Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement, GAO-18-480, at 39, 40 (June 2018), https://www.gao.gov/assets/700/692697.pdf ("GAO Report"). Last year, the number of participating contract pharmacies reached 28,000—almost half of the U.S. pharmacy industry. *See* 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. And in total, there are currently more than 100,000 arrangements between contract pharmacies and covered entities. *See* 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.

40. But the expansion of contract pharmacy arrangements has undermined the 340B Program's goals in several ways. For one thing, contract pharmacies can and typically do capture significant amounts of the discounts that Congress intended for covered entities

and their patients. Generally, under contract pharmacy arrangements, drugs are provided to the contract pharmacy, who dispenses the drugs and, in turn, collects payment from the patients and/or patients' insurance. Often, contract pharmacies will not pass on the 340B discount to covered entities' patients when billing them. *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. 2014) ("HHS Report"), https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf. And contract pharmacies typically earn significant profits from the difference between what the insurer or patient pays and what they paid to acquire the drug. *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. The contract pharmacy often pockets much of the difference between the 340B price and the higher reimbursement value of the drug, while also paying a typically pre-negotiated amount to the covered entity for each discounted drug it dispenses. Congress never, however, intended for 340B discounts to be corporate largesse. *See* 42 U.S.C. § 256b(a)(4)(A)–(O) (entitling only governmental and non-profit entities to receive 340B discounts).

41. In addition, the expansion of contract pharmacy arrangements has been accompanied by widespread diversion and duplicate discounting, as numerous government

reports attest. As noted, Congress explicitly prohibited these practices when enacting Section 340B.

42. For example, HHS has found that contract pharmacy arrangements "create complications in preventing diversion." HHS Report, *supra*, at 1. Similarly, the GAO has warned that "[i]ncreased use of the 340B program by contract pharmacies and hospitals may result in a greater risk of drug diversion." 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/330/323702.pdf. Bearing out these concerns, a 2018 GAO report determined that approximately two-thirds of diversion findings in HRSA audits involved drugs distributed at contract pharmacies. GAO Report, *supra*, at 44.

43. HHS has also found that contract pharmacy arrangements "create complications in preventing duplicate discounts." HHS Report, *supra*, at 2. According to a 2014 HHS investigation, some covered entities "did not report a method to avoid duplicate discounts," "most covered entities . . . d[id] not conduct all of the oversight activities recommended by HRSA," and "[f]ew covered entities reported retaining independent auditors for their contract pharmacy arrangements." *Id.* It is therefore unsurprising that a limited HRSA audit in 2019 uncovered widespread duplicate discounting at contract pharmacies. *See* HRSA, Program Integrity: FY19 Audit Results (Dec. 3, 2020), https://www.hrsa.gov/opa/program-integrity/audit-results/fy-19-results. Sanofi has discovered similar violations of Section 340B. In a limited analysis of three years of Medicaid rebates from five states for three Sanofi drugs, for example, the company identified over $16 million in duplicate discounts.

44. These duplicate-discounting problems stem in part from an information gap. Whereas 340B discounts are provided to the covered entity, requests for Medicaid reimbursement are made by the pharmacy that fills the prescription. 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. *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. As a result, based on publicly available information, there is no effective or comprehensive way to know whether a contract pharmacy's prescriptions are being submitted for duplicate discounts—*i.e.*, for both a 340B discount (under the covered entity's name) and a Medicaid rebate (under the contract pharmacy's name). Instead, according to CMS, "duplicate discounts can often best be identified from a review of claims level data by the manufacturers." CMS, 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.

III. Sanofi's Integrity Initiative

45. Sanofi shares HHS's concerns about duplicate discounting when prescriptions are filled at contract pharmacies. Accordingly, on July 28, 2020, Sanofi announced an integrity initiative to prevent duplicate discounting. Under the integrity initiative, Sanofi continues to offer discounted pricing to all covered entities, and Sanofi continues to ship discounted drugs to all contract pharmacies. The only change is that Sanofi now requires

covered entities to submit minimal claims data for 340B-priced drugs dispensed by contract pharmacies, subject to limited exceptions. *See* Ex. 1, Letter from G. Gleeson, Vice President & Head, Sanofi US Market Access Shared Services (July 2020); Ex. 2, Letter from A. Gluck to Secretary Azar (August 13, 2020).

46. Specifically, Sanofi asks covered entities to periodically submit anonymized, de-identified claims data for any 340B-priced prescriptions dispensed by contract pharmacies. *See* Ex. 3, Sanofi's New Initiative Combats Waste and Abuse in the 340B Program; Ex. 4, Understanding Sanofi's 340B Data Reporting Requirements. Sanofi requests only eight categories of information—the prescription number, prescribed date, fill date, NDC, quantity, pharmacy ID, prescriber ID, and 340B covered entity ID—which are to be submitted to a third-party vendor that administers the program. Sanofi's request is fully compliant with the Health Insurance Portability and Accountability Act ("HIPAA") and imposes no burden on covered entities. Nor does Sanofi discriminate against covered entities as compared to commercial customers. Indeed, this information is just a subset of what third-party payors already require for insurance reimbursement and is included in the data elements that drug manufacturers require of insurance companies when paying rebates on prescriptions. Any additional claims information that might be submitted by covered entities is automatically scrubbed during the submission process and not uploaded to Sanofi's or its vendor's systems.

47. The collected information enables Sanofi to identify and halt impermissible duplicate discounts that would otherwise go undetected. For example, by comparing the information to Medicaid payor data, Sanofi can detect duplicate discounts for drugs

dispensed to Medicaid patients. And the information also enables Sanofi to flag when Medicare Part D and commercial rebates are being sought for 340B-priced drugs.

48. Under Sanofi's integrity initiative, covered entities have no obligation to provide the requested claims data. If a covered entity declines to provide the claims data, Sanofi continues to offer its drugs at 340B prices for shipment to the covered entity's own facilities; the entity simply may not order discounted drugs for shipment to contract pharmacies. If a covered entity provides the requested claims data, the entity remains able to pay the discounted price for drugs shipped to contract pharmacies or its own facilities.

49. Since announcing the integrity initiative, Sanofi has continued to provide discounted drugs to contract pharmacies for the many covered entities that are providing the requested claims data. Sanofi has also excepted certain covered entities from this integrity initiative.

IV. The Advisory Opinion

50. In recent months, various 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* Ex. 5, Letter from California Attorney General Becerra to Secretary Azar (Dec. 14, 2020); Ex. 2, Letter from A. Gluck to Secretary Azar (Aug. 13, 2020); Ex. 6, Letter from A. Gluck to American Hospital Association (Aug. 28, 2020); Ex. 7, Letter from American Hospital Association, et al. to Secretary Azar (Aug. 26, 2020). Various covered entities also filed lawsuits seeking to require HHS to take such action. *See Ryan White Clinics for 340B Access v. Azar*, No. 1:20-cv-2906 (D.D.C.); *Am. Hosp.*

Ass'n v. HHS, No. 4:20-cv-8806 (N.D. Cal.). (Sanofi has filed motions to intervene in both suits; both motions remain pending.)

51. On December 30, 2020, HHS took action against drug manufacturers such as Sanofi when HHS's General Counsel published the Advisory Opinion, concluding (for the first time) that drug manufacturers are legally obligated to provide 340B-priced drugs to contract pharmacies—notwithstanding the widespread recognition (including by HHS itself) of waste and abuse at contract pharmacies. In particular, 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." Advisory Opinion at 1, 8.

52. In addition, the Advisory Opinion prohibits manufacturers from imposing conditions on the delivery of discounted drugs to contract pharmacies based on concerns about duplicate discounting or diversion. In particular, HHS determined that "private actor[s]" are not "authorized by section 340B to add requirements to the statute." *Id.* at 2. 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.'" *Id.* at 5 (quoting 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1210, 1223 (Jan. 5, 2017)). As per the Advisory Opinion, "[i]f a manufacturer is concerned that a covered entity has engaged in duplicate discounting or diversion, *see* 42 U.S.C. § 256b(a)(5)(A), (B), it must

(1) conduct an audit, and (2) submit the claim to the administrative dispute resolution ('ADR') process, *see* §256b(d)(3)(A)." *Id.* & n.5.

53. Under the Advisory Opinion, because of its integrity initiative, Sanofi is exposed to government enforcement actions for noncompliance, including civil monetary penalties in the amount of $5,000 for each instance of noncompliance, *see* 42 U.S.C. § 256b(d)(1)(B)(vi)(II), and the revocation of its ability to participate in Medicare and Medicaid.

54. Third parties have already recognized that the Advisory Opinion requires Sanofi to provide 340B-priced drugs to contract pharmacies without any conditions. For example, certain covered entities recently notified Sanofi that the Advisory Opinion requires "drug companies to provide 340B entities covered outpatient drugs . . . when those covered entities use contract pharmacies to dispense the drugs." *See* Ex. 8, Letter From W. Schultz to C. Lee (Jan. 7, 2021). These covered entities contend that the Advisory Opinion requires Sanofi to pay them reimbursements and justifies imposition of civil monetary penalties for Sanofi's integrity initiative. *Id.* at 2.

55. Given their repeated threats against Sanofi, covered entities will almost certainly file ADR claims against Sanofi challenging the integrity initiative once the ADR Rule takes effect on January 13, 2021. As noted, the ADR Panel will consist of representatives from the HHS Office of General Counsel (which issued the Advisory Opinion) and from HRSA and CMS, both of which are HHS agencies and subject to the Office of General Counsel's legal advice and supervision. Given this composition, the ADR Panel will treat the Advisory Opinion as binding in any ADR proceeding, almost certainly

find that Sanofi's integrity initiative violates Section 340B as interpreted by HHS, and potentially impose crippling sanctions.

STANDING

56. Sanofi is injured by the Advisory Opinion because Sanofi now must provide its drugs to contract pharmacies at discounted prices, cannot impose conditions on the delivery of 340B-priced drugs to contract pharmacies, and is exposed to sanctions (including enforcement actions, civil monetary penalties, and revocation of its participation in the Medicare and Medicaid programs) that are certainly impending if Sanofi fails to comply with HHS's new rule.

57. Sanofi's injuries are fairly traceable to the Advisory Opinion because the Advisory Opinion contains binding legal requirements that drug manufactures must provide discounted drugs to contract pharmacies and that manufacturers cannot impose conditions on the delivery of 340B-priced drugs to contract pharmacies. Neither Section 340B nor any existing regulation contains these binding legal requirements. Through the Advisory Opinion, HHS has effectively outlawed Sanofi's integrity initiative for imposing a condition on the delivery of 340B-priced drugs to contract pharmacies. As a result of the Advisory Opinion, Sanofi is exposed to enforcement actions and civil monetary penalties, as well as the revocation of its participation in the Medicare and Medicaid programs, if it fails to comply with the Advisory Opinion by continuing to operate the integrity initiative.

58. A favorable ruling is likely to redress Sanofi's injuries. Vacating the Advisory Opinion would redress Sanofi's injury because Sanofi would not be required to provide 340B-priced drugs to contract pharmacies, and Sanofi could impose conditions on the

delivery of such drugs to contract pharmacies (such as through its integrity initiative). Likewise, a declaratory judgment that Sanofi's integrity initiative complies with Section 340B would redress Sanofi's injuries because Sanofi would not be exposed to enforcement actions, civil monetary penalties, or revocation of its participation in Medicare and Medicaid for continuing to operate the integrity initiative.

FINAL AGENCY ACTION

59. Although the Advisory Opinion self-servingly claims that it "is not a final agency action" and "does not have the force or effect of law," Advisory Opinion at 8, the Advisory Opinion is in fact "[a]gency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court." 5 U.S.C. § 704.

60. The Advisory Opinion represents the consummation of HHS's decision-making process, through which HHS concluded that drug manufacturers must provide drugs discounted under the 340B Program to contract pharmacies. *See* Advisory Opinion at 1–4. HHS also concluded that drug manufacturers cannot impose conditions on the delivery of discounted covered outpatient drugs to contract pharmacies. *See id.* at 5. Indeed, the Secretary recently admitted that these conclusions have "been set forth *conclusively* in the recently issued advisory opinion." Dkt. 64, Defs.' Mot to Dismiss, at 9, No. 4:20-cv-8806 (N.D. Cal.) (filed Jan. 11, 2021) (emphasis added). HHS reached these conclusions after years of study and after reviewing complaints from covered entities and government officials about Sanofi's integrity initiative and other drug manufacturers' compliance with Section 340B. The Advisory Opinion was issued by HHS's chief legal officer, who "supervises all legal activities of the Department and its operating agencies," *see* Statement of Organization,

85 Fed. Reg. at 47,230, and the Advisory Opinion is not subject to further review or appeal within HHS. And because the Advisory Opinion will be treated as binding in any ADR proceeding against Sanofi, any attempt to contest the Advisory Opinion's determinations before an ADR Panel would be futile.

61. The Advisory Opinion determines Sanofi's rights and legal obligations under Section 340B, and legal consequences will inevitably flow from the Advisory Opinion. Sanofi must now provide 340B-priced drugs to contract pharmacies. Sanofi is now forbidden from imposing conditions on the delivery of 340B-priced drugs to contract pharmacies. And Sanofi is now exposed to enforcement actions and civil monetary penalties if it fails to comply with the Advisory Opinion by continuing with the integrity initiative, even though neither Section 340B nor any existing regulation contains these binding legal requirements. Indeed, as the Secretary recently stated, the Advisory Opinion sets forth the agency's "legal interpretation that the statute *requires* manufacturers to make discounts available regardless whether covered entities choose to disburse drugs through contract pharmacies." Dkt. 64, Defs.' Mot to Dismiss, at 16, No. 4:20-cv-8806 (N.D. Cal.) (filed Jan. 11, 2021) (emphasis added). Noncompliance with the Advisory Opinion—which will be treated as binding in any ADR proceeding against Sanofi—also jeopardizes Sanofi's participation in Medicare and Medicaid by risking termination of Sanofi's PPA.

62. Sanofi is thus now put to a painful choice: either comply with the unlawful obligations in the Advisory Opinion by abandoning a reasonable integrity initiative which Sanofi believes fully complies with Section 340B, or risk devastating financial penalties by

continuing to operate the integrity initiative in the face of the Advisory Opinion and repeated threats of enforcement.

CLAIMS FOR RELIEF

Count I—Violation of Administrative Procedure Act
HHS Failed to Observe the Notice and Comment Procedure Required by Law

63. Sanofi incorporates by reference the allegations contained in all of the preceding paragraphs as though set forth fully herein.

64. A court must "hold unlawful and set aside agency action, findings, and conclusions found to be … without observance of procedure required by law." 5 U.S.C. § 706(2)(D).

65. The APA requires agencies to issue rules through a notice-and-comment process. *See id.* § 553.

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

67. The Advisory Opinion is a rule within the meaning of the APA because it is an agency statement of general applicability to all drug manufacturers, applies prospectively, and implements, interprets, or prescribes HHS's law or policy with respect to drug manufacturers' obligations under Section 340B.

68. In particular, the Advisory Opinion requires drug manufacturers to provide drugs discounted under the 340B Program to contract pharmacies. It also prohibits drug

manufacturers from imposing conditions on the delivery of 340B-priced drugs to contract pharmacies.

69. The Advisory Opinion has the force and effect of law because it imposes binding obligations that exceed existing law. Neither Section 340B nor any regulation requires drug manufactures to provide discounted drugs to contract pharmacies or restricts the ability of manufacturers to impose conditions on the delivery of drugs to contract pharmacies. But the Advisory Opinion does both. *See* Advisory Opinion at 1–5. Sanofi is exposed to enforcement actions and civil monetary penalties if it fails to comply with the Advisory Opinion and continues to operate the integrity initiative. Noncompliance with the Advisory Opinion also puts at risk Sanofi's participation in Medicare and Medicaid.

70. HHS issued the Advisory Opinion without engaging in the notice-and-comment process. 5 U.S.C. § 553.

71. This Court should hold unlawful and set aside the Advisory Opinion because it violates the APA's notice-and-comment requirement. *Id.* § 706(2)(D).

Count II—Violation of Administrative Procedure Act
HHS Failed to Follow Its Good Guidance Rule

72. Sanofi incorporates by reference the allegations contained in all of the preceding paragraphs as though set forth fully herein.

73. A court must "hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" as well as agency action "found to be without observance of procedure required by law." *Id.* § 706(2)(A), (D).

74. Through the "Good Guidance Rule," HHS regulations subject guidance documents to various requirements. *See* Department of Health and Human Services Good Guidance Practices, 85 Fed. Reg. 78,770 (Dec. 7, 2020) (to be codified at 45 C.F.R. pt. 1).

75. The Good Guidance Rule defines a "guidance document" as "any Department statement of general applicability, intended to have future effect on the behavior of regulated parties and which sets forth a policy on a statutory, regulatory, or technical or scientific issue, or an interpretation of a statute or regulation." *Id.* at 78,785, 45 C.F.R. § 1.2.

76. The Good Guidance Rule defines "a significant guidance document" as "a guidance document that may reasonably be anticipated to lead to an annual effect on the economy of $100 million or more." *Id.* A guidance document can also be a "significant guidance document" if it "raise[s] novel legal or policy issues arising out of legal mandates." *Id.*

77. The Advisory Opinion is a guidance document within the meaning of the Good Guidance Rule because it interprets Section 340B to require manufacturers to provide 340B-priced drugs to contract pharmacies and because it prohibits manufacturers from imposing conditions on such delivery. It is generally applicable to manufacturers participating in the 340B Program and is intended to have future effect on the behavior of participants in the 340B Program because it exposes them to the potential for enforcement actions, the imposition of civil monetary penalties, and other consequences of non-compliance.

78. The Advisory Opinion is a significant guidance document within the meaning of the Good Guidance Rule because it "raise[s] novel legal or policy issues arising out of legal mandates." *Id.* In particular, the Advisory Opinion raises a novel legal issue relating to the meaning of Section 340B arising out of its mandates that manufacturers participating in the 340B Program provide 340B-priced drugs to contract pharmacies and that they not impose conditions on such delivery.

79. The Advisory Opinion is also a significant guidance document within the meaning of the Good Guidance Rule because it "may reasonably be anticipated to lead to an annual effect on the economy of $100 million or more." *Id.*

80. The Advisory Opinion violates the Good Guidance Rule because it "establishes a legal obligation that is not reflected in a duly enacted statute or in a regulation lawfully promulgated under a statute." *Id.* at 78,786, 45 C.F.R. § 1.3(a)(1). In particular, the Advisory Opinion requires drug manufacturers to provide drugs covered under the 340B Program to contract pharmacies. It also prohibits drug manufacturers from imposing conditions on the delivery of 340B-priced drugs to contract pharmacies.

81. The Advisory Opinion violates the Good Guidance Rule because it "requir[es] a person or entity outside of the Department to take an[] action, or refrain from taking an[] action, beyond what is required by the terms of an applicable statute or regulation." *Id.* 78,785–86, 45 C.F.R. § 1.3(a)(2). In particular, the Advisory Opinion's requirement that manufacturers provide discounted covered outpatient drugs under the 340B Program to contract pharmacies is "beyond what is required by the terms" of Section 340B. *Id.* In addition, the Advisory Opinion's determination that manufacturers participating in the 340B

Program may not impose conditions on the delivery of discounted covered outpatient drugs to contract pharmacies requires those manufacturers to "refrain from taking an[] action" when Section 340B imposes no such limit.

82. The Advisory Opinion violates the Good Guidance Rule because it does not "identify itself as 'guidance.'" *Id.* at 78,786, 45 C.F.R. § 1.3(a)(3)(i).

83. The Advisory Opinion violates the Good Guidance Rule because it "directs parties outside the federal government to take or refrain from taking action." *Id.* at 78,786, 45 C.F.R. § 1.3(a)(3)(ii). In particular, the Advisory Opinion directs drug manufacturers to provide covered outpatient drugs to contract pharmacies at discounted prices under Section 340B. The Advisory Opinion also directs drug manufacturers to refrain from imposing conditions on deliveries of covered outpatient drugs to contract pharmacies at discounted prices under Section 340B.

84. The Advisory Opinion violates the Good Guidance Rule because HHS did not follow the procedures required by the Good Guidance Rule for significant guidance documents. *Id.* at 85 Fed. Reg. at 78,785, 45 C.F.R. § 1.3(b)(2). Specifically, the Advisory Opinion was not subject to "at least a 30-day public notice and comment period" or "approved, on a non-delegable basis, by the Secretary." *Id.*

85. This Court should hold unlawful and set aside the Advisory Opinion as contrary to law and arbitrary and capricious in light of these violations of the Good Guidance Rule. *See* 5 U.S.C. § 706(2)(A), (D).

Count III—Violation of Administrative Procedure Act
The Advisory Opinion Is Contrary to Law and in Excess of Statutory Authority

86. Sanofi incorporates by reference the allegations contained in all of the preceding paragraphs as though set forth fully herein.

87. A court must "hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" as well as agency action "in excess of statutory authority." 5 U.S.C. § 706(2)(A), (C).

88. The Advisory Opinion's conclusion that drug manufacturers must provide discounted covered outpatient drugs to contract pharmacies is contrary to law and in excess of statutory authority because Section 340B does not require drug manufacturers to provide discounted covered outpatient drugs to contract pharmacies. *See* 42 U.S.C. § 256b.

89. The Advisory Opinion's conclusion that drug manufacturers cannot impose conditions on the use of contract pharmacies is contrary to law and in excess of statutory authority because Section 340B does not prohibit manufacturers from imposing conditions on the use of contract pharmacies—particularly when such conditions are reasonable. *See id.*

90. Even if the Advisory Opinion is correct that manufacturers must provide 340B-priced drugs to contract pharmacies, Sanofi's integrity initiative complies with Section 340B because it imposes a permissible condition on the delivery of discounted covered outpatient drugs to contract pharmacies. Sanofi ships discounted drugs to contract pharmacies—and, moreover, will do so for all covered entities. So long as a covered entity provides the claims data requested by Sanofi, Sanofi provides discounted pricing wherever

the prescriptions are filled. This request for claims data is a reasonable condition that is not burdensome and that does not discriminate against covered entities as compared to commercial customers.

91. The Advisory Opinion is not entitled to *Chevron* or *Skidmore* deference. *See generally Chevron USA, Inc. v. Natural Res. Def. Council*, 467 U.S. 837 (1984); *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944).

92. This Court should hold unlawful and set aside the Advisory Opinion because it is contrary to law and in excess of statutory authority. 5 U.S.C. § 706(2)(A).

Count IV—Violation of Administrative Procedure Act
The Advisory Opinion Is Arbitrary and Capricious

93. Sanofi incorporates by reference the allegations contained in all of the preceding paragraphs as though set forth fully herein.

94. A court must "hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

95. The Advisory Opinion's conclusion that drug manufacturers must provide discounted covered outpatient drugs to contract pharmacies is arbitrary and capricious because HHS failed to reasonably explain this aspect of the Advisory Opinion.

96. The Advisory Opinion's conclusion that drug manufacturers cannot impose conditions on the use of contract pharmacies is arbitrary and capricious because HHS failed to reasonably explain this aspect of the Advisory Opinion.

97. This Court should hold unlawful and set aside the Advisory Opinion because it is arbitrary and capricious. *Id.* § 706(2)(A).

PRAYER FOR RELIEF

Wherefore, Plaintiff prays for the following relief:

1. A declaration, order, and judgment holding unlawful, enjoining, and setting aside the Advisory Opinion;

2. A declaration, order, and judgment holding that Section 340B does not require drug manufacturers to provide discounted covered outpatient drugs to contract pharmacies;

3. A declaration, order, and judgment holding that Section 340B does not prohibit drug manufacturers from imposing conditions on the provision of discounted covered outpatient drugs to contract pharmacies;

4. A declaration, order, and judgment holding that Sanofi's integrity initiative complies with Section 340B because it imposes a permissible condition on the provision of discounted covered outpatient drugs to contract pharmacies;

5. A preliminary and permanent injunction enjoining Defendants from enforcing the Advisory Opinion in any administrative proceeding;

6. An award of all costs and attorneys' fees pursuant to any applicable statute or authority; and

7. Any other relief this Court deems just and proper.

Dated: January 12, 2021

Respectfully submitted,

s/ Jennifer L. Del Medico

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Counsel for Plaintiff
Sanofi-Aventis U.S. LLC

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).

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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

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.

SANOFI

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.

SANOFI

EXHIBIT 4

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 5

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
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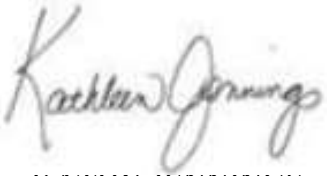
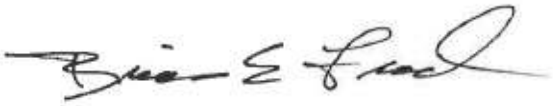
Attorney General of Maine



KATHY JENNINGS
Attorney General of Delaware



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MAURA HEALEY
Attorney General of Massachusetts

CLARE E. CONNORS
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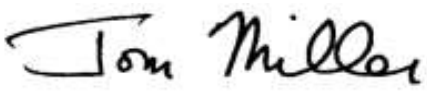
DANA NESSEL
Attorney General of Michigan

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
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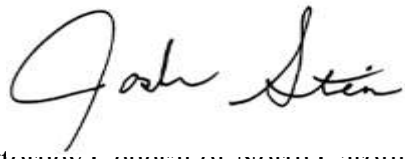
HECTOR BALDERAS
Attorney General of New Mexico

PETER F. NERONHA
Attorney General of Rhode Island

LETITIA A. JAMES
Attorney General of New York

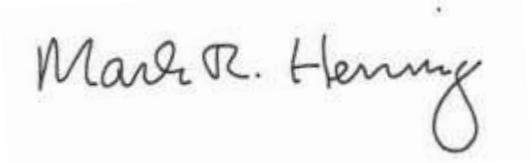
Attorney General of South Dakota



Attorney General of North Carolina

THOMAS J. DONOVAN, JR.
Attorney General of Vermont

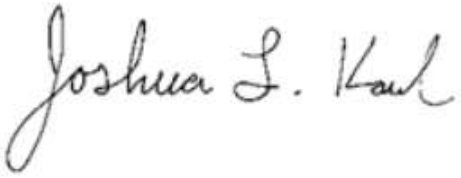
MIKE HUNTER
Attorney General of Oklahoma



Attorney General of Virginia

ELLEN F. ROSENBLUM
Attorney General of Oregon

BOB FERGUSON
Attorney General of Washington



Attorney General of Wisconsin

EXHIBIT 6

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]

[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.

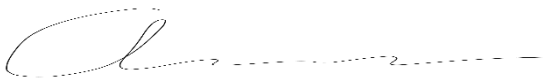
Contrary to your hyperbolic language, our initiative will not burden covered entities. Our data submission portal will be user-friendly and the data elements submitted will be limited and of the type commonly included in insurance reimbursement claims. Moreover, we do not request data on physician-administered 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 7

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 8

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

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

JS 44 (Rev. 10/20)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

Sanofi-Aventis U.S., LLC

(b) County of Residence of First Listed Plaintiff Somerset County
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Jennifer L. Del Medico, JONES DAY
250 Vesey Street
New York, New York, 10281 Ph.: (212) 326-3939

DEFENDANTS

U.S. Department of Health and Human Services; Alex M. Azar, II, in his official capacity; Robert P. Charrow, in his official capacity ; Health Resources and Services Administration; Thomas J. Engels, in his official capacity.

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☒ 2 U.S. Government Defendant
- ☐ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark
- ☐ 880 Defend Trade Secrets Act of 2016

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit (15 USC 1681 or 1692)
- ☐ 485 Telephone Consumer Protection Act
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
5 U.S.C. § 702

Brief description of cause: Defendants' advisory opinion was issued without observance of procedure required by law and is arbitrary and capricious and contrary to law.

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:

JURY DEMAND: ☐ Yes ☒ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
January 12, 2021

SIGNATURE OF ATTORNEY OF RECORD
s/ Jennifer L. Del Medico

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

IN THE 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,

ALEX M. AZAR II, in his official capacity as Secretary of Health and Human Services,

ROBERT P. CHARROW, in his official capacity as General Counsel of the United States Department of Health and Human Services,

HEALTH RESOURCES AND SERVICES ADMINISTRATION,

THOMAS J. ENGELS, in his official capacity as Administrator of the Health Resources and Services Administration

Defendants.

Civil Action No. 3:21-cv-634

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

CERTIFICATION

Pursuant to Local Civil Rule 11.2, the undersigned hereby certifies that to the best of my knowledge, the matters raised herein are not the subject of any other pending lawsuit, arbitration, or administrative proceeding.

Dated: January 12, 2021

Respectfully submitted,

s/ Jennifer L. Del Medico

Jennifer L. Del Medico
Toni-Ann Citera
(application *pro hac vice* forthcoming)
Rajeev Muttreja
(application *pro hac vice* forthcoming)
JONES DAY
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Brett A. Shumate
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Megan Lacy Owen
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Counsel for Plaintiff
Sanofi-Aventis U.S. LLC