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,

NORRIS COCHRAN, in his official capacity as Acting Secretary of Health and Human Services,

DANIEL J. BARRY, in his official capacity as Acting General Counsel of the United States Department of Health and Human Services,

HEALTH RESOURCES AND SERVICES ADMINISTRATION,

DIANA ESPINOSA, in her official capacity as Acting Administrator of the Health Resources and Services Administration,

Defendants.

Civil Action No. 3:21-cv-634

SECOND AMENDED 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 two new rules governing the 340B drug-discounting program (the "340B Program") issued by the U.S. Department of Health and Human Services ("HHS") and final agency action enforcing one of those rules against Sanofi. These rules were issued without statutory

authority, without following the requirements for issuing rules having the force and effect of law, and without complying with Articles II and III of the United States Constitution. The legality of the agency's enforcement action depends upon the legality of the agency's new rule imposing extra-statutory obligations on pharmaceutical manufacturers.

2. Section 340B of the Public Health Service Act, 42 U.S.C. § 256b, requires pharmaceutical manufacturers to discount their drugs (often quite significantly) for fifteen types of "covered entities"—governmental and non-profit entities that mostly provide care for underserved areas or populations—that are enumerated in the statute. 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 the discounted drugs and dispense them 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 far 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. After Sanofi's integrity initiative took effect, HHS issued two new rules that together prohibit the initiative and expose Sanofi to crippling financial penalties. HHS first created an unconstitutional process for adjudicating covered entities' claims against drug manufacturers and then preordained the outcome of those claims against Sanofi. Covered entities have already sought to leverage this regulatory one-two punch by asking an unconstitutional administrative body within HHS to grant a

preliminary injunction quashing Sanofi's integrity initiative. Moreover, an agency within HHS, Defendant Health Resources and Services Administration ("HRSA"), took action to enforce one of these rules against Sanofi in a May 17, 2021 Letter (the "HRSA Letter") determining that Sanofi's integrity initiative violates Section 340B.

7. In its first new rule (the "ADR Rule"), HHS adopted Administrative Dispute Resolution ("ADR") procedures under which covered entities can, among other things, submit claims alleging that drug manufacturers have overcharged for drugs in the 340B Program or limited covered entities' ability to purchase these drugs. The ADR Rule empowers ADR Panels—which will consist of three HHS employees—to wield full judicial authority with respect to any claims asserted in the ADR process. For example, the ADR process will operate under the Federal Rules of Civil Procedure and Evidence, an ADR Panel can award money damages and equitable relief, and all ADR decisions will be binding and precedential.

8. This new administrative process violates Article II and Article III of the Constitution. The ADR Rule violates the Appointments Clause in Article II of the Constitution because the members of the ADR Panels are principal officers under the Appointments Clause—which means they must be appointed by the President and confirmed by the Senate. But the ADR Rule calls for neither, instead installing in this role agency employees who are not Senate-confirmed and, worse, are protected by for-cause removal restrictions and thus not even politically accountable. In addition,

the ADR Rule violates Article III of the Constitution by granting unaccountable bureaucrats the power to issue final judgments for money damages and equitable relief in order to resolve disputes between private parties over private rights—namely, the price of a drug. The Constitution reserves this authority to Article III courts.

9. The ADR Rule also violates the APA in several respects, especially in light of these constitutional concerns that HHS ignored. The rule improperly allows ADR Panels to adjudicate claims and award remedies that fall outside HHS's statutory authority. Section 340B authorizes HHS to adjudicate only overcharge claims, *i.e.*, claims that a manufacturer has charged a covered entity too much for a drug. Under Section 340B, HHS does *not* have the authority to decide whether manufacturers have improperly limited a covered entity's ability to purchase 340B-priced drugs. Nor does HHS have statutory authority to usurp the judicial function by awarding money damages and equitable relief. HHS also failed to comply with the APA's notice-and-comment requirement when promulgating the ADR Rule. Although HHS gave notice of a rule regarding ADR proceedings at the end of the Obama Administration in 2016, HHS *withdrew* that notice in early 2017—but then issued the ADR Rule without warning during the last month of the Trump Administration, and without going through the notice-and-comment process again. Finally, the ADR Rule is also arbitrary and capricious because HHS failed to reasonably explain key aspects of the rule.

10. The second new rule issued by HHS is entitled Advisory Opinion 20-06 (the "Advisory Opinion"). In the Advisory Opinion, HHS has preordained the outcome of any ADR claim against Sanofi by imposing 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 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 both to require drug manufacturers to provide 340B discounts to for-profit contract pharmacies and also 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. Covered entities have already filed ADR claims alleging that Sanofi's integrity initiative violates the Advisory Opinion and requesting equitable relief—including a preliminary injunction—to stop the integrity initiative. (Notably, however, none of the plaintiffs in those actions has ever alleged that Sanofi's integrity initiative is unreasonable.)

11. 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. Further, HHS's limited rulemaking authority under Section 340B does not allow for a rule requiring drug manufacturers to provide 340B-priced drugs to contract pharmacies. The Advisory Opinion thus exceeds HHS's statutory authority, and Sanofi's integrity initiative is fully consistent with Section 340B.

12. HHS also failed to comply with the APA's notice-and-comment requirement before issuing the Advisory Opinion. That requirement applies because 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. For similar reasons, HHS failed to comply with its own procedural regulations when issuing the Advisory Opinion. HHS's failure to comply with these requirements means the Advisory Opinion is procedurally unlawful and must be vacated.

13. In the midst of briefing the merits of Sanofi's claims in cross-motions for summary judgment, on May 17, 2021, Defendant HRSA sent Sanofi its letter

enforcing the new rule announced in the Advisory Opinion against Sanofi while that new rule's validity is simultaneously being litigated in this action. *See* Ex. 17.

14. The HRSA Letter notifies Sanofi that HRSA has "completed its review of Sanofi's" integrity initiative—despite Sanofi having never been given the opportunity to meet with HRSA to explain why its initiative complies with Section 340B. *Id.* at 1. The HRSA Letter then informs Sanofi that, after "an analysis of the complaints HRSA has received from covered entities, HRSA has determined that Sanofi's actions have resulted in overcharges and are in direct violation of the 340B statute." *Id.* The HRSA Letter also concludes that Section 340B prohibits Sanofi's request for "claims data" as part of its integrity initiative. *Id.*

15. The HRSA Letter follows these conclusions with a clear and explicit threat of further enforcement: "Continued failure to provide the 340B price to covered entities utilizing contract pharmacies, and the resultant charges to covered entities of more than the 340B ceiling price, may result in [civil monetary penalties]." *Id.* at 2. The letter explains that "[t]he Department of Health and Human Services will determine whether [civil monetary penalties] are warranted based on Sanofi's willingness to comply with its obligations" as HRSA interprets them, and demands a response by June 1, 2021. *Id.*

16. HRSA's Letter enforcing against Sanofi the new rule announced in the Advisory Opinion is substantively and procedurally unlawful for the same reasons that

the Advisory Opinion is unlawful. In addition, HRSA's Letter fails to offer any reasonable explanation for HRSA's conclusions, which are inconsistent with the agency's past guidance and the reasoning in the Advisory Opinion and unsupported by evidence.

17. For these reasons, the Court should (a) hold unlawful and set aside the ADR Rule, the Advisory Opinion, and the HRSA Letter, (b) declare that the ADR Rule violates Article II and Article III of the Constitution and also exceeds HHS's statutory authority, (c) hold 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, (d) confirm that Sanofi's integrity initiative comports with the statute, and (e) enjoin HHS from implementing or enforcing the ADR Rule, the Advisory Opinion, and the HRSA Letter in any administrative proceeding or from taking any other enforcement action against Sanofi for operating its integrity initiative.

JURISDICTION AND VENUE

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

19. This Court has the authority to grant declaratory relief and to vacate and set aside the ADR Rule and 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.

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

PARTIES

21. 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 at 55 Corporate Drive, Bridgewater, New Jersey.

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

23. Defendant Norris Cochran is the Acting Secretary of HHS (the "Secretary") and is sued in his official capacity.

24. Defendant Daniel J. Barry is Acting General Counsel of HHS and is sued in his official capacity.

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

26. Defendant Diana Espinosa is Acting Administrator of HRSA and is sued in her official capacity.

STATEMENT OF FACTS

I. The 340B Program

27. 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.

28. 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).

29. 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.*

30. 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.

31. 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.

32. 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.

33. 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).

34. 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).

35. 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).

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://pharma.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 (last updated Jan. 15, 2021), 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 the Centers for Medicare and Medicaid Services ("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 (Aug. 13, 2020); Ex. 3, Letter from G. Gleeson (August 2020); Ex. 4, Letter from G. Gleeson (September 2020); Ex. 5, Letter from A. Gluck and G. Gleeson (September 29, 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. 6, Sanofi's New Initiative Combats Waste and Abuse in the 340B Program; Ex. 7, 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 exempted from this integrity initiative many types of covered entities that, based on Sanofi's experience, present a reduced risk of duplicate discounting.

50. In addition, beginning on March 1, 2021, any covered entity that does not have its own in-house pharmacy may designate a single contract pharmacy to receive 340B-priced drugs for the covered entity's patients, regardless of whether the covered entity provides the data Sanofi requests through the integrity initiative. *See* Ex. 8, Program Announcement.

IV. The ADR Rule

51. 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. 9, 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. 10, Letter from A. Gluck to American Hospital Association (Aug. 28, 2020); Ex. 11, Letter from American Hospital Association, et al. to Secretary Azar (Aug. 26, 2020); Ex. 12, Letter from T. Nova to J. Jehnke (Oct. 6, 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 filed motions to intervene in both suits.)

52. These lawsuits were filed against the government, and not against manufacturers directly, because Section 340B does not have a private right of action.

See Astra, 563 U.S. at 113-14. Under Section 340B, a covered entity that wishes to seek relief directly from a manufacturer must instead file a claim in an administrative process. Specifically, in 2010, the Affordable Care Act amended Section 340B to direct the Secretary to promulgate regulations establishing such a 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* 42 U.S.C. § 256b(d)(3)(A).

53. The Affordable Care Act required these ADR regulations to be promulgated within 180 days of enactment. But HHS missed that deadline—by years.

54. Shortly after passage of the Affordable Care Act, HRSA did issue an advanced notice of proposed rulemaking regarding the ADR process. 75 Fed. Reg. 57,233 (Sept. 20, 2010). But HRSA waited until 2016 to issue a notice of proposed rulemaking ("NPRM") for such a rule, in order to formally start the notice-and-comment process required under the APA. 81 Fed. Reg. 53,381 (Aug. 12, 2016).

55. The 2016 NPRM drew many comments from manufacturers, including Sanofi. But instead of responding to these comments, HRSA abandoned the proposed rule on August 1, 2017. *See* OMB/OIRA, Unified Agenda, Summary of Regulatory Action for RIN-0906-AA90 (Spring 2017), *available at* https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201704&RIN=0906-

AA90. After that, HRSA took no public action regarding an ADR rule for more than four years.

56. In 2020, however, covered entities began clamoring for the enactment of an ADR process—as Congress had directed over a decade earlier. In late 2020, multiple lawsuits—including the *Ryan White Clinics* suit noted above—were filed seeking mandamus relief directing the government to promulgate the statutorily required ADR regulations.

57. Manufacturers became concerned that HHS might attempt to revive and finalize the abandoned 2016 proposed rule without addressing the problems with that rule raised during the 2016 comment period, and also without considering how circumstances had subsequently changed. On November 24, 2020, the trade association Pharmaceutical Research and Manufacturers of America ("PhRMA") filed a petition for rulemaking that raised such concerns. PhRMA's petition asked HHS to consider new evidence before finalizing any ADR rule.

58. But HHS did not initiate another round of notice and comment to update the record. Instead, in the face of lawsuits demanding that HHS issue the ADR Rule, and in the closing weeks of the Trump Administration, the Secretary—relying on the 2016 NPRM—promulgated the ADR Rule on December 14, 2020. *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"). The ADR Rule took effect on January 13, 2021.

59. The ADR Rule provides that the Secretary will create an ADR Board "consisting of at least six members appointed by the Secretary with equal numbers" from HRSA, CMS, and the HHS Office of the General Counsel. *Id.* at 80,634. From this Board, HRSA will select three-member panels with "relevant expertise and experience" to adjudicate each dispute. *Id.* The rule provides that individual panel members can be removed from a panel, but only "for cause." *Id.* The rule lists "a conflict of interest" as the only grounds for a panelist's removal. *Id.*

60. Every member of the ADR Board—and, thus, every ADR Panel member—receives legal advice from the HHS Office of the General Counsel, the author of the Advisory Opinion. CMS, like HRSA, is an HHS agency. And 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).

61. 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).

62. The ADR Rule expressly grants panel members "significant discretion" in their adjudicative functions. *Id.* at 80,635. A panel may "determine, in its own discretion, the most efficient and practical form of the ADR proceeding." *Id.* at 80,645. It may require "submission of additional information," and it has discretion to choose from an array of formidable sanctions if it concludes that its instructions were inadequately complied with. *See id.*; 42 C.F.R § 10.22(c) (permitting panel to "[p]reclud[e] a party from presenting or contesting a particular issue" or even enter judgment as a sanction). It has "discretion in admitting evidence and testimony" during the proceeding, for which the Federal Rules of Civil Procedure and Federal Rules of Evidence presumptively apply. *Id.* at 80,641; *see* 42 C.F.R. § 10.23. The panel even has the discretion to issue whatever "additional instructions as may be necessary or desirable governing the conduct of ADR proceedings." 42 C.F.R. § 10.21(f). Finally, its decision "will" be based on its own "review and evaluation of the evidence." *Id.* § 10.24(b).

63. In sum, the ADR Rule empowers ADR panels to function like federal courts. It states that "[e]ach 340B ADR Panel will necessarily have jurisdiction to resolve all issues underlying any claim or defense, including, by way of example, those

having to do with covered entity eligibility, patient eligibility, or manufacturer restrictions on 340B sales that the 340B ADR Panel deems relevant for resolving an overcharge, diversion, or duplicate discount claim." 85 Fed. Reg. at 80,636. The ADR panel can even award "money damages" as well as "equitable relief." *Id.* at 80,633.

64. The ADR Rule provides that ADR panel decisions are both "binding" on the parties and "precedential" for purposes of future adjudications. 42 C.F.R. § 10.20. Specifically, the ADR panel's decision "constitutes a final agency decision that is precedential and binding on the parties involved unless invalidated by an order of a court of competent jurisdiction." *Id.* § 10.24(d); *see also* 42 U.S.C. § 256b(d)(3)(C) ("The administrative resolution of a claim or claims under the regulations promulgated under subparagraph (A) shall be a final agency decision and shall be binding upon the parties involved, unless invalidated by an order of a court of competent jurisdiction."). The ADR Rule does not provide for any internal review of ADR panel judgments by a superior Executive Branch official.

65. Notably, in the ADR Rule, HHS did not respond to the concerns raised in the petition for rulemaking filed by PhRMA in November 2020. Nor did HHS acknowledge the explicit constraints placed on the ADR process by Section 340B itself, which authorized such a process only "for reviewing and finally resolving claims by covered entities that they have been charged prices for covered outpatient drugs in

excess of the ceiling price … and claims by manufacturers that violations of [statutory prohibitions on conduct like diversion] have occurred." 42 U.S.C. § 256b(d)(3)(B)(i).

V. The Advisory Opinion

66. On December 30, 2020, less than three weeks after publishing the ADR Rule, HHS's Office of General Counsel issued the Advisory Opinion—which effectively dooms Sanofi's integrity initiative within the ADR process, before even giving Sanofi an opportunity to defend its program.

67. The Advisory Opinion concludes (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.

68. 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 the preamble to the 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.* at 5 & n.5.

69. 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.

70. 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. 13, Letter From W. Schultz to C. Lee (Jan. 7, 2021); *see also* Ex. 14, Letter from Jamestown S'Klallam Tribe to A. Gluck (January 19, 2021). These covered entities

contend that the Advisory Opinion entitles them to reimbursements and justifies imposition of civil monetary penalties for Sanofi's integrity initiative. *See* Ex. 13 at 2; Ex. 14 at 2-3.

71. One association representing hundreds of covered entities has already filed an ADR claim against Sanofi alleging that the integrity initiative violates the Advisory Opinion and requesting equitable relief, including a preliminary injunction. *See* Ex. 15, Petition for Declaratory and Injunctive Relief (Jan. 13, 2021); Ex. 16, Motion for Preliminary Injunction (Jan. 14, 2021). Given their repeated threats against Sanofi, many more covered entities will almost certainly follow suit.

72. As noted, an 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. Given this composition, any ADR Panel will treat the Advisory Opinion as binding in an ADR proceeding, almost certainly find that Sanofi's integrity initiative violates Section 340B as interpreted by HHS, and potentially impose crippling sanctions.

VI. The HRSA Letter

73. On May 17, 2021, after the parties had filed their opening briefs in support of cross-motions for summary judgment on Sanofi's claims in this lawsuit, Defendant HRSA surprisingly sent Sanofi a letter demanding that Sanofi agree to

HRSA's litigating position in this case by June 1, 2021, on threat of civil monetary penalties (or worse). *See* Ex. 17, HRSA Letter.

74. The HRSA Letter first notifies Sanofi that it HRSA "has completed its review of Sanofi's" integrity initiative—a review in which Sanofi has never been permitted an opportunity to participate, although HRSA has "analy[zed] [] the complaints [it] has received from covered entities." *Id.* at 1.

75. The HRSA Letter then informs Sanofi that "HRSA has determined that Sanofi's actions have resulted in overcharges and are in direct violation of the 340B statute." *Id.* The HRSA Letter goes on to explain that Sanofi's integrity initiative supposedly violates Section 340B because that "statute does not permit manufacturers to impose conditions on covered entities' access to 340B pricing, including the production of claims data" required by Sanofi's integrity initiative. *Id.*

76. The HRSA Letter's demands are imminent and authoritative. It declares: "Sanofi *must immediately* begin offering its covered outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements, regardless of whether they purchase through an in-house pharmacy." *Id.* at 2 (emphasis added). And the HRSA Letter backs its demands up with a clear and explicit threat that continued operation of Sanofi's integrity initiative "may result in [civil monetary penalties]." *Id.*

77. The HRSA Letter demands a response by June 1, 2021, still two weeks before the parties will have filed their reply briefs in support of their cross-motions for summary judgment in this matter. At that time, according to the letter, "[t]he Department of Health and Human Services will determine whether [civil monetary penalties] are warranted based on Sanofi's willingness to comply with" HRSA's interpretation of the statute—before this Court has even had the opportunity to address the statute's meaning.

STANDING

78. Sanofi has standing to challenge the ADR Rule, the Advisory Opinion, and the HRSA Letter because Sanofi is suffering injuries that are fairly traceable to HHS's rules and likely to be redressed by a favorable ruling.

79. Sanofi is injured by the ADR Rule because that rule exposes Sanofi to ADR claims by covered entities alleging that Sanofi overcharged for 340B-priced drugs or limited covered entities' ability to purchase these drugs. Indeed, covered entities have already filed ADR claims against Sanofi requesting equitable relief, including a preliminary injunction, from the ADR Panel. Sanofi is further injured because the ADR Panel that will adjudicate ADR claims against Sanofi is unconstitutionally structured. The ADR Panel members are principal officers of the United States, but they have not been confirmed by the Senate, in violation of the

Constitution's Appointments Clause—and they will wield judicial power in violation of Article III of the Constitution.

80. Sanofi's injuries are fairly traceable to the ADR Rule because that rule authorizes covered entities to file ADR claims before the unconstitutionally structured ADR Panel alleging that Sanofi overcharged for 340B-priced drugs or limited covered entities' ability to purchase these drugs.

81. A favorable ruling vacating the ADR Rule is likely to redress Sanofi's injuries from the ADR Rule, because Sanofi would not have to defend itself before an unconstitutionally structured ADR Panel against claims that it overcharged for 340B-priced drugs or limited covered entities' ability to purchase these drugs.

82. Sanofi is likewise 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. HRSA's Letter confirms that Sanofi is injured by the Advisory Opinion because Sanofi faces crushing financial penalties for failing to comply with the Advisory Opinion's new rule.

83. 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 through the termination of its PPA, if it fails to comply with the Advisory Opinion by continuing to operate the integrity initiative.

84. A favorable ruling is likely to redress Sanofi's injuries from the Advisory Opinion. 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.

85. Sanofi is also injured by the HRSA Letter because, by the letter's terms, Sanofi must now 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 abandon its integrity initiative in favor of HRSA's litigating position.

86. Sanofi's injuries are fairly traceable to the HRSA Letter because the HRSA Letter determines that Sanofi's integrity initiative violates Section 340B. The HRSA Letter also makes plain its direct consequences. Continued operation of Sanofi's integrity initiative "may result in [civil monetary penalties]" unless Sanofi "immediately" complies with the terms of the HRSA Letter. Ex. 17, HRSA Letter, at 2.

87. A favorable ruling is likely to redress Sanofi's injuries from the HRSA Letter. An order setting aside the HRSA Letter would allow Sanofi to continue to operate its integrity initiative and relieve Sanofi from the threat of civil monetary penalties and other enforcement actions.

FINAL AGENCY ACTION

88. The APA provides that "[a]gency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court are subject

to judicial review." 5 U.S.C. § 704. The ADR Rule, Advisory Opinion, and the HRSA letter are final agency actions for which Sanofi has no other adequate remedy in court.

89. The ADR Rule, which became effective on January 13, 2021, represents the consummation of HHS's decision-making process with respect to the implementation of Section 340B's dispute resolution process between covered entities and drug manufacturers.

90. The ADR Rule also determines Sanofi's rights and legal obligations under Section 340B, and legal consequences will inevitably flow from the ADR Rule, because Sanofi must now defend itself before an unconstitutionally structured ADR Panel against claims that it overcharged for 340B-priced drugs or limited covered entities' ability to purchase these drugs. Indeed, covered entities have already filed ADR claims against Sanofi requesting equitable relief, including a preliminary injunction. *See* Ex. 15, Petition for Declaratory and Injunctive Relief; Ex. 16, Motion for Preliminary Injunction.

91. 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 also final agency action.

92. 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 id.* 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, HHS recently admitted that these conclusions have "been set forth *conclusively* in the recently issued advisory opinion." Dkt. 64, Defs.' Mot to Dismiss, at 9, *Am. Hosp. Ass'n*, 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 "[s]upervises 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.

93. The Advisory Opinion determines Sanofi's rights and legal obligations under Section 340B, and legal consequences will inevitably flow from the Advisory Opinion. Sanofi now has a legal obligation to 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 HHS 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, *Am Hosp. Ass'n*, 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. HRSA's Letter enforcing the Advisory Opinion's new rule against Sanofi confirms that the Advisory Opinion determines Sanofi's rights and legal obligations.

94. If there were any room for doubt about the finality of the Advisory Opinion, there can be none after the HRSA Letter, which is also final agency action. As HHS conceded in parallel litigation regarding a similar letter sent to a different manufacturer, "the violation letter determines the legality of [the manufacturer's] actions, finds it to be out of statutory compliance, and sets out consequences should [the manufacturer] continue to flout its obligations." *AstraZeneca Pharmaceuticals LP v. Becerra et al.*, No. 1:21-cv-00027-LPS, ECF 74, at 4 (D. Del. May 24, 2021).

95. By its own terms, the HRSA Letter represents the consummation of HHS's decision-making process about the legality of Sanofi's integrity initiative. The letter explains that HRSA has conducted a "review of [Sanofi's] policy and an analysis of the complaints HRSA has received from covered entities." Ex. 17, HRSA Letter, at 1. After conducting that review, the letter explains that "HRSA has determined that Sanofi's actions have resulted in overcharges and are in direct violation of the 340B statute." *Id.* The HRSA Letter also rejects Sanofi's "rationale for its restrictive action," *i.e.*, Sanofi's reasonable request for claims data through its integrity initiative. *Id.* at 2.

96. Legal consequences will flow directly from the HRSA Letter. The HRSA Letter declares that "Sanofi must immediately begin offering its covered outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements, regardless of whether they purchase through an in-house pharmacy." *Id.* at 2. The HRSA Letter goes on to state the consequences of any refusal to abide by its terms: "Continued failure to provide the 340B price to covered entities utilizing contract pharmacies … may result in [civil monetary penalties]." *Id.*

97. Sanofi is thus now put to a painful choice: either comply with the unlawful obligations in the Advisory Opinion (as HRSA demands in its May 17 Letter) by abandoning a reasonable integrity initiative that 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 the HRSA Letter's plain threat of further enforcement action.

CLAIMS FOR RELIEF

Count I—Violation of Administrative Procedure Act The ADR Rule Violates Article II of the U.S. Constitution (Appointments Clause)

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

99. A court must "hold unlawful and set aside agency action … found to be … contrary to constitutional right, power, privilege, or immunity." 5 U.S.C. § 706(2)(B).

100. The Constitution's Appointments Clause provides that executive branch officers shall be appointed by the President "by and with the Advice and Consent of the Senate," except that "Congress may by Law vest the Appointment of such inferior Officers, as they think proper, in the President alone, in the Courts of Law, or in the Heads of Departments." U.S. Const. Art. II, § 2, cl. 2.

101. ADR Panel members are "officers" of the United States. They are appointed for a continuing term, they control the proceedings before them and issue final precedential decisions, and they exercise significant authority pursuant to the laws of the United States. Further, they can take testimony, conduct trials, rule on the admissibility of evidence, have the power to enforce compliance with discovery

orders, and have the power to award money damages and equitable relief. 42 C.F.R. §§ 10.23, .22(b)-(c); 85 Fed. Reg. at 80,641.

102. ADR Panel members are "principal officers" of the United States. They independently determine how to conduct proceedings, and they make final precedential determinations on behalf of HHS that are not subject to any further executive branch review. ADR Board members may also be removed from ADR Panels only "for cause." 85 Fed. Reg. at 80,634. Thus, in their conduct of ADR proceedings, ADR Panel members are not supervised or directed by any superior officer.

103. Because ADR Panel members are principal officers, the Appointments Clause requires them to be appointed only by the President with the Senate's advice and consent. By instead vesting the power to appoint ADR Panel members in the Secretary alone, the ADR Rule therefore violates the Appointments Clause.

104. This Court should hold unlawful and set aside the ADR Rule because it violates the Constitution. 5 U.S.C. § 706(2)(B).

Count II—Violation of Administrative Procedure Act
The ADR Rule Violates Article III of the Constitution

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

106. A court must "hold unlawful and set aside agency action … found to be … contrary to constitutional right, power, privilege, or immunity." 5 U.S.C. § 706(2)(B).

107. The Constitution vests the judicial power of the United States "in one supreme Court, and in such inferior Courts as the Congress may from time to time ordain and establish." U.S. Const. Art. III, § 1. The adjudication of private rights must be overseen by Article III courts.

108. The ADR Rule violates Article III by allowing ADR Panels to adjudicate private rights. Specifically, by enabling panels to mandate that manufacturers transfer property (*i.e.*, the drugs they produce) to covered entities, often at an extreme financial loss to the manufacturers, and by enabling those panels to enforce such decisions through binding money judgments, the ADR Rule empowers ADR Panels to determine the liability of one individual to another. Moreover, manufacturers have not consented to ADR Panels exercising this authority. Such authority may be constitutionally vested only in Article III courts.

109. This Court should hold unlawful and set aside the ADR Rule because it violates the Constitution. 5 U.S.C. § 706(2)(B).

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

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

111. 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).

112. The ADR Rule is contrary to law and in excess of statutory authority because it violates Article II and Article III of the Constitution.

113. The ADR Rule is contrary to law and in excess of statutory authority because HHS exceeded its statutory authority by allowing claims "that a manufacturer has limited the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price." 42 C.F.R. 10.21(c)(1). Section 340B only authorizes "claims by covered entities that they have been overcharged for drugs purchased under this section." 42 U.S.C. 256b(d)(3). The ADR Rule thus impermissibly expands the scope of Section 340B.

114. Moreover, Section 340B does not authorize ADR panels to issue decrees awarding "money damages" or "equitable relief" between private parties. The statute allows HHS only to "promulgate regulations to establish and implement an administrative process[,] … including appropriate procedures for the provision of remedies and enforcement of determinations made pursuant to such process through mechanisms and sanctions." *Id.* Deciding that "money damages" and "equitable relief" are warranted, as ADR Panels may do under the ADR Rule, extends beyond

"appropriate procedures for the provision of remedies," which is all that Section 340B permits for the ADR process.

115. The ADR Rule is not entitled to *Chevron* or *Skidmore* deference on this point. *See generally Chevron USA, Inc. v. Nat. Res. Def. Council*, 467 U.S. 837 (1984); *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944).

116. This Court should hold unlawful and set aside the ADR Rule 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 HHS Failed to Observe the Notice-and-Comment Procedure Required by Law in Promulgating the ADR Rule

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

118. 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).

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

120. 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).

121. The ADR Rule is undoubtedly a rule within the meaning of the APA.

122. HHS failed to comply with the APA's notice-and-comment requirement in promulgating the ADR Rule. Although HHS provided notice and comment for an ADR-related rule through the 2016 NPRM, HHS withdrew that notice in 2017. Thus, to promulgate the ADR Rule, HHS was required to—but did not—engage in the notice-and-comment process again.

123. Separately, HHS never provided affected parties with the opportunity to comment on several provisions that appear in the ADR Rule but that were absent from, and do not logically grow from, the original NPRM. Such provisions include the proposal that ADR panels can issue binding judgments for money damages, can award equitable relief, and will render decisions that are precedential.

124. This Court should hold unlawful and set aside the ADR Rule because it violates the APA's notice-and-comment requirement. 5 U.S.C. § 706(2)(D).

Count V—Violation of Administrative Procedure Act
The ADR Rule Is Arbitrary and Capricious

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

126. 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).

127. The ADR Rule is arbitrary and capricious because HHS failed to account for changed legal and factual circumstances in the years after it withdrew the 2016

NPRM. For example, HHS failed to consider new evidence submitted in PhRMA's petition for rulemaking. HHS's failure to consider new information shows that the ADR Rule is not based on meaningful consideration of the surrounding circumstances.

128. The ADR Rule is arbitrary and capricious also because HHS failed to reasonably explain its reasons for choosing the design of the ADR process.

129. The ADR Rule is arbitrary and capricious additionally because HHS failed to address commenters' concerns about HHS's outdated and burdensome guidelines that govern the audit prerequisite for manufacturers to initiate ADR claims.

130. This Court should hold unlawful and set aside the ADR Rule because it is arbitrary and capricious. 5 U.S.C. § 706(2)(A).

Count VI—Violation of Administrative Procedure Act
HHS Failed to Observe the Notice-and-Comment Procedure Required by Law in Promulgating the Advisory Opinion

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

132. 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.

133. 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.

134. 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.

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

136. 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 VII—Violation of Administrative Procedure Act
HHS Failed to Follow Its Good Guidance Rule

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

138. 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).

139. 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).

140. 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.

141. 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.*

142. 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.

143. 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.

144. 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.*

145. 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 78,785, 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.

146. The Advisory Opinion violates the Good Guidance Rule because it "requir[es] a person or entity outside 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.

147. 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).

148. 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.

149. 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 78,786, 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.*

150. 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 VIII—Violation of Administrative Procedure Act
The Advisory Opinion Is Contrary to Law and in Excess of Statutory Authority

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

152. 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).

153. 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.

154. 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.*

155. 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 offers discounted drugs to all covered entities through contract pharmacies. So long as a covered entity provides the claims data requested by Sanofi, Sanofi provides discounted pricing wherever the prescriptions are filled. In addition, beginning on March 1, 2021, any covered entity that does not have its own in-house pharmacy may designate a single contract pharmacy to receive 340B-priced drugs for the covered entity's patients, regardless of whether the covered entity provides the data Sanofi requests through the integrity initiative. Sanofi's 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.

156. The Advisory Opinion is not entitled to *Chevron* or *Skidmore* deference.

157. 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 IX—Violation of Administrative Procedure Act
The Advisory Opinion Is Arbitrary and Capricious

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

159. 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).

160. 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.

161. 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.

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

Count X—Violation of Administrative Procedure Act
The HRSA Letter Is Contrary to Law and in Excess of Statutory Authority

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

164. 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).

165. In its Letter, HRSA enforced against Sanofi the Advisory Opinion's new rule that drug manufacturers must provide 340B-priced drugs to contract pharmacies and may not impose conditions on the delivery of 340B-priced drugs to contract pharmacies.

166. Because the Advisory Opinion's new rule is contrary to law and in excess of statutory authority, *see* Count VIII, HRSA's enforcement of the new rule announced in the Advisory Opinion against Sanofi in the HRSA Letter is also contrary to law and in excess of statutory authority. All of the flaws that render the Advisory Opinion unlawful also render unlawful HRSA's attempt in its May 17 Letter to enforce the obligations that its Advisory Opinion seeks to impose on manufacturers.

167. The HRSA Letter's determination that Sanofi's integrity initiative violates Section 340B 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. Nor does Section 340B prohibit manufacturers from imposing conditions on the delivery of 340B-priced drugs to contract pharmacies—particularly when such conditions are reasonable. *See id.*

168. Even if the HRSA Letter 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 offers discounted drugs to all covered entities through contract pharmacies. So long as a covered entity provides the claims data requested by Sanofi, Sanofi provides discounted pricing wherever the prescriptions are filled. In addition, any covered entity that does not have its own in-house pharmacy may designate a single contract pharmacy to receive 340B-priced drugs for the covered entity's patients, regardless of whether the covered entity provides the data Sanofi requests through the integrity initiative. Sanofi's 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.

169. The HRSA Letter is not entitled to *Chevron* or *Skidmore* deference.

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

Count XI—Violation of Administrative Procedure Act
The HRSA Letter Is Arbitrary and Capricious

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

172. 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).

173. In its Letter, HRSA enforced against Sanofi the Advisory Opinion's new rule that drug manufacturers must provide 340B-priced drugs to contract pharmacies and may not impose conditions on the delivery of 340B-priced drugs to contract pharmacies.

174. Because the Advisory Opinion's new rule is arbitrary and capricious, *see* Count IX, HRSA's enforcement of the new rule announced in the Advisory Opinion against Sanofi in the HRSA Letter is also arbitrary and capricious.

175. In addition, the HRSA Letter's determination that Sanofi's integrity initiative violates Section 340B is arbitrary and capricious because HRSA failed to reasonably explain this determination. The HRSA Letter engages in no substantive interpretation of Section 340B and fails to explain why contract pharmacies should be entitled to 340B-priced drugs when such pharmacies are never mentioned in Section 340B. The HRSA Letter is also inconsistent with the agencies' prior guidance and reasoning, including HHS's reasoning just months ago in the Advisory Opinion that

contract pharmacies are entitled to 340B-priced drugs because they act as agents of covered entities. *See* Advisory Opinion 1, 6.

176. The HRSA Letter's determination that Sanofi may not impose reasonable conditions on the delivery of 340B-priced drugs to contract pharmacies is similarly arbitrary and capricious because HRSA failed to reasonably explain this determination. On this question as well, the HRSA Letter engages in no substantive interpretation of Section 340B to explain why the statute prohibits manufacturers from offering 340B-priced drugs subject to reasonable conditions. The HRSA Letter is also inconsistent with the agencies' prior guidance permitting manufacturers to impose certain conditions on the provision of discounted drugs under Section 340B, such as agreement to the manufacturer's normal business policies and the collection of standard information.

177. The HRSA Letter's determination that Sanofi's integrity initiative has resulted in overcharges is arbitrary and capricious because HRSA failed to reasonably explain this determination. Again, the HRSA Letter offers no explanation of why the statute requires manufacturers to deliver 340B-priced drugs to contract pharmacies when such pharmacies are never mentioned in Section 340B. Nor does the HRSA Letter explain how such an overcharge could have taken place, in light of the prevalent replenishment model through which covered entities place orders for and pay for 340B-priced drugs. Under this model, when a manufacturer declines to

provide a 340B discount (and instead charges standard commercial prices) for drugs shipped to a contract pharmacy, a covered entity is not "overcharged"—indeed, it typically is not charged at all.

178. The HRSA Letter's determination that Sanofi's integrity initiative has resulted in overcharges is arbitrary and capricious also because HRSA failed to support this determination with any evidence and failed to account for evidence contrary to its determination. The HRSA Letter baldly asserts that "Sanofi's actions have resulted in overcharges," Ex. 17, HRSA Letter, at 1, but it identifies no covered entity that Sanofi has purportedly overcharged and no transaction in which Sanofi has allegedly done so.

179. This Court should hold unlawful and set aside the HRSA Letter because it is arbitrary and capricious. *Id.* § 706(2)(A).

Count XII—Violation of Administrative Procedure Act
The HRSA Letter Enforces the Procedurally Unlawful Rule Announced in the Advisory Opinion

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

181. In its Letter, HRSA enforced against Sanofi the Advisory Opinion's new rule that drug manufacturers must provide 340B-priced drugs to contract pharmacies and may not impose conditions on the delivery of 340B-priced drugs to contract pharmacies.

182. Because HHS failed to observe the notice-and-comment procedure required by law in promulgating the new rule announced in the Advisory Opinion, *see* Count VI, HRSA's enforcement of the Advisory Opinion's new rule against Sanofi in the HRSA Letter is unlawful.

183. This Court should hold unlawful and set aside the HRSA Letter because HRSA may not enforce a rule that violates the APA's notice-and-comment requirement. 5 U.S.C. § 706(2)(D).

PRAYER FOR RELIEF

Wherefore, Plaintiff prays for the following relief:

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

2. A declaration, order, and judgment holding that the ADR Rule violates the Appointments Clause of Article II of the Constitution;

3. A declaration, order, and judgment holding that the ADR Rule violates Article III of the Constitution;

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

5. 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;

6. 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;

7. A preliminary and permanent injunction enjoining Defendants from implementing or enforcing the ADR Rule, the Advisory Opinion, and the HRSA Letter in any administrative proceeding or taking any other enforcement action against Sanofi for operating its integrity initiative;

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

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

Dated: May 25, 2021

Respectfully submitted,

s/ Jennifer L. Del Medico

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Counsel for Plaintiff
Sanofi-Aventis U.S. LLC

CERTIFICATE OF SERVICE

I hereby certify that on May 25, 2021, a copy of the foregoing was filed with the Clerk of the Court by using the CM/ECF system. I certify that all participants in this case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

May 25, 2021 *s/ Jennifer L. Del Medico*

EXHIBIT 1

To Whom It May Concern:

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

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

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

Best regards,

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

NEXT STEPS AND FREQUENTLY ASKED QUESTIONS

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

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

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

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

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

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

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

Q: Is Sanofi requesting data for all Sanofi products?

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

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

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

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

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

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

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

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

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

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

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

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

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

EXHIBIT 2

August 13, 2020

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

Dear Secretary Azar,

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

I. Duplicate Discounts Pose a Widespread Compliance Threat

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

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

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

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

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

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

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

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

[4] Memorandum Report: Contract Pharmacy Arrangements in the

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

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

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

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

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

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

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

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

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

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

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

SANOFI

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

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

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

Sincerely,

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

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

EXHIBIT 3

To Whom It May Concern:

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

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

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

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

Best regards,

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

NEXT STEPS AND FREQUENTLY ASKED QUESTIONS

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

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

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

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

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

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

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

Q: Is Sanofi requesting data for all Sanofi products?

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

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

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

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

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

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

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

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

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

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

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

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

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

EXHIBIT 4

To Whom It May Concern:

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

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

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

Sincerely,

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

NEXT STEPS AND FREQUENTLY ASKED QUESTIONS (UPDATED)

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

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

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

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

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

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

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

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

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

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

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

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

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

Q: Is Sanofi requesting data for all Sanofi products?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

EXHIBIT 5

September 29, 2020

Dear xxx,

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

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

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

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

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

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

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

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

Sincerely,

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

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

Enclosure

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

EXHIBIT 6

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

SANOFI'S INITIATIVE WILL NOT HARM PATIENTS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

SANOFI

EXHIBIT 7

UNDERSTANDING SANOFI'S 340B DATA REPORTING REQUIREMENTS

A New Simple Process That Combats Abuse

THE PROBLEM

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

OUR SOLUTION

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

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

THE REQUIRED DATA FIELDS

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

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

SANOFI

EXHIBIT 8

To Whom It May Concern:

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

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

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

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

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

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

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

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

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

Sincerely,

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

EXHIBIT 9

Xavier Becerra
Attorney General

William Tong
Attorney General

Derek Schmidt
Attorney General

Doug Peterson
Attorney General

December 14, 2020

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

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

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

Dear Secretary Azar and Administrator Engels:

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

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

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

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

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

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

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

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[1] 42 U.S.C. § 256b(1).

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

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

As Congress explained, 340B "provides protection from drug price increases to specified federally-funded clinics and public hospitals that provide direct clinical care to large numbers of uninsured Americans."[6] The purpose of the statute is "to enable" 340B entities "to obtain lower prices on the drugs that they provide to their patients," thus "reaching more eligible patients and providing more comprehensive services."[7] To that end, covered entities treating vulnerable patient populations can "stretch scarce federal resources as far as possible, reaching more eligible patients.''[8] Without these lower prices, community health centers may be forced to restrict healthcare services provided to at-risk patients in a time of great need.

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

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

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

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

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

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

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

[8] *Id.*

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

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

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

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

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

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

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[9] *See* 42 U.S.C. § 256b(a).

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

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

[12] 42 U.S.C. § 1396r–8(a)(1), (5).

[13] 42 U.S.C. § 256b(d)(1).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

* *

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

Sincerely,

Attorney General of California

DEREK SCHMIDT
Attorney General of Kansas

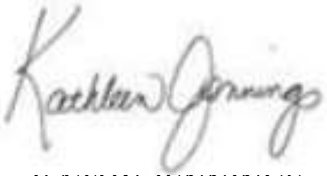
Attorney General of Connecticut

DOUG PETERSON
Attorney General of Nebraska

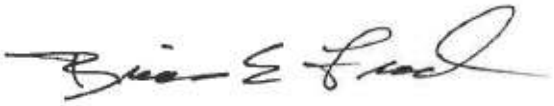
cc: Robert P. Charrow
General Counsel
Office of the Secretary
U.S. Department of Health & Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

PHIL WEISER
Attorney General of Colorado

Attorney General of Maine



KATHY JENNINGS
Attorney General of Delaware



BRIAN FROSH
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KARL A. RACINE
Attorney General of the District of Columbia

MAURA HEALEY
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CLARE E. CONNORS
Attorney General of Hawaii

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Attorney General of Illinois

KEITH ELLISON
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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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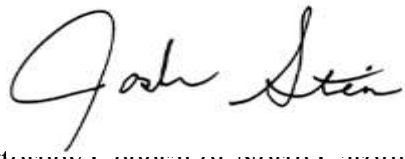
HECTOR BALDERAS
Attorney General of New Mexico

PETER F. NERONHA
Attorney General of Rhode Island

LETITIA A. JAMES
Attorney General of New York

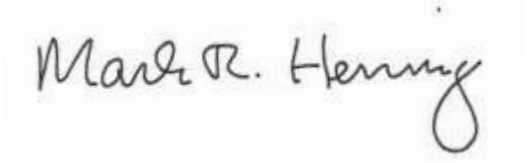
Attorney General of South Dakota



Attorney General of North Carolina

THOMAS J. DONOVAN, JR.
Attorney General of Vermont

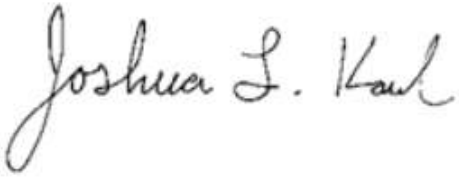
MIKE HUNTER
Attorney General of Oklahoma



Attorney General of Virginia

ELLEN F. ROSENBLUM
Attorney General of Oregon

BOB FERGUSON
Attorney General of Washington



Attorney General of Wisconsin

EXHIBIT 10

August 28, 2020

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

Dear Mr. Pollack,

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

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

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

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

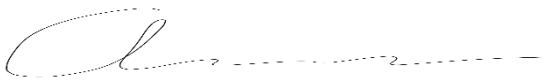
Contrary to your hyperbolic language, our initiative will not burden covered entities. Our data submission portal will be user-friendly and the data elements submitted will be limited and of the type commonly included in insurance reimbursement claims. Moreover, we do not request data on physician-administered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

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

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

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

Sincerely,



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

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[5] 42 U.S.C. § 256b(a)(1).

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

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

EXHIBIT 11

August 26, 2020

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

Dear Secretary Azar:

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

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

Eli Lilly

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

AstraZeneca

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

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

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

Merck

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

Sanofi

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

Novartis

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

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

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

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

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

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

Sincerely,

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

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

EXHIBIT 12

HALL RENDER
KILLIAN HEATH & LYMAN

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

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

October 6, 2020

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

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

RE: Illegal and Discriminatory 340B Limited Distribution Model

Dear Ms. Jehnke:

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

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

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

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

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

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

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

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

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

[3] *Id.*

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

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

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

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

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

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

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

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

[7] 42 U.S.C. § 1396r-8(a)(1).

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

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

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

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

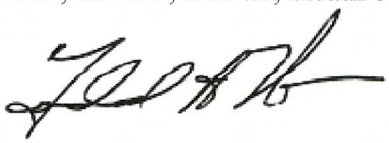
The power and responsibility to enforce the 340B Statute rest with HRSA, by delegation of the Secretary. As recognized by a bipartisan majority of the U.S. House of Representatives, "[t]here are no provisions in the statute that allow manufacturers to set conditions or otherwise impede a provider's ability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

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

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

Very truly yours,

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



Todd A. Nova

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

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

[12] Letter from 243 Members of Congress.

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

Jeannie Jehnke
October 6, 2020
Exhibit A

EXHIBIT A

Covered Entities

Advocate Christ Medical Center
DSH140208

Advocate Lutheran General Hospital
RRC140223-00

Advocate North Side Health Network
DSH140182

Advocate Trinity Hospital
DSH140048

Alamance Regional Medical Center
DSH340070

Aria Health Jefferson Northeast
DSH390115

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

Aurora Health Care Metro, Inc.
DSH520138

Baraga County Memorial Hospital
CAH231307

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

Bon Secours Maryview Medical Center
DSH490017

Bon Secours Richmond Community
Hospital
DSH490094

Centura Health - Avista Adventist Hospital
DSH060103

Children's Hospital of San Antonio
PED453315

Children's Hospital of Wisconsin
PED523300

Children's National Medical Center
PED093300-00

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

CHRISTUS Hospital
RRC450034

CHRISTUS Jasper Memorial Hospital
DSH450573

CHRISTUS Lake Area Hospital
DSH190201

CHRISTUS Mother Frances Hospital –
Tyler
RRC450102

CHRISTUS Santa Rosa Hospital - San
Marcos
DSH450272

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

CHRISTUS Spohn Hospital Alice
DSH450828

CHRISTUS Spohn Hospital Beeville
DSH450082

CHRISTUS Spohn Hospital Corpus Christi
Memorial
DSH450046

Jeannie Jehnke
October 6, 2020
Exhibit A

CHRISTUS Spohn Hospital Kleberg
DSH450163

CHRISTUS St. Frances Cabrini Hospital
DSH190019

CHRISTUS St. Michael
DSH450801

CHRISTUS Health Shreveport - Bossier
DSH190041

Clara Maass Medical Center
DSH310009

Clermont Mercy Hospital
DSH360236

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

Cookeville Regional Medical Center
RRC440059-00

Cottage Grove Community Hospital
CAH381301-00

D.W. McMillan Memorial Hospital
DSH010099

Defiance Regional Hospital
CAH361328-00

Dickenson Community Hospital
CAH491303-00

Dickinson County Healthcare System
SCH230055-00

Eaton Rapids Medical Center
CAH231324-00

Ephraim McDowell Regional Medical Center, Inc.
DSH180048

Fisher-Titus Medical Center
RRC360065

Fort Logan Hospital
CAH181315-00

Fostoria Community Hospital
CAH361318-00

Franklin Woods Community Hospital
DSH440184

Good Samaritan Hospital Corvallis
RRC380014-00

Good Samaritan Regional Health Center
RRC140046-00

Good Shepherd Medical Center - Marshall
DSH450032

Greeneville Community Hospital
DSH440050

Gundersen Lutheran Medical Center, Inc.
DSH520087

Hancock County Hospital
CAH441313

Harbor Beach Community Hospital, Inc.
CAH231313-00

Helen Newberry Joy Hospital
CAH231304-00

Herrick Memorial Hospital
CAH231334-00

Holston Valley Medical Center
RRC440017

Holy Rosary Healthcare
CAH271347

HSHS Holy Family Hospital, Inc.
DSH140137

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Exhibit A

Indian Path Community Hospital
DSH440176

James B. Haggin Memorial Hospital
CAH181302-00

Jersey City Medical Center, Inc.
DSH310074

Johnson City Medical Center
DSH440063

Johnson County Community Hospital
CAH441304-00

Kennedy University Hospital - New Jersey
DSH310086

Lake View Memorial Hospital Inc.
CAH241308-00

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

Lonesome Pine Hospital
DSH490114

Lutheran Medical Center
DSH060009

Longmont United Hospital
DSH060003

McKenzie Memorial Hospital
CAH231314-00

Memorial Hospital of Boscobel
CAH521344-00

Mercy Allen Hospital
CAH361306-00

Mercy Health - St. Charles Hospital
DSH360081

Mercy Health - St. Vincent Medical Center
DSH360112

Mercy Health Lourdes Hospital LLC
RRC180102-00

Mercy Health-Love County
CAH371306-00

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

Mercy Hospital - St. Louis
DSH260020

Mercy Hospital ADA Inc.
DSH370020

Mercy Hospital Ardmore Inc.
SCH370047-00

Mercy Hospital Aurora
CAH261316-00

Mercy Hospital Berryville
CAH041329-00

Mercy Hospital Booneville
CAH041318-00

Mercy Hospital Carthage
CAH261338-00

Mercy Hospital Cassville
CAH261317-00

Mercy Hospital Columbus
CAH171308-00

Mercy Hospital Fort Smith
DSH040062

Mercy Hospital Healdton Inc.
CAH371310-00

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Exhibit A

Mercy Hospital Joplin
DSH260001

Mercy Hospital Kingfisher Inc.
CAH371313-00

Mercy Hospital Lebanon
DSH260059

Mercy Hospital Lincoln
CAH261319-00

Mercy Hospital Logan County
CAH371317-00

Mercy Hospital OKC
RRC370013-00

Mercy Hospital Springfield
DSH260065

Mercy Hospital Tishomingo Inc.
CAH371304-00

Mercy Hospital Watonga Inc.
CAH371302-00

Mercy Memorial Hospital
CAH361312-00

Mercy Regional Medical Center
DSH060013

Mercy St. Francis Hospital
CAH261335-00

Mercy Willard Hospital
CAH361310-00

MidMichigan Medical Center
SCH230222-00

MidMichigan Medical Center - Alpena
DSH230036

MidMichigan Medical Center - Gladwin
CAH231325-00

MidMichigan Medical Center - Gratiot
DSH230030

Molokai General Hospital
CAH121303-00

Monmouth Medical Center, Inc.
DSH310075

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

Monument Health Custer Hospital
CAH431323-00

Monument Health Lead - Deadwood Hospital
CAH431320-00

Monument Health Rapid City Hospital
DSH430077

Monument Health Spearfish Hospital
SCH430048

Monument Health Sturgis Hospital
CAH431321-00

Mother Frances Hospital – Jacksonville
CAH451319

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

Mother Frances Hospital – Winnsboro
CAH451381

Moundview Memorial Hospital and Clinics, Inc.
CAH521309-00

New Hanover Regional Medical Center
DSH340141

Jeannie Jehnke
October 6, 2020
Exhibit A

Newark Beth Israel Medical Center, Inc.
DSH310002

Niagara Falls Memorial Medical Center
DSH330065

North Hawaii Community Hospital
DSH120028

Northeast Alabama Regional Medical Center
DSH010078

Northwest Ohio Hemophilia Treatment Center
HM11574

Norton Community Hospital
DSH490001

Palmer Lutheran Health Center
CAH161316-00

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

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

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

PeaceHealth Southwest Medical Center
DSH500050

PeaceHealth St. John Medical Center
DSH500041

Penn State –Milton S. Hershey Medical Center
DSH390256

Penrose/St. Francis Healthcare
DSH060031

ProMedica Memorial Hospital
DSH360156

Platte Valley Medical Center
DSH060004

Raphael Health Center, Inc.
CH0514720

Rappahannock General Hospital
CAH491308-00

Regional One Health
DSH440152

Ripon Medical Center, Inc.
CAH521321-00

Robert Wood Johnson University Hospital, Inc.
DSH310038

Russell County Hospital
DSH490002

St. Mary's Hospital and Medical Center
HV00593

Sanford Bagley Medical Center
CAH241328-00

Sanford Bemidji Medical Center
DSH240100

Sanford Bismarck
DSH350015

Sanford Canton - Inwood Medical Center
CAH431333-00

Sanford Clinic Brookings
FP572012

Jeannie Jehnke
October 6, 2020
Exhibit A

Sanford Clinic Watertown
FP572011

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

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

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

Sanford Health Physicians Partners
FP571057

Sanford Health Westbrook Medical Center
CAH241302-00

Sanford Hillsboro
CAH351329-00

Sanford Hospital Webster
CAH431311-00

Sanford Jackson Medical Center
CAH241315-00

Sanford Medical Center Fargo
DSH350011 + HM10193

Sanford Medical Center Luverne
CAH241371-00

Sanford Medical Center Mayville
CAH351309-00

Sanford Medical Center Wheaton
CAH241304-00

Sanford Sheldon Medical Center
CAH161381-00

Sanford Thief River Falls
CAH241381-00

Sanford Tracy Medical Center
CAH241303-00

Sanford USB Medical Center Sioux Falls
HM57117

Sanford USD Medical Center
DSH430027

Sanford Vermillion Medical Center
CAH431336-00

Sanford Worthington Medical Center
DSH240022

Schneck Medical Center
DSH150065

Sedgwick County Hospital & Nursing Home
CAH061310-00

Shawnee Health Service and Development Corporation
CH050040

St. James Healthcare
SCH270017

Saint Joseph Hospital
DSH060028

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

South Suburban Hospital
RRC140250-00

Spectrum Health Big Rapids Hospital
SCH230093-00

Spectrum Health Gerber
CAH231338-00

Spectrum Health Hospitals
HM935

Jeannie Jehnke
October 6, 2020
Exhibit A

Spectrum Health Hospitals
DSH230038

Spectrum Health Ludington
SCH230110-00

Spectrum Health Pennock Hospital
CAH231339-00

Spectrum Health Reed City Hospital
CAH231323-00

Spectrum Health United Hospital
DSH230035

Springfield Regional Medical Center
DSH360086

SSM Cardinal Glennon Children's Medical Center
HM13100

SSM DePaul Health Center
DSH260104

SSM Health Saint Louis University Hospital
DSH260105

SSM St. Anthony Hospital
DSH370037

SSM St. Joseph Health Center
DSH260005

SSM St. Mary's Health Center
DSH260091

St. Anthony North Health Campus
DSH060104

St. Anthony Shawnee Hospital
DSH370149

St. Anthony Summit Medical Center
DSH060118

St. Catherine Hospital
SCH170023-00

St. Elizabeth Boardman Health Center
DSH360276

St. Elizabeth Health Center
RRC360064-00

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

St. Joseph Health Center
DSH360161

St. Joseph Medical Center
RRC390096

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

St. Luke's Hospital of Duluth
DSH240047

St. Mary-Corwin Medical Center
DSH060012

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

St. Ritas Medical Center LLC
DSH360066

St. Thomas More Hospital
CAH061344-00

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

St. Vincent Hospital
DSH320002

St. Vincent Healthcare
DSH270049

Jeannie Jehnke
October 6, 2020
Exhibit A

The Moses H. Cone Memorial Hospital
Operating Corporation
DSH340091

The Queen's Medical Center
DSH120001

The Toledo Hospital
DSH360068

Thomas Jefferson University Hospitals
DSH390174

Tri-County Memorial Hospital, Inc.
CAH521316-00

Twin Lakes Regional Medical Center
DSH180070

United General Medical Center
CAH501329-00

University of Connecticut Health Center
RWI06030

University of Connecticut Hemophilia
Treatment Center
HM06030

University of Toledo Medical Center
DSH360048

Waupun Memorial Hospital
CAH521327-00

Wayne County Hospital, Inc.
CAH181321-00

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

EXHIBIT 13

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

January 7, 2021

VIA EMAIL

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

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

Dear Mr. Lee and Mr. Siedel:

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

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

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

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

We look forward to your response.

Sincerely,

William B. Schultz

William B. Schultz
Margaret M. Dotzel

EXHIBIT 14

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

January 19, 2021

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

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

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

To Whom It May Concern:

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

Importance of 340B Access and Contract Pharmacies to the Tribe

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

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

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

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

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

Illegal Restriction of 340B Access

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

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

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

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

Sanofi's Reporting Platform Requirements are Impermissible

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

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

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

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[4] Advisory Op. 20-06 at 3–4.

[5] *Id.* at 8.

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

[7] *Id.* at 3.

[8] *Id.* at 2.

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

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

Repayment of Overcharges

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

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

Conclusion

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

Sincerely,

W. Ron Allen, Chairman/CEO

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

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

EXHIBIT 15

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

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS
7501 Wisconsin Ave Suite 1100W
Bethesda, MD 20814,

Petitioner,

v.

ELI LILLY AND COMPANY
Lilly Corporate Center
893 Delaware Street
Indianapolis, IN 46225,

and

SANOFI-AVENTIS U.S. LLC
55 Corporate Drive
Bridgewater, NJ 08807

and

ASTRAZENECA PLC
AstraZeneca
1800 Concord Pike
Wilmington, DE 19803,

Respondents.

Petition No: 210112-2

PETITION FOR DECLARATORY AND INJUNCTIVE RELIEF

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

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

NATURE OF ACTION

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

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

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

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

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

PARTIES

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

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

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

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

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

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

JURISDICTION

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

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

ALLEGATIONS

I. The 340B Program

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

II. FQHC Participation in the 340B Program

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

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

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

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

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

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

III. The Drug Manufacturers' Unlawful Overcharging

A. Lilly

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

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

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

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

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

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

B. Sanofi

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

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

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

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

C. AstraZeneca

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

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

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

IV. Harm to the FQHC Covered Entities

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

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

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

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

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

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

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

COUNT ONE: LILLY

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

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

COUNT TWO: SANOFI

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

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

it "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price."

COUNT THREE: ASTRAZENECA

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

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

REQUEST FOR RELIEF

Petitioner respectfully requests equitable relief as follows:

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

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

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

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

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

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

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

Dated: January 13, 2021

Respectfully submitted,

/s/ *Matthew S. Freedus*
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EXHIBIT 16

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

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

PETITIONER'S MOTION FOR PRELIMINARY INJUNCTION

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

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MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

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

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

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

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

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

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

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

II. BACKGROUND

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

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

Although FQHC covered entities have flexibility in determining how best to meet the needs of their patient population and communities, any operational savings or revenue an FQHC generates—through 340B Program participation or otherwise—must be used to further the health center's project. *See* 42 U.S.C. §§ 254b(e)(5)(A) (defining non-grant funds as "state, local, and other operational funding provided to the center" and "fees, premiums, and third-party reimbursements . . . the center may . . . receive for its operations"), (D) (mandating that non-

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

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

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

III. ARGUMENT

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

B. The Joint Claimants Will Continue to Suffer Irreparable Harm Absent Preliminary Injunctive Relief

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

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

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

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

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

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

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

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

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

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

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

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

D. The Requested Relief is in the Public Interest

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

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

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

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

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

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

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

IV. CONCLUSION

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

Dated: January 14, 2021

Respectfully submitted,

/s/ *Matthew S. Freedus*
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EXHIBIT 17

DEPARTMENT OF HEALTH & HUMAN SERVICES
Health Resources and Services Administration
Rockville, MD 20857

May 17, 2021

Mr. Gerald Gleeson
VP & Head, Sanofi US Market Access Shared Services
Sanofi
55 Corporate Drive
Bridgewater, NJ 08807

Dear Mr. Gleeson:

The Health Resources and Services Administration (HRSA) has completed its review of Sanofi's policy that places restrictions on 340B pricing to covered entities that dispense medication through pharmacies, unless the covered entities provide claims data to a third-party platform. After review of this policy and an analysis of the complaints HRSA has received from covered entities, HRSA has determined that Sanofi's actions have resulted in overcharges and are in direct violation of the 340B statute.

Section 340B(a)(1) of the Public Health Service (PHS) Act requires that manufacturers "shall…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." This requirement is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs. Nothing in the 340B statute grants a manufacturer the right to place conditions on its fulfillment of its statutory obligation to offer 340B pricing on covered outpatient drugs purchased by covered entities. Furthermore, the 340B statute does not permit manufacturers to impose conditions on covered entities' access to 340B pricing, including the production of claims data. Section 340B(a)(1) of the PHS Act also requires manufacturers that have signed a Pharmaceutical Pricing Agreement (PPA) and PPA addendum to comply with these requirements. Sanofi is bound by the terms of the PPA and must ensure that the 340B ceiling price is available to all covered entities.

Also consistent with section 340B(a)(1) of the PHS Act, manufacturers are expected to provide the same opportunity for 340B covered entities and non-340B purchasers to purchase covered outpatient drugs. This extends to the manner in which 340B drugs are made available to covered entities (e.g., access to 340B ceiling prices through wholesalers that make products available at non-340B ceiling prices).[1] The 340B Program Ceiling Price and Civil Monetary Penalties Final Rule (CMP final rule)[2] further specifies that a manufacturer's failure to provide 340B ceiling prices through the manufacturer's distribution agreements with wholesalers may violate a manufacturer's obligation under the 340B statute. HRSA has made plain, consistently since the issuance of its 1996 contract pharmacy guidance, that the 340B statute requires manufacturers to honor such purchases regardless of the dispensing mechanism.

[1] 82 Fed. Reg. 1210, 1230 (Jan. 5, 2017); 42 C.F.R. §10.11(b)(2)
[2] 82 Fed. Reg. 1210, 1230 (Jan. 5, 2017)

Sanofi purports that the rationale for its restrictive action is to prevent diversion and duplicate discounts. The 340B statute provides a mechanism by which a manufacturer can address these concerns. Specifically, the manufacturer must (1) conduct an audit and (2) submit a claim through the Administrative Dispute Resolution process as described in section 340B(d)(3)(A) of the PHS Act. The 340B statute does not permit a manufacturer to impose industry-wide, universal restrictions.

For the reasons set forth above, Sanofi must immediately begin offering its covered outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements, regardless of whether they purchase through an in-house pharmacy. Sanofi must comply with its 340B statutory obligations and the 340B Program's CMP final rule and credit or refund all covered entities for overcharges that have resulted from Sanofi's policy. Sanofi must work with all of its distribution/wholesale partners to ensure all impacted covered entities are contacted and efforts are made to pursue mutually agreed upon refund arrangements.

Continued failure to provide the 340B price to covered entities utilizing contract pharmacies, and the resultant charges to covered entities of more than the 340B ceiling price, may result in CMPs as described in the CMP final rule. The CMP final rule states that any manufacturer with a PPA that knowingly and intentionally charges a covered entity more than the ceiling price for a covered outpatient drug may be subject to a CMP not to exceed $5,000 for each instance of overcharging.[3] Assessed CMPs would be in addition to repayment for an instance of overcharging as required by section 340B(d)(1)(B)(ii) of the PHS Act. The Department of Health and Human Services will determine whether CMPs are warranted based on Sanofi's willingness to comply with its obligations under section 340B(a)(1) of the PHS Act.

HRSA requests that Sanofi provide an update on its plan to restart selling, without restriction, 340B covered outpatient drugs at the 340B price to covered entities with contract pharmacy arrangements by **June 1, 2021**, to 340Bpricing@hrsa.gov.

Thank you for your commitment to the 340B Program.

Sincerely,

Diana Espinosa
Acting Administrator

[3] Note, the Department of Health and Human Services publishes inflation-adjusted increases for various CMPs annually. The 2020 inflation adjusted penalty for 340B overcharging violations is $5,883. 85 Fed. Reg. 2,869, 2,873 (Jan. 17, 2020).

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,

NORRIS COCHRAN, in his official capacity as Acting Secretary of Health and Human Services,

DANIEL J. BARRY, in his official capacity as Acting General Counsel of the United States Department of Health and Human Services,

HEALTH RESOURCES AND SERVICES ADMINISTRATION,

DIANA ~~ESPOSITO~~ESPINOSA, in her official capacity as
Acting Administrator of the Health Resources and Services Administration,

Defendants.[‡]

~~Civil Action No. 3:21-cv-634~~
Civil Action No. 3:21-cv-634

~~SECOND~~ AMENDED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

[‡] ~~The original complaint named these officials' predecessors as Defendants. Where, as here, "a public officer who is a party in an official capacity … ceases to hold office while the action is pending," "[t]he officer's successor is automatically substituted as a party. Later proceedings should be in the substituted party's name . . . ." Fed. R. Civ. P. 25(d).~~

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 two new rules governing the 340B drug-discounting program (the "340B Program") issued by the U.S. Department of Health and Human Services ("HHS") and final agency action enforcing one of those rules against Sanofi. These rules were issued without statutory authority, without following the requirements for issuing rules having the force and effect of law, and without complying with Articles II and III of the United States Constitution. The legality of the agency's enforcement action depends upon the legality of the agency's new rule imposing extra-statutory obligations on pharmaceutical manufacturers.

2. Section 340B of the Public Health Service Act, 42 U.S.C. § 256b, requires pharmaceutical manufacturers to discount their drugs (often quite significantly) for fifteen types of "covered entities"—governmental and non-profit entities that mostly provide care for underserved areas or populations—that are enumerated in the statute. 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 the discounted drugs and dispense them 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 far 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. After Sanofi's integrity initiative took effect, HHS issued two new rules that together prohibit the initiative and expose Sanofi to crippling financial penalties. HHS first created an unconstitutional process for adjudicating covered entities' claims against drug manufacturers and then preordained the outcome of those claims against Sanofi. Covered entities have already sought to leverage this regulatory one-two punch by asking an unconstitutional administrative body within HHS to grant a preliminary injunction quashing Sanofi's integrity initiative. ~~Sanofi now amends its complaint to challenge this process and seeks preliminary injunctive relief to avoid the irreparable harm from having to defend itself before an unconstitutional administrative body in which the judgment has already been decided, the opinion already written, and the penalties could be astronomical.~~Moreover, an agency within HHS, Defendant Health Resources and Services Administration ("HRSA"), took action to enforce one of these rules against Sanofi in a May 17, 2021 Letter (the "HRSA Letter") determining that Sanofi's integrity initiative violates Section 340B.

7. In its first new rule (the "ADR Rule"), HHS adopted Administrative Dispute Resolution ("ADR") procedures under which covered entities can, among other things, submit claims alleging that drug manufacturers have overcharged for drugs in the 340B Program or limited covered entities' ability to purchase these drugs. The ADR Rule empowers ADR Panels—which will consist of three HHS employees—to wield full judicial authority with respect to any claims asserted in the

ADR process. For example, the ADR process will operate under the Federal Rules of Civil Procedure and Evidence, an ADR Panel can award money damages and equitable relief, and all ADR decisions will be binding and precedential.

8. This new administrative process violates Article II and Article III of the Constitution. The ADR Rule violates the Appointments Clause in Article II of the Constitution because the members of the ADR Panels are principal officers under the Appointments Clause—which means they must be appointed by the President and confirmed by the Senate. But the ADR Rule calls for neither, instead installing in this role agency employees who are not Senate-confirmed and, worse, are protected by for-cause removal restrictions and thus not even politically accountable. In addition, the ADR Rule violates Article III of the Constitution by granting unaccountable bureaucrats the power to issue final judgments for money damages and equitable relief in order to resolve disputes between private parties over private rights—namely, the price of a drug. The Constitution reserves this authority to Article III courts.

9. The ADR Rule also violates the APA in several respects, especially in light of these constitutional concerns that HHS ignored. The rule improperly allows ADR Panels to adjudicate claims and award remedies that fall outside HHS's statutory authority. Section 340B authorizes HHS to adjudicate only overcharge claims, *i.e.*, claims that a manufacturer has charged a covered entity too much for a drug. Under Section 340B, HHS does *not* have the authority to decide whether manufacturers have

improperly limited a covered entity's ability to purchase 340B-priced drugs. Nor does HHS have statutory authority to usurp the judicial function by awarding money damages and equitable relief. HHS also failed to comply with the APA's notice-and-comment requirement when promulgating the ADR Rule. Although HHS gave notice of a rule regarding ADR proceedings at the end of the Obama Administration in 2016, HHS *withdrew* that notice in early 2017—but then issued the ADR Rule without warning during the last month of the Trump Administration, and without going through the notice-and-comment process again. Finally, the ADR Rule is also arbitrary and capricious because HHS failed to reasonably explain key aspects of the rule.

10. The second new rule issued by HHS is entitled Advisory Opinion 20-06 (the "Advisory Opinion"). In the Advisory Opinion, HHS has preordained the outcome of any ADR claim against Sanofi by imposing 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 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 both to require drug manufacturers to provide 340B discounts to for-profit contract pharmacies and also 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. Covered entities have already filed ADR claims alleging that Sanofi's integrity initiative violates the Advisory Opinion and requesting equitable relief—including a preliminary injunction—to stop the integrity initiative. (Notably, however, ~~no covered entity~~none of the plaintiffs in those actions has ever alleged that Sanofi's integrity initiative is unreasonable.)

11. 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. Further, HHS's limited rulemaking authority under Section 340B does not allow for a rule requiring drug manufacturers to provide 340B-priced drugs to contract pharmacies. The Advisory

Opinion thus exceeds HHS's statutory authority, and Sanofi's integrity initiative is fully consistent with Section 340B.

12. HHS also failed to comply with the APA's notice-and-comment requirement before issuing the Advisory Opinion. That requirement applies because 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. For similar reasons, HHS failed to comply with its own procedural regulations when issuing the Advisory Opinion. HHS's failure to comply with these requirements means the Advisory Opinion is procedurally unlawful and must be vacated.

13. In the midst of briefing the merits of Sanofi's claims in cross-motions for summary judgment, on May 17, 2021, Defendant HRSA sent Sanofi its letter enforcing the new rule announced in the Advisory Opinion against Sanofi while that new rule's validity is simultaneously being litigated in this action. *See* Ex. 17.

14. The HRSA Letter notifies Sanofi that HRSA has "completed its review of Sanofi's" integrity initiative—despite Sanofi having never been given the opportunity to meet with HRSA to explain why its initiative complies with Section 340B. *Id.* at 1. The HRSA Letter then informs Sanofi that, after "an analysis of the complaints HRSA has received from covered entities, HRSA has determined that Sanofi's actions have resulted in overcharges and are in direct violation of the 340B

statute." *Id.* The HRSA Letter also concludes that Section 340B prohibits Sanofi's request for "claims data" as part of its integrity initiative. *Id.*

15. The HRSA Letter follows these conclusions with a clear and explicit threat of further enforcement: "Continued failure to provide the 340B price to covered entities utilizing contract pharmacies, and the resultant charges to covered entities of more than the 340B ceiling price, may result in [civil monetary penalties]." *Id.* at 2. The letter explains that "[t]he Department of Health and Human Services will determine whether [civil monetary penalties] are warranted based on Sanofi's willingness to comply with its obligations" as HRSA interprets them, and demands a response by June 1, 2021. *Id.*

16. HRSA's Letter enforcing against Sanofi the new rule announced in the Advisory Opinion is substantively and procedurally unlawful for the same reasons that the Advisory Opinion is unlawful. In addition, HRSA's Letter fails to offer any reasonable explanation for HRSA's conclusions, which are inconsistent with the agency's past guidance and the reasoning in the Advisory Opinion and unsupported by evidence.

~~13~~17. For these reasons, the Court should (a) hold unlawful and set aside the ADR Rule ~~and~~, the Advisory Opinion, and the HRSA Letter, (b) declare that the ADR Rule violates Article II and Article III of the Constitution and also exceeds HHS's statutory authority, (c) hold 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, (d) confirm that Sanofi's integrity initiative comports with the statute, and (e) enjoin HHS from implementing or enforcing the ADR Rule ~~and~~, the Advisory Opinion, and the HRSA Letter in any administrative proceeding or from taking any other enforcement action against Sanofi for operating its integrity initiative.

JURISDICTION AND VENUE

~~14~~18. This Court has jurisdiction over this case under 28 U.S.C. § 1331 because Sanofi's claims arise under the APA and the U.S. Constitution. *See* 5 U.S.C. § 702.

~~15~~19. This Court has the authority to grant declaratory relief and to vacate and set aside the ADR Rule and 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.

~~16~~20. Venue is proper in this district under 28 U.S.C. § 1391(e)(1)(C) and 5 U.S.C. § 703.

PARTIES

~~17~~21. 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 at 55 Corporate Drive, Bridgewater, New Jersey.

~~18~~22. Defendant HHS is an agency of the United States government.

~~19~~23. Defendant Norris Cochran is the Acting Secretary of HHS (the "Secretary") and is sued in his official capacity.

~~20~~24. Defendant Daniel J. Barry is Acting General Counsel of HHS and is sued in his official capacity.

~~21~~25. Defendant Health Resources and Services Administration ("HRSA") is an HHS agency.

~~22~~26. Defendant Diana ~~Esposito~~Espinosa is Acting Administrator of HRSA and is sued in her official capacity.

STATEMENT OF FACTS

I. The 340B Program

~~23~~27. 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.

~~24~~28. 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).

~~25~~29. 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.*

~~26~~30. 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.

~~27~~31. 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.

~~28~~32. 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.

~~29~~33. 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).

~~30~~34. 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).

~~31~~35. 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).

II. Covered Entities' Use of Contract Pharmacies

~~32~~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.

~~33~~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.

~~34~~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.

~~35~~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.

~~36~~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://pharma.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).

~~37~~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.

~~38~~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.

~~39~~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 (last updated Jan. 15, 2021), 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.

~~40~~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 the Centers for Medicare and Medicaid Services ("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

~~41~~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 (Aug. 13, 2020); Ex. 3, Letter from G. Gleeson (August 2020); Ex. 4, Letter from G. Gleeson (September 2020); Ex. 5, Letter from A. Gluck and G. Gleeson (September 29, 2020).

~~42~~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. 6, Sanofi's New Initiative Combats Waste and Abuse in the 340B Program; Ex. 7, 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.

~~43~~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.

~~44~~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.

~~45~~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 exempted from this integrity initiative many types of covered entities that, based on Sanofi's experience, present a reduced risk of duplicate discounting.

~~46~~50. In addition, beginning on March 1, 2021, any covered entity that does not have its own in-house pharmacy may designate a single contract pharmacy to receive 340B-priced drugs for the covered entity's patients, regardless of whether the covered entity provides the data Sanofi requests through the integrity initiative. *See* Ex. 8, Program Announcement.

IV. The ADR Rule

~~47~~51. 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. 9, 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. 10, Letter from A. Gluck to

American Hospital Association (Aug. 28, 2020); Ex. 11, Letter from American Hospital Association, et al. to Secretary Azar (Aug. 26, 2020); Ex. 12, Letter from T. Nova to J. Jehnke (Oct. 6, 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~~.)

~~48~~52. These lawsuits were filed against the government, and not against manufacturers directly, because Section 340B does not have a private right of action. *See Astra*, 563 U.S. at 113-14. Under Section 340B, a covered entity that wishes to seek relief directly from a manufacturer must instead file a claim in an administrative process. Specifically, in 2010, the Affordable Care Act amended Section 340B to direct the Secretary to promulgate regulations establishing such a 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* 42 U.S.C. § 256b(d)(3)(A).

~~49~~53. The Affordable Care Act required these ADR regulations to be promulgated within 180 days of enactment. But HHS missed that deadline—by years.

~~50~~54. Shortly after passage of the Affordable Care Act, HRSA did issue an advanced notice of proposed rulemaking regarding the ADR process. 75 Fed. Reg.

57,233 (Sept. 20, 2010). But HRSA waited until 2016 to issue a notice of proposed rulemaking ("NPRM") for such a rule, in order to formally start the notice-and-comment process required under the APA. 81 Fed. Reg. 53,381 (Aug. 12, 2016).

~~51~~55. The 2016 NPRM drew many comments from manufacturers, including Sanofi. But instead of responding to these comments, HRSA abandoned the proposed rule on August 1, 2017. *See* OMB/OIRA, Unified Agenda, Summary of Regulatory Action for RIN-0906-AA90 (Spring 2017), *available at* https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201704&RIN=0906-AA90. After that, HRSA took no public action regarding an ADR rule for more than four years.

~~52~~56. In 2020, however, covered entities began clamoring for the enactment of an ADR process—as Congress had directed over a decade earlier. In late 2020, multiple lawsuits—including the *Ryan White Clinics* suit noted above—were filed seeking mandamus relief directing the government to promulgate the statutorily required ADR regulations.

~~53~~57. Manufacturers became concerned that HHS might attempt to revive and finalize the abandoned 2016 proposed rule without addressing the problems with that rule raised during the 2016 comment period, and also without considering how circumstances had subsequently changed. On November 24, 2020, the trade association Pharmaceutical Research and Manufacturers of America ("PhRMA") filed

a petition for rulemaking that raised such concerns. PhRMA's petition asked HHS to consider new evidence before finalizing any ADR rule.

~~54~~58. But HHS did not initiate another round of notice and comment to update the record. Instead, in the face of lawsuits demanding that HHS issue the ADR Rule, and in the closing weeks of the Trump Administration, the Secretary—relying on the 2016 NPRM—promulgated the ADR Rule on December 14, 2020. *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"). The ADR Rule took effect on January 13, 2021.

~~55~~59. The ADR Rule provides that the Secretary will create an ADR Board "consisting of at least six members appointed by the Secretary with equal numbers" from HRSA, CMS, and the HHS Office of the General Counsel. *Id.* at 80,634. From this Board, HRSA will select three-member panels with "relevant expertise and experience" to adjudicate each dispute. *Id.* The rule provides that individual panel members can be removed from a panel, but only "for cause." *Id.* The rule lists "a conflict of interest" as the only grounds for a panelist's removal. *Id.*

~~56~~60. Every member of the ADR Board—and, thus, every ADR Panel member—receives legal advice from the HHS Office of the General Counsel, the author of the Advisory Opinion. CMS, like HRSA, is an HHS agency. And 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).

~~57~~61. 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).

~~58~~62. The ADR Rule expressly grants panel members "significant discretion" in their adjudicative functions. *Id.* at 80,635. A panel may "determine, in its own discretion, the most efficient and practical form of the ADR proceeding." *Id.* at 80,645. It may require "submission of additional information," and it has discretion to choose from an array of formidable sanctions if it concludes that its instructions were inadequately complied with. *See id.*; 42 C.F.R § 10.22(c) (permitting panel to "[p]reclud[e] a party from presenting or contesting a particular issue" or even enter judgment as a sanction). It has "discretion in admitting evidence and testimony" during the proceeding, for which the Federal Rules of Civil Procedure and Federal Rules of Evidence presumptively apply. *Id.* at 80,641; *see* 42 C.F.R. § 10.23. The panel

even has the discretion to issue whatever "additional instructions as may be necessary or desirable governing the conduct of ADR proceedings." 42 C.F.R. § 10.21(f). Finally, its decision "will" be based on its own "review and evaluation of the evidence." *Id.* § 10.24(b).

~~59~~63. In sum, the ADR Rule empowers ADR panels to function like federal courts. It states that "[e]ach 340B ADR Panel will necessarily have jurisdiction to resolve all issues underlying any claim or defense, including, by way of example, those having to do with covered entity eligibility, patient eligibility, or manufacturer restrictions on 340B sales that the 340B ADR Panel deems relevant for resolving an overcharge, diversion, or duplicate discount claim." 85 Fed. Reg. at 80,636. The ADR panel can even award "money damages" as well as "equitable relief." *Id.* at 80,633.

~~60~~64. The ADR Rule provides that ADR panel decisions are both "binding" on the parties and "precedential" for purposes of future adjudications. 42 C.F.R. § 10.20. Specifically, the ADR panel's decision "constitutes a final agency decision that is precedential and binding on the parties involved unless invalidated by an order of a court of competent jurisdiction." *Id.* § 10.24(d); *see also* 42 U.S.C. § 256b(d)(3)(C) ("The administrative resolution of a claim or claims under the regulations promulgated under subparagraph (A) shall be a final agency decision and shall be binding upon the parties involved, unless invalidated by an order of a court of

competent jurisdiction."). The ADR Rule does not provide for any internal review of ADR panel judgments by a superior Executive Branch official.

~~61~~65. Notably, in the ADR Rule, HHS did not respond to the concerns raised in the petition for rulemaking filed by PhRMA in November 2020. Nor did HHS acknowledge the explicit constraints placed on the ADR process by Section 340B itself, which authorized such a process only "for reviewing and finally resolving claims by covered entities that they have been charged prices for covered outpatient drugs in excess of the ceiling price … and claims by manufacturers that violations of [statutory prohibitions on conduct like diversion] have occurred." 42 U.S.C. § 256b(d)(3)(B)(i).

V. The Advisory Opinion

~~62~~66. On December 30, 2020, less than three weeks after publishing the ADR Rule, HHS's Office of General Counsel issued the Advisory Opinion—which effectively dooms Sanofi's integrity initiative within the ADR process, before even giving Sanofi an opportunity to defend its program.

~~63~~67. The Advisory Opinion concludes (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.

~~64~~68. 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 the preamble to the 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.* at 5 & n.5.

~~65~~69. 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.

~~66~~70. 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. 13, Letter From W. Schultz to C. Lee (Jan. 7, 2021); *see also* Ex. 14, Letter from Jamestown S'Klallam Tribe to A. Gluck (January 19, 2021). These covered entities contend that the Advisory Opinion entitles them to reimbursements and justifies imposition of civil monetary penalties for Sanofi's integrity initiative. *See* Ex. 13 at 2; Ex. 14 at 2-3.

~~67~~71. One association representing hundreds of covered entities has already filed an ADR claim against Sanofi alleging that the integrity initiative violates the Advisory Opinion and requesting equitable relief, including a preliminary injunction. *See* Ex. 15, Petition for Declaratory and Injunctive Relief (Jan. 13, 2021); Ex. 16, Motion for Preliminary Injunction (Jan. 14, 2021). Given their repeated threats against Sanofi, many more covered entities will almost certainly follow suit.

~~68~~72. As noted, an 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. Given this composition, any ADR Panel will treat the Advisory Opinion as binding in an ADR proceeding, almost certainly find that Sanofi's integrity initiative violates Section 340B as interpreted by HHS, and potentially impose crippling sanctions.

VI. The HRSA Letter

73. On May 17, 2021, after the parties had filed their opening briefs in support of cross-motions for summary judgment on Sanofi's claims in this lawsuit, Defendant HRSA surprisingly sent Sanofi a letter demanding that Sanofi agree to HRSA's litigating position in this case by June 1, 2021, on threat of civil monetary penalties (or worse). *See* Ex. 17, HRSA Letter.

74. The HRSA Letter first notifies Sanofi that it HRSA "has completed its review of Sanofi's" integrity initiative—a review in which Sanofi has never been permitted an opportunity to participate, although HRSA has "analy[zed] [] the complaints [it] has received from covered entities." *Id.* at 1.

75. The HRSA Letter then informs Sanofi that "HRSA has determined that Sanofi's actions have resulted in overcharges and are in direct violation of the 340B statute." *Id.* The HRSA Letter goes on to explain that Sanofi's integrity initiative supposedly violates Section 340B because that "statute does not permit manufacturers

to impose conditions on covered entities' access to 340B pricing, including the production of claims data" required by Sanofi's integrity initiative. *Id.*

76. The HRSA Letter's demands are imminent and authoritative. It declares: "Sanofi *must immediately* begin offering its covered outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements, regardless of whether they purchase through an in-house pharmacy." *Id.* at 2 (emphasis added). And the HRSA Letter backs its demands up with a clear and explicit threat that continued operation of Sanofi's integrity initiative "may result in [civil monetary penalties]." *Id.*

77. The HRSA Letter demands a response by June 1, 2021, still two weeks before the parties will have filed their reply briefs in support of their cross-motions for summary judgment in this matter. At that time, according to the letter, "[t]he Department of Health and Human Services will determine whether [civil monetary penalties] are warranted based on Sanofi's willingness to comply with" HRSA's interpretation of the statute—before this Court has even had the opportunity to address the statute's meaning.

STANDING

~~69~~78. Sanofi has standing to challenge the ADR Rule ~~and~~, the Advisory Opinion, and the HRSA Letter because Sanofi is suffering injuries that are fairly traceable to HHS's rules and likely to be redressed by a favorable ruling.

~~70~~79. Sanofi is injured by the ADR Rule because that rule exposes Sanofi to ADR claims by covered entities alleging that Sanofi overcharged for 340B-priced drugs or limited covered entities' ability to purchase these drugs. Indeed, covered entities have already filed ADR claims against Sanofi requesting equitable relief, including a preliminary injunction, from the ADR Panel. Sanofi is further injured because the ADR Panel that will adjudicate ADR claims against Sanofi is unconstitutionally structured. The ADR Panel members are principal officers of the United States, but they have not been confirmed by the Senate, in violation of the Constitution's Appointments Clause—and they will wield judicial power in violation of Article III of the Constitution.

~~71~~80. Sanofi's injuries are fairly traceable to the ADR Rule because that rule authorizes covered entities to file ADR claims before the unconstitutionally structured ADR Panel alleging that Sanofi overcharged for 340B-priced drugs or limited covered entities' ability to purchase these drugs.

~~72~~81. A favorable ruling vacating the ADR Rule is likely to redress Sanofi's injuries from the ADR Rule, because Sanofi would not have to defend itself before an unconstitutionally structured ADR Panel against claims that it overcharged for 340B-priced drugs or limited covered entities' ability to purchase these drugs.

~~73~~82. Sanofi is likewise 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. HRSA's Letter confirms that Sanofi is injured by the Advisory Opinion because Sanofi faces crushing financial penalties for failing to comply with the Advisory Opinion's new rule.

~~74~~83. 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 through the termination of its PPA, if it fails to comply with the Advisory Opinion by continuing to operate the integrity initiative.

~~75~~84. A favorable ruling is likely to redress Sanofi's injuries from the Advisory Opinion. 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.

85. Sanofi is also injured by the HRSA Letter because, by the letter's terms, Sanofi must now 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 abandon its integrity initiative in favor of HRSA's litigating position.

86. Sanofi's injuries are fairly traceable to the HRSA Letter because the HRSA Letter determines that Sanofi's integrity initiative violates Section 340B. The HRSA Letter also makes plain its direct consequences. Continued operation of Sanofi's integrity initiative "may result in [civil monetary penalties]" unless Sanofi

"immediately" complies with the terms of the HRSA Letter. Ex. 17, HRSA Letter, at 2.

87. A favorable ruling is likely to redress Sanofi's injuries from the HRSA Letter. An order setting aside the HRSA Letter would allow Sanofi to continue to operate its integrity initiative and relieve Sanofi from the threat of civil monetary penalties and other enforcement actions.

FINAL AGENCY ACTION

~~76~~88. The APA provides that "[a]gency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court are subject to judicial review." 5 U.S.C. § 704. ~~Both the~~The ADR Rule ~~and the~~, Advisory Opinion, and the HRSA letter are final agency actions for which Sanofi has no other adequate remedy in court.

~~77~~89. The ADR Rule, which became effective on January 13, 2021, represents the consummation of HHS's decision-making process with respect to the implementation of Section 340B's dispute resolution process between covered entities and drug manufacturers.

~~78~~90. The ADR Rule also determines Sanofi's rights and legal obligations under Section 340B, and legal consequences will inevitably flow from the ADR Rule, because Sanofi must now defend itself before an unconstitutionally structured ADR Panel against claims that it overcharged for 340B-priced drugs or limited covered

entities' ability to purchase these drugs. Indeed, covered entities have already filed ADR claims against Sanofi requesting equitable relief, including a preliminary injunction. *See* Ex. 15, Petition for Declaratory and Injunctive Relief; Ex. 16, Motion for Preliminary Injunction.

~~79~~91. 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 also final agency action.

~~80~~92. 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 id.* 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, HHS recently admitted that these conclusions have "been set forth *conclusively* in the recently issued advisory opinion." Dkt. 64, Defs.' Mot to Dismiss, at 9, *Am. Hosp. Ass'n*, 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 "[s]upervises 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.

~~81~~93. The Advisory Opinion determines Sanofi's rights and legal obligations under Section 340B, and legal consequences will inevitably flow from the Advisory Opinion. Sanofi now has a legal obligation to 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 HHS 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, *Am Hosp. Ass'n*, 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. HRSA's Letter enforcing the Advisory Opinion's new

rule against Sanofi confirms that the Advisory Opinion determines Sanofi's rights and legal obligations.

94. If there were any room for doubt about the finality of the Advisory Opinion, there can be none after the HRSA Letter, which is also final agency action. As HHS conceded in parallel litigation regarding a similar letter sent to a different manufacturer, "the violation letter determines the legality of [the manufacturer's] actions, finds it to be out of statutory compliance, and sets out consequences should [the manufacturer] continue to flout its obligations." *AstraZeneca Pharmaceuticals LP v. Becerra et al.*, No. 1:21-cv-00027-LPS, ECF 74, at 4 (D. Del. May 24, 2021).

95. By its own terms, the HRSA Letter represents the consummation of HHS's decision-making process about the legality of Sanofi's integrity initiative. The letter explains that HRSA has conducted a "review of [Sanofi's] policy and an analysis of the complaints HRSA has received from covered entities." Ex. 17, HRSA Letter, at 1. After conducting that review, the letter explains that "HRSA has determined that Sanofi's actions have resulted in overcharges and are in direct violation of the 340B statute." *Id.* The HRSA Letter also rejects Sanofi's "rationale for its restrictive action," *i.e.*, Sanofi's reasonable request for claims data through its integrity initiative. *Id.* at 2.

96. Legal consequences will flow directly from the HRSA Letter. The HRSA Letter declares that "Sanofi must immediately begin offering its covered

outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements, regardless of whether they purchase through an in-house pharmacy." *Id.* at 2. The HRSA Letter goes on to state the consequences of any refusal to abide by its terms: "Continued failure to provide the 340B price to covered entities utilizing contract pharmacies … may result in [civil monetary penalties]." *Id.*

~~82~~97. Sanofi is thus now put to a painful choice: either comply with the unlawful obligations in the Advisory Opinion (as HRSA demands in its May 17 Letter) by abandoning a reasonable integrity initiative ~~which~~that Sanofi believes fully complies with Section 340B, or risk devastating financial penalties~~ at the hands of an unconstitutional ADR Panel, no less~~ by continuing to operate the integrity initiative in the face of the Advisory Opinion and ~~repeated threats of~~the HRSA Letter's plain threat of further enforcement action.

CLAIMS FOR RELIEF

Count I—Violation of Administrative Procedure Act
The ADR Rule Violates Article II of the U.S. Constitution (Appointments Clause)

~~83~~98. Sanofi incorporates by reference the allegations contained in all of the preceding paragraphs as though set forth fully herein.

~~84~~99. A court must "hold unlawful and set aside agency action … found to be … contrary to constitutional right, power, privilege, or immunity." 5 U.S.C. § 706(2)(B).

~~85~~100.The Constitution's Appointments Clause provides that executive branch officers shall be appointed by the President "by and with the Advice and Consent of the Senate," except that "Congress may by Law vest the Appointment of such inferior Officers, as they think proper, in the President alone, in the Courts of Law, or in the Heads of Departments." U.S. Const. Art. II, § 2, cl. 2.

~~86~~101.ADR Panel members are "officers" of the United States. They are appointed for a continuing term, they control the proceedings before them and issue final precedential decisions, and they exercise significant authority pursuant to the laws of the United States. Further, they can take testimony, conduct trials, rule on the admissibility of evidence, have the power to enforce compliance with discovery orders, and have the power to award money damages and equitable relief. 42 C.F.R. §§ 10.23, .22(b)-(c); 85 Fed. Reg. at 80,641.

~~87~~102.ADR Panel members are "principal officers" of the United States. They independently determine how to conduct proceedings, and they make final precedential determinations on behalf of HHS that are not subject to any further executive branch review. ADR Board members may also be removed from ADR Panels only "for cause." 85 Fed. Reg. at 80,634. Thus, in their conduct of ADR proceedings, ADR Panel members are not supervised or directed by any superior officer.

~~88~~103.Because ADR Panel members are principal officers, the Appointments Clause requires them to be appointed only by the President with the Senate's advice and consent. By instead vesting the power to appoint ADR Panel members in the Secretary alone, the ADR Rule therefore violates the Appointments Clause.

~~89~~104.This Court should hold unlawful and set aside the ADR Rule because it violates the Constitution. 5 U.S.C. § 706(2)(B).

Count II—Violation of Administrative Procedure Act
The ADR Rule Violates Article III of the Constitution

~~90~~105.Sanofi incorporates by reference the allegations contained in all of the preceding paragraphs as though set forth fully herein.

~~91~~106.A court must "hold unlawful and set aside agency action … found to be … contrary to constitutional right, power, privilege, or immunity." 5 U.S.C. § 706(2)(B).

~~92~~107.The Constitution vests the judicial power of the United States "in one supreme Court, and in such inferior Courts as the Congress may from time to time ordain and establish." U.S. Const. Art. III, § 1. The adjudication of private rights must be overseen by Article III courts.

~~93~~108.The ADR Rule violates Article III by allowing ADR Panels to adjudicate private rights. Specifically, by enabling panels to mandate that manufacturers transfer property (*i.e.*, the drugs they produce) to covered entities, often at an extreme financial loss to the manufacturers, and by enabling those panels to enforce such decisions

through binding money judgments, the ADR Rule empowers ADR Panels to determine the liability of one individual to another. Moreover, manufacturers have not consented to ADR Panels exercising this authority. Such authority may be constitutionally vested only in Article III courts.

~~94~~109. This Court should hold unlawful and set aside the ADR Rule because it violates the Constitution. 5 U.S.C. § 706(2)(B).

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

~~95~~110. Sanofi incorporates by reference the allegations contained in all of the preceding paragraphs as though set forth fully herein.

~~96~~111. 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).

~~97~~112. The ADR Rule is contrary to law and in excess of statutory authority because it violates Article II and Article III of the Constitution.

~~98~~113. The ADR Rule is contrary to law and in excess of statutory authority because HHS exceeded its statutory authority by allowing claims "that a manufacturer has limited the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price." 42 C.F.R. 10.21(c)(1). Section 340B only authorizes "claims by covered entities that they have been overcharged for drugs purchased

under this section." 42 U.S.C. 256b(d)(3). The ADR Rule thus impermissibly expands the scope of Section 340B.

~~99~~114.Moreover, Section 340B does not authorize ADR panels to issue decrees awarding "money damages" or "equitable relief" between private parties. The statute allows HHS only to "promulgate regulations to establish and implement an administrative process[,] … including appropriate procedures for the provision of remedies and enforcement of determinations made pursuant to such process through mechanisms and sanctions." *Id.* Deciding that "money damages" and "equitable relief" are warranted, as ADR Panels may do under the ADR Rule, extends beyond "appropriate procedures for the provision of remedies," which is all that Section 340B permits for the ADR process.

~~100~~115. The ADR Rule is not entitled to *Chevron* or *Skidmore* deference on this point. *See generally Chevron USA, Inc. v. Nat. Res. Def. Council*, 467 U.S. 837 (1984); *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944).

~~101~~116. This Court should hold unlawful and set aside the ADR Rule 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
HHS Failed to Observe the Notice-and-Comment Procedure Required by Law in Promulgating the ADR Rule

~~102~~117. Sanofi incorporates by reference the allegations contained in all of the preceding paragraphs as though set forth fully herein.

~~103~~118. 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).

~~104~~119. The APA requires agencies to issue rules through a notice-and-comment process. *See id.* § 553.

~~105~~120. 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).

~~106~~121. The ADR Rule is undoubtedly a rule within the meaning of the APA.

~~107~~122. HHS failed to comply with the APA's notice-and-comment requirement in promulgating the ADR Rule. Although HHS provided notice and comment for an ADR-related rule through the 2016 NPRM, HHS withdrew that notice in 2017. Thus, to promulgate the ADR Rule, HHS was required to—but did not—engage in the notice-and-comment process again.

~~108~~123. Separately, HHS never provided affected parties with the opportunity to comment on several provisions that appear in the ADR Rule but that were absent from, and do not logically grow from, the original NPRM. Such provisions include the proposal that ADR panels can issue binding judgments for

money damages, can award equitable relief, and will render decisions that are precedential.

~~109~~124. This Court should hold unlawful and set aside the ADR Rule because it violates the APA's notice-and-comment requirement. 5 U.S.C. § 706(2)(D).

Count V—Violation of Administrative Procedure Act
The ADR Rule Is Arbitrary and Capricious

~~110~~125. Sanofi incorporates by reference the allegations contained in all of the preceding paragraphs as though set forth fully herein.

~~111~~126. 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).

~~112~~127. The ADR Rule is arbitrary and capricious because HHS failed to account for changed legal and factual circumstances in the years after it withdrew the 2016 NPRM. For example, HHS failed to consider new evidence submitted in PhRMA's petition for rulemaking. HHS's failure to consider new information shows that the ADR Rule is not based on meaningful consideration of the surrounding circumstances.

~~113~~128. The ADR Rule is arbitrary and capricious also because HHS failed to reasonably explain its reasons for choosing the design of the ADR process.

~~114~~129. The ADR Rule is arbitrary and capricious additionally because HHS failed to address commenters' concerns about HHS's outdated and burdensome guidelines that govern the audit prerequisite for manufacturers to initiate ADR claims.

~~115~~130. This Court should hold unlawful and set aside the ADR Rule because it is arbitrary and capricious. 5 U.S.C. § 706(2)(A).

Count VI—Violation of Administrative Procedure Act
HHS Failed to Observe the Notice-and-Comment Procedure Required by Law in Promulgating the Advisory Opinion

~~116~~131. Sanofi incorporates by reference the allegations contained in all of the preceding paragraphs as though set forth fully herein.

~~117~~132. 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.

~~118~~133. 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.

~~119~~134. 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.

~~120~~135. HHS issued the Advisory Opinion without engaging in the notice-and-comment process. 5 U.S.C. § 553.

~~121~~136. 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 VII—Violation of Administrative Procedure Act
HHS Failed to Follow Its Good Guidance Rule

~~122~~137. Sanofi incorporates by reference the allegations contained in all of the preceding paragraphs as though set forth fully herein.

~~123~~138. 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).

~~124~~139. 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).

~~125~~140. 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.

~~126~~141. 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.*

~~127~~142. 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.

~~128~~143. 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.

~~129~~144. 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.*

~~130~~145. 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 78,785, 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.

~~131~~146. The Advisory Opinion violates the Good Guidance Rule because it "requir[es] a person or entity outside 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.

~~132~~147. 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).

~~133~~148. 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.

~~134~~149. 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 78,786, 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.*

~~135~~150. 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 VIII—Violation of Administrative Procedure Act
The Advisory Opinion Is Contrary to Law and in Excess of Statutory Authority

~~136~~151. Sanofi incorporates by reference the allegations contained in all of the preceding paragraphs as though set forth fully herein.

~~137~~152. 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).

~~138~~153. 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.

~~139~~154. 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.*

~~140~~155. 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~~offers discounted drugs to ~~contract pharmacies—and, moreover, will do so for~~ all covered entities through contract pharmacies. So long as a covered entity provides the claims data requested by Sanofi, Sanofi provides discounted pricing wherever the prescriptions are filled. In addition, beginning on March 1, 2021, any covered entity that does not have its own in-house pharmacy may designate a single contract pharmacy to receive 340B-priced drugs for the covered entity's patients, regardless of whether the covered entity provides the data Sanofi requests through the integrity initiative. Sanofi's 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.

~~141~~156. The Advisory Opinion is not entitled to *Chevron* or *Skidmore* deference.

~~142~~157. 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 IX—Violation of Administrative Procedure Act
The Advisory Opinion Is Arbitrary and Capricious

~~143~~158. Sanofi incorporates by reference the allegations contained in all of the preceding paragraphs as though set forth fully herein.

~~144~~159. 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).

~~145~~160. 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.

~~146~~161. 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.

~~147~~162. This Court should hold unlawful and set aside the Advisory Opinion because it is arbitrary and capricious. *Id.* § 706(2)(A).

Count X—Violation of Administrative Procedure Act
The HRSA Letter Is Contrary to Law and in Excess of Statutory Authority

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

164. 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).

165. In its Letter, HRSA enforced against Sanofi the Advisory Opinion's new rule that drug manufacturers must provide 340B-priced drugs to contract pharmacies and may not impose conditions on the delivery of 340B-priced drugs to contract pharmacies.

166. Because the Advisory Opinion's new rule is contrary to law and in excess of statutory authority, *see* Count VIII, HRSA's enforcement of the new rule announced in the Advisory Opinion against Sanofi in the HRSA Letter is also contrary to law and in excess of statutory authority. All of the flaws that render the Advisory Opinion unlawful also render unlawful HRSA's attempt in its May 17 Letter to enforce the obligations that its Advisory Opinion seeks to impose on manufacturers.

167. The HRSA Letter's determination that Sanofi's integrity initiative violates Section 340B 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. Nor does Section 340B prohibit manufacturers from imposing conditions on the delivery of 340B-priced drugs to contract pharmacies—particularly when such conditions are reasonable. *See id.*

168. Even if the HRSA Letter 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 offers discounted drugs to all covered entities through contract pharmacies. So long as a covered entity provides the claims data requested by Sanofi, Sanofi provides discounted pricing wherever the prescriptions are filled. In addition, any covered entity that does not have its own in-house pharmacy may designate a single contract pharmacy to receive 340B-priced drugs for the covered entity's patients, regardless of whether the covered entity provides the data Sanofi requests through the integrity initiative. Sanofi's 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.

169. The HRSA Letter is not entitled to *Chevron* or *Skidmore* deference.

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

Count XI—Violation of Administrative Procedure Act
The HRSA Letter Is Arbitrary and Capricious

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

172. 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).

173. In its Letter, HRSA enforced against Sanofi the Advisory Opinion's new rule that drug manufacturers must provide 340B-priced drugs to contract pharmacies and may not impose conditions on the delivery of 340B-priced drugs to contract pharmacies.

174. Because the Advisory Opinion's new rule is arbitrary and capricious, *see* Count IX, HRSA's enforcement of the new rule announced in the Advisory Opinion against Sanofi in the HRSA Letter is also arbitrary and capricious.

175. In addition, the HRSA Letter's determination that Sanofi's integrity initiative violates Section 340B is arbitrary and capricious because HRSA failed to reasonably explain this determination. The HRSA Letter engages in no substantive interpretation of Section 340B and fails to explain why contract pharmacies should be entitled to 340B-priced drugs when such pharmacies are never mentioned in Section 340B. The HRSA Letter is also inconsistent with the agencies' prior guidance and reasoning, including HHS's reasoning just months ago in the Advisory Opinion that

contract pharmacies are entitled to 340B-priced drugs because they act as agents of covered entities. *See* Advisory Opinion 1, 6.

176. The HRSA Letter's determination that Sanofi may not impose reasonable conditions on the delivery of 340B-priced drugs to contract pharmacies is similarly arbitrary and capricious because HRSA failed to reasonably explain this determination. On this question as well, the HRSA Letter engages in no substantive interpretation of Section 340B to explain why the statute prohibits manufacturers from offering 340B-priced drugs subject to reasonable conditions. The HRSA Letter is also inconsistent with the agencies' prior guidance permitting manufacturers to impose certain conditions on the provision of discounted drugs under Section 340B, such as agreement to the manufacturer's normal business policies and the collection of standard information.

177. The HRSA Letter's determination that Sanofi's integrity initiative has resulted in overcharges is arbitrary and capricious because HRSA failed to reasonably explain this determination. Again, the HRSA Letter offers no explanation of why the statute requires manufacturers to deliver 340B-priced drugs to contract pharmacies when such pharmacies are never mentioned in Section 340B. Nor does the HRSA Letter explain how such an overcharge could have taken place, in light of the prevalent replenishment model through which covered entities place orders for and pay for 340B-priced drugs. Under this model, when a manufacturer declines to

provide a 340B discount (and instead charges standard commercial prices) for drugs shipped to a contract pharmacy, a covered entity is not "overcharged"—indeed, it typically is not charged at all.

178. The HRSA Letter's determination that Sanofi's integrity initiative has resulted in overcharges is arbitrary and capricious also because HRSA failed to support this determination with any evidence and failed to account for evidence contrary to its determination. The HRSA Letter baldly asserts that "Sanofi's actions have resulted in overcharges," Ex. 17, HRSA Letter, at 1, but it identifies no covered entity that Sanofi has purportedly overcharged and no transaction in which Sanofi has allegedly done so.

179. This Court should hold unlawful and set aside the HRSA Letter because it is arbitrary and capricious. *Id.* § 706(2)(A).

Count XII—Violation of Administrative Procedure Act
The HRSA Letter Enforces the Procedurally Unlawful Rule Announced in the Advisory Opinion

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

181. In its Letter, HRSA enforced against Sanofi the Advisory Opinion's new rule that drug manufacturers must provide 340B-priced drugs to contract pharmacies and may not impose conditions on the delivery of 340B-priced drugs to contract pharmacies.

182. Because HHS failed to observe the notice-and-comment procedure required by law in promulgating the new rule announced in the Advisory Opinion, *see* Count VI, HRSA's enforcement of the Advisory Opinion's new rule against Sanofi in the HRSA Letter is unlawful.

183. This Court should hold unlawful and set aside the HRSA Letter because HRSA may not enforce a rule that violates the APA's notice-and-comment requirement. 5 U.S.C. § 706(2)(D).

PRAYER FOR RELIEF

Wherefore, Plaintiff prays for the following relief:

1. A declaration, order, and judgment holding unlawful, enjoining, and setting aside the ADR Rule ~~and~~, the Advisory Opinion, and the HRSA Letter;

2. A declaration, order, and judgment holding that the ADR Rule violates the Appointments Clause of Article II of the Constitution;

3. A declaration, order, and judgment holding that the ADR Rule violates Article III of the Constitution;

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

5. 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;

6. 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;

7. A preliminary and permanent injunction enjoining Defendants from implementing or enforcing the ADR Rule ~~and~~, the Advisory Opinion, and the HRSA Letter in any administrative proceeding or taking any other enforcement action against Sanofi for operating its integrity initiative;

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

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

Dated: ~~February 2~~May 25, 2021

Respectfully submitted,

s/ Jennifer L. Del Medico

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CERTIFICATE OF SERVICE

I hereby certify that on ~~February 2~~May 25, 2021, a copy of the foregoing was filed with the Clerk of the Court by using the CM/ECF system. ~~In addition, I caused a copy of the foregoing to be served on the following via certified mail on this date:~~certify that all participants in this case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

~~UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES~~
~~200 Independence Avenue, S.W.~~
~~Washington, D.C. 20201~~
~~NORRIS COCHRAN,~~
~~in his official capacity as Acting Secretary of Health and Human Services~~
~~200 Independence Avenue, S.W.~~
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~~DANIEL J. BARRY,~~
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~~February 2~~May 25, 2021 *s/ Jennifer L. Del Medico*