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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