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Via Electronic Mail to 340Bpricing@hrsa.gov

Diana Espinosa
Acting Administrator
Health Resources & Services Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Ms. Espinosa:

On behalf of Sanofi-Aventis U.S., LLC ("Sanofi"), I write in response to your May 17, 2021 letter ("Letter") addressed to Gerald Gleeson, Vice President and Head of Sanofi US Market Access Shared Services.

As you are aware, Sanofi has filed a complaint in federal court challenging the Department of Health & Human Services' ("HHS") conclusion that drug manufacturers must provide 340B-priced drugs to an unlimited number of contract pharmacies without condition.[1] It should thus come as no surprise that Sanofi objects in the strongest possible terms to HRSA's interference with that lawsuit through its "determin[ation]"[2] that Sanofi has violated Section 340B. Because the question whether Sanofi's integrity initiative complies with Section 340B is currently the subject of ongoing litigation—and has been presented to the court in motions that will be fully briefed in the coming weeks—HRSA should not take any further action against Sanofi out of respect for the judicial process. Imposing civil monetary penalties ("CMPs") while the litigation is pending would be particularly inappropriate in light of the government's representations to the court that "HRSA has not even decided whether to impose CMPs, and that if HRSA did impose such

[1] *See Sanofi-Aventis U.S., LLC v. Dep't of Health and Human Servs., et al.*, No. 21-cv-634 (D.N.J.).

[2] Letter at 1.

penalties, 'Sanofi would receive process before any sanctions were imposed.'"[3] Given these representations, the court cautioned that it would be open to issuing injunctive relief to Sanofi "if Defendants were to impose CMPs prior to the Court's resolution of this case."[4]

In the pending litigation, Sanofi has explained in detail why its integrity initiative complies with Section 340B. This response letter reiterates Sanofi's position on that question and explains why HRSA's contrary view misunderstands the statutory language. In addition, this response explains why HRSA's determination that Sanofi's integrity initiative violates Section 340B is arbitrary and capricious and why imposing civil monetary penalties would be unjustified and illegal. This letter also highlights some of the unique features of Sanofi's integrity initiative that would make any enforcement action against Sanofi especially inappropriate.

If there is a final judgment in the pending litigation holding that Sanofi's integrity initiative is impermissible under Section 340B, Sanofi will of course abide by that decision. But unless and until that occurs, Sanofi intends to continue operating its integrity initiative, which fully complies with Section 340B and can play a critical role in preventing waste and abuse in the 340B Program. Sanofi expressly reserves all of its rights, including the right to seek further relief in court and to present its objections to civil monetary penalties through administrative review.

I. Background

A. Section 340B

Enacted in 1992, Section 340B of the Public Health Service Act, 42 U.S.C. § 256b, specifically enumerates the categories of covered entities that must be offered discounts under the 340B Program. When Section 340B was enacted, there were twelve categories of

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[3] *See* Dkt. 83 at 7, *Sanofi-Aventis U.S., LLC v. Dep't of Health and Human Servs., et al.,* No. 21-cv-634 (D.N.J.).

[4] *Id.* at 8.

covered entities.[5] Today, there are fifteen.[6] Only Congress can expand this list of covered entities; HHS lacks authority to do so.[7]

As enacted in 1992, Section 340B required the Secretary to ensure, through Pharmaceutical Pricing Agreements ("PPAs"), that "the amount required to be paid . . . to the manufacturer for covered outpatient drugs . . . purchased by a covered entity" does not exceed a maximum price determined through a prescribed formula.[8] In 2010, as part of the Affordable Care Act, this provision was amended to further impose what is known as the "must offer" requirement—namely, that PPAs must "require that the manufacturer *offer* each covered entity covered outpatient drugs for purchase at or below" the statutory maximum price.[9] The government may institute enforcement actions, seek civil monetary penalties, and even terminate the PPA—and with it the manufacturer's participation in Medicaid and Medicare Part B—for violations of Section 340B.[10]

Section 340B also includes provisions that aim to prohibit waste and abuse within the program. Specifically, Section 340B prohibits "duplicate discounts or rebates," which occur when the same prescription receives both a 340B discount and a Medicaid rebate—as covered entities' patients are frequently insured by Medicaid, such that their prescriptions are eligible for Medicaid rebates.[11] Section 340B also prohibits "diversion," which occurs when covered entities resell or transfer discounted drugs to persons other than their patients.[12]

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[5] *See* Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602(a), 106 Stat. 4943, 4967 (1992).

[6] *See* 42 U.S.C. § 256b(a)(1), (4)(A)–(O).

[7] *See Pharm. Rsch. & Mfrs. of Am. v. HHS*, 43 F. Supp. 3d 28, 35 (D.D.C. 2014) (holding HHS lacks general rulemaking authority under Section 340B).

[8] 42 U.S.C. § 256b(a)(1).

[9] *See* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 7102(b), 124 Stat. 119, 827 (2010), *codified at* 42 U.S.C. § 256b(a)(1) (emphasis added).

[10] *See* 42 U.S.C. §§ 256b(d)(1)(B)(vi), 1396r-8(b)(4)(B)(v); HRSA, Manufacturer Audit Guidelines and Dispute Resolution Process 0905-ZA-19, 61 Fed. Reg. 65,406, 65,412–13 (Dec. 12, 1996).

[11] 42 U.S.C. § 256b(a)(5)(A).

[12] *Id.* § 256b(d)(2)(A).

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

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

Explaining that Section 340B has "many gaps" and "is silent as to permissible drug distribution systems," the 1996 guidance took the position—to facilitate program participation by covered entities without in-house pharmacies—that a covered entity could contract with a maximum of one third party to provide pharmacy services for 340B-priced drugs.[13] The 2010 guidance expanded this supposed authorization, expressing HHS's view that *all* covered entities could contract with an *unlimited* number of outside pharmacies.[14] But neither the 1996 nor 2010 guidance purported to be binding or to impose legal obligations on manufacturers, and both predated the addition of the "must offer" requirement to Section 340B.

Covered entities' use of contract pharmacies exploded following the 2010 guidance. The number of for-profit contract pharmacies participating in the 340B Program increased from 1,300 in 2010 to 20,000 in 2017 and then to 28,000 last year, with more than 100,000 arrangements between contract pharmacies and covered entities.[15] Indeed, some covered

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[13] Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,550, 43,555 (Aug. 23, 1996).

[14] *See* Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,273 (Mar. 5, 2010).

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

entities contract with pharmacies thousands of miles away from their locations.[16] Not surprisingly, this extraordinary expansion of contract pharmacy arrangements has been accompanied by significant waste and abuse.

For one thing, contract pharmacies often keep sizable portions of the discounts that Congress intended for non-profit covered entities and their patients.[17] Although contract pharmacies acquire the 340B drugs at a significant discount, they charge the insurer or patient at the standard commercial rate. This yields a large profit margin over the 340B price (which can be as low as a penny)—much of which is often pocketed by contract pharmacies, which pay a smaller, pre-negotiated amount to the covered entity for each discounted drug dispensed.[18]

Because a patient's 340B status is not determined by a contract pharmacy until *after* a drug is dispensed, contract pharmacies typically treat covered entities' patients like the general public—using the same supply of drugs to fulfill *all* prescriptions, and then "replenish[ing] [those drugs] with 340B drugs [at 340B prices] once 340B patient eligibility is confirmed and can be documented through auditable records."[19] Partly because of how contract pharmacies commingle 340B-priced drugs with other drugs, the expansion of

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

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

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

[19] HRSA, Statutory Prohibition on Group Purchasing Organization Participation, 340B Drug Pricing Program Release No. 2013-1, at 3 (Feb. 7, 2013), https://www.hrsa.gov/sites/default/files/opa/programrequirements/policyreleases/prohibitionongpoparticipation020713.pdf; *see also* HHS-OIG, *Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431, at 5 (Feb. 4, 2014), https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf (explaining that contract pharmacies dispense drugs from their own supply and then request that the covered entity "replenish" their supply at 340B prices).

contract pharmacy arrangements has led to widespread duplicate discounting, in direct violation of Section 340B.[20] Drugs acquired at 340B-discounted pricing in order to replenish a contract pharmacy's inventory may be dispensed to any individual, including an individual who is not a patient of a covered entity. As a result, the replenishment model also creates the potential for diversion, again in violation of Section 340B.[21] It is thus no surprise that the government has noted that contract pharmacy use "creates more opportunities for drug diversion compared to in-house pharmacies."[22]

Duplicate-discounting problems stem in part from an information gap. Requests for Medicaid reimbursement are made by the pharmacy that fills the prescription, not the covered entity. But HRSA has only partial insight into which covered entities use which contract pharmacies, and only incomplete information on which covered entities use 340B-priced drugs for Medicaid-insured patients.[23] Likewise, based on publicly available information, there is no effective or comprehensive (much less timely) way to know whether a contract pharmacy's prescriptions are being submitted for *both* a 340B discount and a Medicaid rebate. HHS itself has recognized this gap, noting that contract pharmacy arrangements "create complications in preventing duplicate discounts,"[24] and HRSA audits have uncovered numerous violations linked to contract pharmacies.[25] The government has also recognized that "duplicate discounts can often best be identified from a review of claims level data by the manufacturers."[26] To that end, Sanofi has discovered significant duplicate-

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[20] *See* 42 U.S.C. § 256b(a)(5)(A).

[21] *See id.* § 256b(a)(5)(B).

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

[23] *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.

[24] HHS Report, *supra*, at 1–2.

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

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

discounting violations when analyzing Medicaid rebates for its own drugs and is seeking claims data to promote 340B compliance.

C. Sanofi's Integrity Initiative

Sanofi shares the government's concerns about the unlawful duplicate discounting that has accompanied the explosion in covered entities' use of contract pharmacies. Accordingly, on July 28, 2020, Sanofi informed HRSA of its integrity initiative to prevent duplicate discounts and other waste and abuse. Under the integrity initiative, which took effect on October 1, 2020, Sanofi continues to offer discounted pricing to all covered entities. The program involves one simple change: Sanofi now requests that a subset of covered entities submit minimal, de-identified claims data for 340B-priced drugs dispensed by contract pharmacies, subject to limited exceptions.[27] Sanofi requests such data only from five categories of covered entities that have historically accounted for a significant share of contract pharmacy dispensing and, therefore, duplicate-discount risk.[28] Sanofi's program is thus unique among the 340B integrity programs that HRSA is reviewing. Sanofi heard nothing from HRSA from the time it notified HRSA of its integrity initiative until HRSA's May 17 letter.

The modest information requested by Sanofi is just a subset of what third-party payors, including Medicare and Medicaid, require from covered entities for insurance reimbursement and, similarly, is only a subset of what drug manufacturers require from insurance companies when paying rebates on prescriptions.[29] In other words, Sanofi is not asking covered entities to do anything more than they are already doing to get reimbursed—indeed it is substantially less. With this information, Sanofi can identify and halt impermissible duplicate discounts that would otherwise go undetected as a result of the current information gap by comparing the claims data to Medicaid payor data.[30]

On February 1, 2021, Sanofi further announced that, as of March 1, 2021, any covered entity without its own in-house pharmacy may designate a single contract pharmacy

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[27] *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).

[28] *See* Ex. 8, Program Announcement.

[29] *See* Ex. 6, "Understanding Sanofi's 340B Data Reporting Requirements."

[30] *See id.*; Ex. 7, "Sanofi's New Initiative Combats Waste and Abuse in the 340B Program."

at which its patients can receive 340B-priced drugs—regardless of whether the covered entity provides the data Sanofi requests through the integrity initiative.[31]

In sum, under its integrity initiative, Sanofi now offers 340B-priced drugs to all covered entities in three ways: (i) through the covered entity's own in-house pharmacy; (ii) through a single, designated contract pharmacy, if the covered entity has no in-house pharmacy; and (iii) through multiple contract pharmacies, if the covered entity provides the data Sanofi requests.

Many covered entities have registered to provide claims data to Sanofi's integrity initiative. But, as unobtrusive as the integrity initiative is, many more covered entities have refused to participate—and have instead clamored for HHS to shut down Sanofi's integrity initiative. In late 2020, covered entities took the matter to federal court, seeking to compel enforcement action by HHS.[32] Tellingly, however, none of these plaintiffs argued that participating in Sanofi's integrity initiative would be unduly burdensome. Nor did any allege that Sanofi's program improperly discriminated against covered entities as compared to commercial customers. Nor, for that matter, has any of these covered entities ever denied the importance of the fight against duplicate discounting or the value of Sanofi's integrity initiative in that battle—if only they would cooperate and provide the requested data.

II. Sanofi's Integrity Initiative Complies with Section 340B.

HRSA's determination that Sanofi's integrity initiative does not comply with Section 340B is contrary to law. Section 340B does not *require* drug manufacturers to deliver discounted drugs to contract pharmacies. Nor does Section 340B prohibit manufacturers from imposing conditions on providing discounted drugs to contract pharmacies. Even if that were not the case, HRSA has identified no instance in which Sanofi has overcharged any covered entity. And in all events, Sanofi's integrity initiative complies with Section 340B because Sanofi offers 340B-priced drugs to all covered entities as explained above. HRSA thus has no basis to take any further action against Sanofi for operating the integrity initiative.

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[31] *See* Ex. 8, Program Announcement.

[32] *See Ryan White Clinics for 340B Access v. Azar*, No. 20-cv-2906 (D.D.C.); *Am. Hosp. Ass'n v. HHS*, No. 20-cv-8806 (N.D. Cal.).

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

Section 340B requires drug manufacturers to "offer each covered entity covered outpatient drugs for purchase at or below" discounted prices calculated according to a prescribed statutory formula.[33] That is exactly what Sanofi continues to do. The statute's exhaustive list of fifteen types of healthcare providers that qualify as "covered entities" does not include "contract pharmacies," a term that appears nowhere in Section 340B.[34] HRSA's letter nevertheless concludes that "Sanofi must immediately begin offering its covered outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements."[35] That conclusion represents a stark departure from the plain meaning of Section 340B.

Congress took care in delineating the categories of covered entities entitled to receive 340B discounts. And the statutory text shows that this list is exclusive, because the statute states that the term "covered entity" "*means*" the itemized list of provider categories.[36] Particularly when Congress used "means" and not a more open-ended verb like "includes," the list is exclusive.[37]

The exclusive nature of the list is underscored by the fact that the enumerated covered entities themselves are similar—"providers of safety net services"—and together quite different from large commercial entities like contract pharmacies.[38] Section 340B even draws careful distinctions between *types* of covered entities: Where a covered entity "is a distinct part of a hospital, the hospital shall not be considered a covered entity."[39] Nor has

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[33] 42 U.S.C. § 256b(a)(1).

[34] *Id.* § 256b(a)(4).

[35] Letter at 2.

[36] 42 U.S.C. § 256b(a)(4) (emphasis added).

[37] *See Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 162 (2012) ("Congress used the narrower word 'means' in other provisions … when it wanted to cabin a definition to a specific list of enumerated items.").

[38] *Pharm. Rsch. & Mfrs. of Am. v. HHS*, 138 F. Supp. 3d 31, 34 (D.D.C. 2015) (quoting *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 113 (2011)); *see Barnhart v. Peabody Coal Co.*, 537 U.S. 149, 168 (2003) (explaining that where "items expressed are members of an associated group or series," courts infer that "items not mentioned were excluded by deliberate choice, not inadvertence") (internal quotation marks omitted).

[39] 42 U.S.C. § 256b(a)(6).

that list been static. In 2010, Congress amended Section 340B to add three categories of providers—certain types of "children's hospital[s]," "free-standing cancer hospital[s]," and "critical access hospital[s]"—to the list of covered entities.[40] To add for-profit contract pharmacies to this list of enumerated covered entities would obliterate Congress's careful work.

The statutory text and structure further demonstrate that Section 340B's enumerated list of covered entities does not *also* sweep in contract pharmacies. For one thing, a different provision of Section 340B specifically addresses agents acting on behalf of covered entities.[41] Moreover, in another portion of the same law that created Section 340B, Congress specifically prescribed special treatment for commercial agency arrangements.[42] And Section 340B likewise prescribes rules for "distributors" and "wholesalers" acting on behalf of covered entities.[43]

Congress thus plainly addressed agency and agency-type relationships elsewhere in Section 340B and related statutes. Yet when listing the entities to which manufacturers must "offer" 340B-discounted drugs, Congress specified only an enumerated list of covered entities without mentioning covered entities' agents or third-party representatives—which thus represents a deliberate choice that HRSA disregards by expanding the list to include contract pharmacies.[44]

Moreover, Section 340B's remedial provisions illustrate that 340B pricing extends only to covered entities—and not to contract pharmacies. Under Section 340B, manufacturers that fail to offer discounted drugs may face administrative "claims by covered

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[40] *See id.* § 256b(a)(4)(M)–(O).

[41] *See id.* § 256b(d)(3)(B)(vi) (addressing claims asserted "on behalf of covered entities by associations or organizations representing the interests of … covered entities").

[42] *See* Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 603(a)(1), 106 Stat. at 4974, *codified at* 38 U.S.C. § 8126(h)(3)(A) (addressing treatment for discounted drugs purchased by a federal agency but "delivered through … a commercial entity operating under contract with such agency").

[43] *See* 42 U.S.C. § 256b(d)(2)(B)(iv) (describing an identification system for "distributors"); *id.* § 256b(d)(1)(B)(v) (describing an auditing system for "wholesalers").

[44] *See Barnhart v. Sigmon Coal Co.*, 534 U.S. 438, 452 (2002) (where "Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion") (internal quotation marks and citation omitted).

entities that they have been overcharged."[45] HHS likewise can impose penalties on a manufacturer that knowingly and intentionally "charges a covered entity a price for purchase of a drug that exceeds the [statutory] maximum."[46] But when a manufacturer declines to provide a 340B discount (and instead charges standard commercial prices) for drugs shipped to a contract pharmacy, a covered entity is not "overcharged"—indeed, it typically is not charged at all under the standard "replenishment" model described above. This underscores that such arrangements fall outside the scope of manufacturers' statutory obligations.

Finally, legislative history confirms that Congress did not intend to require manufacturers to provide 340B-priced drugs to contract pharmacies. In 1992, when reviewing the bill that eventually enacted Section 340B, Congress considered expressly requiring manufacturers to provide discounts for drugs "purchased and dispensed by, *or under a contract entered into for on-site pharmacy services with*," a covered entity.[47] Because Congress explicitly *declined* to require 340B pricing for prescriptions dispensed by on-site contract pharmacies, Section 340B cannot be interpreted as requiring manufacturers to deliver 340B-priced drugs to *all* contract pharmacies.

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

Nor does Section 340B restrict manufacturers from imposing conditions on the provision of 340B-priced drugs to contract pharmacies. Nothing in the statute supports HRSA's conclusion that a drug manufacturer's offer of 340B pricing cannot include reasonable conditions on the delivery of the drugs (as, for example, Sanofi has done in its integrity initiative). HRSA's conclusion on this point underscores the inconsistency in its position. HRSA contends that Section 340B does not permit manufacturers to add conditions to the bare statutory command to "offer" drugs at the 340B price; yet HRSA itself would add an entire unspoken category—contract pharmacies—to the list of covered entities enumerated in the statute.

When stating that manufacturers must "offer" discounted pricing to covered entities, Section 340B does not define the term "offer." The word thus carries its ordinary

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[45] 42 U.S.C. § 256b(d)(3)(A).

[46] *Id.* § 256b(d)(1)(B)(vi)(III).

[47] S. Rep. No. 102-259, at 2 (1992) (quoting S. 1729, 102d Cong. (1992)) (emphases added).

meaning.[48] To "offer" means to "manifest[] … willingness to enter into a bargain,"[49] or to "present[] something for acceptance."[50] In other words, an offer is one party's "propos[al] to the other [of] the promise which it will make for a certain consideration, or … the consideration which it will give for a certain promise."[51]

The ordinary meaning of the word "offer" hardly precludes imposing conditions on accepting a covered entity's requests that Sanofi provide 340B-priced drugs to contract pharmacies.[52] Except for the price, Section 340B does not purport to specify any of the terms under which manufacturers must "offer" 340B-priced drugs to covered entities. There is thus no support in the statute for the agency's conclusion that any additional conditions—especially reasonable ones—are impermissible.

Indeed, HHS has previously *agreed* that conditions on a manufacturer's offer are permissible under Section 340B. For example, HHS has long advised that manufacturers may condition an offer of 340B-priced drugs on a covered entity's provision of "standard information."[53] HHS has also opined that manufacturers may require that covered entities agree to "the manufacturer's normal business policies."[54] And HHS guidance has approved of manufacturers placing limits on the quantity of drugs offered at a discounted price during shortages, so long as "340B providers are treated the same as non-340B providers."[55]

Sanofi's unique integrity initiative is simply another example of a permissible condition on the delivery of 340B-priced drugs. Sanofi places no conditions of the provision of 340B-priced drugs either to a covered entity's own in-house pharmacy or to a single, designated contract pharmacy, if the covered entity has no in-house pharmacy. The only condition Sanofi imposes is that covered entities must provide the minimal data Sanofi

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[48] *See Asgrow Seed Co. v. Winterboer*, 513 U.S. 179, 187 (1995) ("When terms used in a statute are undefined, we give them their ordinary meaning.").

[49] Restatement (Second) of Contracts § 24 (1981).

[50] *Offer*, Black's Law Dictionary (11th ed. 2019).

[51] 1 Williston on Contracts § 4:3 (4th ed. May 2021 update).

[52] Nor, as HRSA's letter suggests, does the "must offer" provision require Sanofi to "ensure that the 340B ceiling price is available to all covered entities" in any manner beyond offering its drugs to covered entities at that price. Letter at 1–2.

[53] Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. 25,110-01, 25,114 (May 13, 1994).

[54] *Id.* at 25,112, 25,113–14.

[55] 340B Drug Pricing Program Notice, Release No. 2011-1.1 (May 23, 2012).

requests if they wish to use additional contract pharmacies.[56] This is plainly a reasonable condition, when providing this information through Sanofi's program imposes no logistical or financial burden on covered entities (who already provide this information to insurance companies), and when no party has ever denied that Sanofi's program can help eliminate duplicate discounting—which Congress expressly prohibited.[57] Nor does this condition discriminate against covered entities when, again, the information being requested is already being sought from *all* providers by third-party payors. Particularly when manufacturers are not even required to offer 340B-priced drugs to covered entities through contract pharmacies, Sanofi's integrity initiative is a permissible condition under Section 340B.

III. HRSA's Determination That Sanofi Has Violated Section 340B Is Arbitrary and Capricious.

HRSA's determination that Sanofi's integrity initiative violates Section 340B is arbitrary and capricious. Not only is that conclusion premised on an erroneous interpretation of Section 340B, but HRSA's conclusion falls short of the basic requirement that agency action must be reasonable and reasonably explained.

The Administrative Procedure Act ("APA") provides that a "reviewing court" should "hold unlawful and set aside agency action, findings, and conclusions found to be" either (A) "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;" (B) "contrary to constitutional right, power, privilege, or immunity;" (C) "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;" (D) "without observance of procedure required by law;" or (E) "unsupported by substantial evidence."[58] Agency action is "arbitrary" and "capricious," in violation of the APA, where the agency has "failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise."[59]

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[56] *See* Ex. 1, Letter from G. Gleeson (July 2020); Ex. 2, Letter from A. Gluck to Secretary Azar (Aug. 13, 2020); Ex. 3, Letter from G. Gleeson (Aug. 2020); Ex. 4, Letter from G. Gleeson (Sept. 2020); Ex. 5, Letter from A. Gluck and G. Gleeson (Sept. 2020); Ex. 6, "Understanding Sanofi's 340B Data Reporting Requirements."

[57] *See* 42 U.S.C. § 256b(a)(5)(B).

[58] 5 U.S.C. § 706(2).

[59] *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42–43 (1983).

As explained below, HRSA's May 17 letter is arbitrary and capricious in several respects.

A. HRSA's Determination Is Premised on an Incorrect Interpretation of Section 340B.

HRSA's conclusion that Sanofi's integrity initiative violates Section 340B is arbitrary and capricious because it is premised on an erroneous interpretation of Section 340B. "In the absence of statutory authorization for its act, an agency's 'action is plainly contrary to law and cannot stand.'"[60] And "even if an agency possesses delegated authority, if 'Congress has directly spoken to the precise question at issue,'" a court will "'give effect to the unambiguously expressed intent of Congress'" and set aside a contrary agency action.[61]

As Sanofi has explained both above and in litigation, nothing in Section 340B requires manufacturers to deliver discounted drugs to contract pharmacies. Nor does Section 340B restrict manufacturers from imposing conditions on the provision of 340B-priced drugs to contract pharmacies. The statute is unambiguous: It requires Sanofi to "offer" 340B-discounted drugs to covered entities, which Sanofi does in the multiple ways described above. Because the statute is "clear, that is the end of the matter"; a reviewing "court, as well as the agency, must give effect to the unambiguously expressed intent of Congress."[62]

Nor would the conclusion set forth in HRSA's letter be entitled to any deference in court, even if Section 340B were ambiguous. For one thing, the conclusion set forth in HRSA's letter exceeds HRSA's limited rulemaking authority under Section 340B. "It goes without saying that if an agency action exceeds its statutory authority, the agency is entitled to no deference under *Chevron*."[63] HRSA's conclusion as set forth in HRSA's letter would require Sanofi to deliver drugs to an unlimited number of contract pharmacies, without

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[60] *Atl. City Elec. Co. v. FERC*, 295 F.3d 1, 8 (D.C. Cir. 2002) (quoting *Michigan v. EPA*, 268 F.3d 1075, 1081 (D.C. Cir. 2001)).

[61] *Id.*

[62] *City of Arlington v. FCC*, 569 U.S. 290, 296 (2013); *S. Coast Air Quality Mgmt. Dist. v. EPA*, 882 F.3d 1138, 1156 (D.C. Cir. 2018) (holding agency action arbitrary and capricious where it contradicted unambiguous statute).

[63] *Glob. Tel*Link v. FCC*, 866 F.3d 397, 417 (D.C. Cir. 2017).

condition. But the statute itself imposes no such requirement, as we have explained. Instead, HRSA purports to impose obligations on manufacturers with the force and effect of law independent of those the statute itself imposes. And that is rulemaking that exceeds HRSA's statutory authority, because neither HRSA nor HHS has "been granted broad rulemaking authority to carry out all the provisions of the 340B program."[64]

Presumably for this reason, HHS maintained—as recently as *last year*—that it could not enforce any requirement that manufacturers deliver 340B-priced drugs to contract pharmacies: "HRSA Communications Director Martin Kramer wrote via email on July 8, 2020[,] that although the agency 'strongly encourages all manufacturers to sell 340B priced drugs to covered entities through contract pharmacy arrangements,' 'HRSA's current authority to enforce certain 340B policies … is limited' because Congress has not granted it 'comprehensive regulatory authority' 'to develop enforceable policy that ensures clarity in program requirements.'"[65] In a December 2020 report, moreover, the GAO noted that HRSA had stopped auditing contract pharmacies for diversion violations "because the 340B statute does not address contract pharmacy use"—and HRSA cannot add through rulemaking to the statutory requirements.[66] HRSA's May 17 letter ignores these limitations on its authority.

Moreover, HRSA's passing treatment of Section 340B in HRSA's letter cannot be regarded as reasoned agency decision-making. HRSA's letter recounts the statute's basic requirement that manufacturers "offer" discounted drugs to covered entities under Section 340B. But HRSA's letter offers no explanation whatsoever why that provision requires manufacturers to deliver drugs to contract pharmacies, or why the "offer" cannot include

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[64] *Pharm. Rsch. & Mfrs. of Am.*, 43 F. Supp. 3d at 41–42 (noting that HHS's rulemaking authority under Section 340B is limited to establishing an ADR process, "precisely defin[ing] standards of methodology for calculat[ing] … ceiling prices," and providing for "imposition of monetary civil sanctions").

[65] *Am. Hosp. Ass'n v. HHS*, No. 20-cv-8806, 2021 WL 616323, at *3 (N.D. Cal. Feb. 17, 2021); *see* Tom Mirga, HRSA Says Its 340B Contract Pharmacy Guidance Is Not Legally Enforceable, 340B Report (July 9, 2020) (quoting similar statement from HRSA).

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

reasonable conditions. This unreasoned statutory interpretation would merit no judicial deference.[67]

B. HRSA Changed Its Interpretation of Section 340B Without Acknowledgment or Reasoned Explanation.

HRSA's letter is arbitrary and capricious also because it ignores (and certainly does not explain) the changes in HRSA's position over time. "Agencies are free to change their existing policies as long as they provide a reasoned explanation for the change."[68] But when an agency changes its position, it "must at least 'display awareness that it is changing [its] position' and 'show that there are good reasons for the new policy.'"[69] An "[u]nexplained inconsistency in agency policy," on the other hand, makes agency action arbitrary and capricious.[70] HRSA's letter is arbitrary and capricious because it fails to explain several inconsistencies in HRSA's approach to contract pharmacy use in the 340B Program.

For one thing, HRSA's letter fails to account for and explain the statutory and regulatory history of Section 340B. That history belies the assertion in HRSA's letter that HRSA has "consistently, since the issuance of its 1996 contract pharmacy guidance," interpreted the statute to "require[] manufacturers to honor [contract pharmacy] purchases regardless of the dispensing mechanism."[71] Both the 1996 contract pharmacy guidance HRSA's letter invokes and HHS's later 2010 contract pharmacy guidance were issued *before* Section 340B was amended to require that manufacturers "offer" drugs at discounted prices—and necessarily could not have interpreted that statutory language.[72] Yet HRSA's letter relies on the statutory requirement that manufacturers "offer" discounted drugs—a requirement Sanofi satisfies, for the reasons it has explained—without explaining or even acknowledging that the agency is now basing its determination on a different provision of

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[67] *See Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2127 (2016) (denying deference where the agency "did not analyze or explain why the statute should be interpreted" as it said).

[68] *Id.* at 2125 (citing *Nat'l Cable & Telecomms. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 981–82 (2005)).

[69] *Id.* at 2126 (quoting *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009)).

[70] *Id.* (internal quotation marks and citations omitted).

[71] Letter at 1.

[72] *See* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010).

the statute than the one the agency has interpreted previously. This failure to acknowledge or explain that the agency's interpretation now rests on a new statutory provision is arbitrary and capricious.[73]

Likewise, HRSA's conclusion in its letter—based on a purported "consistent" agency interpretation "since the issuance of its 1996 contract pharmacy guidance"—fails to acknowledge and explain the inconsistencies in HHS's own historical guidance over time. HHS's 1996 guidance on contract pharmacies first allowed the use of *only* one contract pharmacy to facilitate program participation for covered entities that lacked an in-house pharmacy.[74] Importantly, that guidance *rejected* a proposal that "[c]overed entities should be permitted to contract with more than one site and contractor."[75] Later, in 2010, HHS changed course to remove the one-contract-pharmacy limit and to allow even covered entities with in-house pharmacies to use contract pharmacies.[76] Indeed, the guidance that HRSA issued in 1996 would be *unlawful* under HRSA's recent conclusion that Sanofi must offer 340B-priced drugs through "contract pharmacy arrangements, regardless of whether [the covered entities] purchase through an in-house pharmacy."[77] As the Department of Justice recently acknowledged in litigation filed by another manufacturer, HRSA's 1996 guidance is "incorrect" under the government's current interpretation.[78] But while HRSA's letter invokes the 1996 guidance, it offers no explanation to address this inconsistency in the agency's historical position—again, a hallmark of arbitrary and capricious agency action.[79]

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[73] *See Encino Motorcars*, 136 S. Ct. at 2126 (holding agency action arbitrary and capricious where it fails to "display awareness that it is changing [its] position" and "show that there are good reasons for the new policy") (quoting *Fox Television Stations*, 556 U.S. at 515).

[74] *See* 61 Fed. Reg. at 43,550, 43,555.

[75] *Id.* at 43,551.

[76] *See* 75 Fed. Reg. at 10,273.

[77] Letter at 2.

[78] *See Tr. of Oral Arg.*, Dkt. 76 at 66-67, *AstraZeneca Pharms. LP v. Becerra*, No. 21-27-LPS (D. Del.) (May 27, 2021) (reflecting government's acknowledgment that "to the extent that the 1996 guidance did limit it to just one contract pharmacy arrangement … the agency's position now is that that … reading of the statute is incorrect.").

[79] *See Encino Motorcars*, 136 S. Ct. at 2127; *Fox Television Stations*, 556 U.S. at 515.

HRSA's letter is also inconsistent with the explanation HHS articulated just months ago in Advisory Opinion 20-06[80] (the "Advisory Opinion") in its attempt to justify its conclusion that manufacturers must provide 340B-priced drugs to contract pharmacies. The Advisory Opinion purported to require contract pharmacy sales to the extent that "contract pharmacies are acting as agents of a covered entity."[81] As Sanofi has explained in litigation, HHS has offered no evidentiary support for any agency relationship between covered entities and contract pharmacies. And HRSA's letter now omits this agency theory entirely. The fact that HRSA's determination makes no mention of the theory that contract pharmacies act as agents of covered entities demonstrates that the government's rationale has apparently shifted yet again without acknowledgment, which violates the APA.[82]

C. HRSA's Determination That Sanofi's Integrity Initiative Violates Section 340B Lacks Factual Support.

HRSA apparently "completed" its review without identifying any evidence whatsoever in support of the conclusion that "Sanofi's actions have resulted in overcharges."[83] A reviewing court must set aside agency action "if the record lacks 'substantial evidence' to support [the agency's] conclusion."[84] As a result, agency action is arbitrary and capricious where the agency fails to supply "evidence" to "support its determination."[85] Likewise, it is arbitrary and capricious for an agency to ignore evidence that contradicts its conclusion without explanation.[86]

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[80] *See supra* n.3.

[81] Advisory Opinion at 1, 6.

[82] *See Encino Motorcars*, 136 S. Ct. at 2126.

[83] Letter at 1.

[84] *AT&T Corp. v. FCC*, 86 F.3d 242, 247–48 (D.C. Cir. 1996) (vacating agency order after concluding that "the record lacks substantial evidence" to support the agency's decision); *see* 5 U.S.C. § 706(2)(E).

[85] *Tripoli Rocketry Ass'n, Inc. v. Bureau of Alcohol, Tobacco, Firearms, & Explosives*, 437 F.3d 75, 82–83 (D.C. Cir. 2006) (holding agency action arbitrary and capricious where the agency "never pointed to evidence establishing the data points necessary" and the "purported evidence cited by the agency does not support its determination").

[86] *See, e.g.*, *Genuine Parts Co. v. EPA*, 890 F.3d 304, 313, 315 (D.C. Cir. 2018) (holding agency action arbitrary and capricious where the agency "ignore[d] evidence contradicting its position" and "failed to support its conclusion with substantial evidence.").

HRSA's letter offers no basis to support the conclusion that Sanofi has overcharged any covered entity. It identifies no covered entity that has been subjected to an overcharge and identifies no evidence demonstrating that such an overcharge has taken place. HRSA's apparent conclusion that overcharges have occurred is thus arbitrary and capricious.

Instead, HRSA's letter asserts that "Sanofi must … begin offering its covered outpatient drugs at the 340B ceiling price to covered entities *through their contract pharmacy arrangements*."[87] But this sleight of hand does not support the conclusion that a manufacturer's decision not to deliver 340B-discounted drugs to an unlimited number of pharmacies without condition amounts to an overcharge under the statute. HRSA's letter offers no reasoning or factual basis to support the conclusion that the statutory term "covered entity" includes contract pharmacies. Nor, again, does it point to any evidence that Sanofi has actually overcharged any covered entity. Instead, as Sanofi has explained, contract pharmacies are not among the list of "covered entit[ies]" enumerated in Section 340B.

Likewise, HRSA's letter makes no finding that any covered entity has actually obtained or retained title to the drugs at issue. HRSA's own 2010 guidance opines that a covered entity must "maintain title to the drug" to be eligible for a 340B discount.[88] But HRSA's letter does not even address whether covered entities obtain or retain title to 340B-priced drugs dispensed through contract pharmacies, let alone supply evidence to suggest that they do.

Nor does HRSA's letter offer any reasoning or evidence to support any theory that contract pharmacies actually operate as agents of covered entities or should otherwise be treated as covered entities under the statute. Indeed, while the Advisory Opinion claimed to rest on such a theory[89] (though again, absent any evidentiary support), HRSA's letter appears to have abandoned it entirely.

Moreover, any conclusion that Sanofi has overcharged covered entities would be *counter-factual*, for several reasons. *First*, as explained, Sanofi continues to offer 340B-discounted drugs to all covered entities in three ways: (i) through the covered entity's own in-house pharmacy; (ii) through a single, designated contract pharmacy, if the covered entity

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[87] Letter at 2 (emphasis added).
[88] *See* 75 Fed. Reg. at 10,277.
[89] *See* Advisory Opinion at 1, 6.

has no in-house pharmacy; and (iii) through multiple contract pharmacies, if the covered entity provides the data Sanofi requests. *Second*, when a manufacturer declines to provide a 340B discount (and instead charges standard commercial prices) for drugs shipped to a contract pharmacy, a covered entity is not "overcharged"—indeed, it typically is not charged at all under the standard "replenishment" model for contract pharmacy use.[90] *Third*, even if HRSA's May 17 letter *had* rested on the agency theory of contract pharmacy use underlying the Advisory Opinion—and it did not—the determination whether a particular contract pharmacy acts as the agent of a particular covered entity would necessarily involve a case-by-case analysis turning on principles of state agency law and the specific provisions of the contract between the covered entity and the contract pharmacy. Moreover, available public information undercuts any conclusion that contract pharmacies operate as agents of covered entities.[91]

The conclusion that Sanofi's 340B integrity initiative has resulted in overcharges prohibited by Section 340B thus "is founded on" nothing more than "unsupported assertions" and "unstated inferences" in violation of the APA.[92]

D. HRSA Failed to Recognize How Sanofi's Integrity Initiative Is Unique and Advances the Statutory Goal of Preventing Duplicate Discounting.

HRSA also acted arbitrarily and capriciously by not recognizing the unique features of Sanofi's integrity initiative, and instead viewing Sanofi's program as no different than the

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[90] HRSA, Statutory Prohibition on Group Purchasing Organization Participation, 340B Drug Pricing Program Release No. 2013-1, at 3 (Feb. 7, 2013), https://www.hrsa.gov/sites/default/files/opa/programrequirements/policyreleases/prohibitionongpoparticipation020713.pdf; *see also* HHS-OIG, *Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431, at 5 (Feb. 4, 2014), https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf (explaining that contract pharmacies dispense drugs from their own supply and then request that the covered entity "replenish" their supply at 340B prices).

[91] *See, e.g.*, 340B Contract Pharm. Servs. Agreement between Jackson Mem'l Hosp. and Walgreens, https://www.jhsmiami.org/WebApps/publicDocs/docLib/PHT_BOT_Meetings_Prior/PHT_BOT_SpecialMeeting/2016-03-23%20-%20PHT%20BOT%20SPECIAL%20MEETING%20AGENDA.pdf ("Servs. Agreement") ("Independent Contractor" provision disclaiming "any relationship between the parties hereto other than that of independent entities contracting").

[92] *Tripoli Rocketry Ass'n*, 437 F.3d at 83.

varying programs adopted by other drug manufacturers. Courts "have long held that an agency must provide adequate explanation before it treats similarly situated parties differently. … But the converse is also true. An agency must justify its failure to take account of circumstances that appear to warrant different treatment for different parties."[93] HRSA's letter violates this principle because it fails to acknowledge or account for the differences between Sanofi's integrity initiative and other drug manufacturers' programs. Sanofi's integrity initiative is unique because it merely imposes a reasonable condition on the delivery of 340B-priced drugs to contract pharmacies, designed to advance the statutory goal of preventing duplicate discounting. As explained above, Sanofi offers 340B-priced drugs to all covered entities: (i) through the covered entity's own in-house pharmacy; (ii) through a single, designated contract pharmacy, if the covered entity has no in-house pharmacy; and (iii) through multiple contract pharmacies, if the covered entity provides the data Sanofi requests. HRSA's failure to acknowledge the unique features of Sanofi's integrity initiative—or the lawful purpose motivating the integrity initiative—demonstrates that the agency's decision is arbitrary and capricious.

E. HRSA's Determination Reflects Prejudgment Without Affording Sanofi Due Process.

HRSA's letter makes plain that HRSA's view of Sanofi's integrity initiative has been predetermined from the beginning. An agency must maintain "a flexible and open-minded attitude towards its own rules"—one of the principle reasons for the APA's notice-and-comment requirement.[94] "Decisionmakers violate the Due Process Clause and must be disqualified when they act with an 'unalterably closed mind' and are 'unwilling or unable' to rationally consider arguments."[95]

HRSA's letter explains that HRSA has "completed its review" of Sanofi's integrity initiative and "determined" that it violates Section 340B.[96] Yet HRSA has reached this conclusion without ever meeting with Sanofi to allow it to explain why its integrity initiative complies with Section 340B, let alone contacting Sanofi at all—before the May 17 letter—since Sanofi announced its integrity initiative in July 2020. The administrative record HRSA

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[93] *Petroleum Commc'ns, Inc. v. FCC*, 22 F.3d 1164, 1172 (D.C. Cir. 1994).

[94] *McLouth Steel Prods. Corp. v. Thomas*, 838 F.2d 1317, 1325 (D.C. Cir. 1988).

[95] *Air Transp. Ass'n of Am., Inc. v. Nat'l Mediation Bd.*, 663 F.3d 476, 487 (D.C. Cir. 2011).

[96] Letter at 1.

has filed in litigation demonstrates that, on the other hand, HRSA *did* meet with contract pharmacies and organizations that represent covered entities before reaching the conclusion that Section 340B requires manufacturers to deliver discounted drugs to an unlimited number of contract pharmacies without condition. Likewise, the administrative record filed in Sanofi's litigation challenge to the Advisory Opinion includes a letter sent by an association of covered entities objecting to Sanofi's policy—but not Sanofi's response to that same letter.[97]

Indeed, Secretary Becerra has essentially conceded that the agency's mind is made up. On May 12, 2021, just five days before HRSA's May 17 letter, members of Congress demanded at a hearing before the House Energy and Commerce Committee that Secretary Becerra "take swift enforcement action" against manufacturers whose policies conflict with HHS's position.[98] Secretary Becerra responded in terms that make the agency's position plain: "We are on this one." HRSA's May 17 letter implements that commitment, without HRSA having offered Sanofi any opportunity to be heard or considering its position. If there were any doubt that Secretary Becerra's mind is closed, one need only recall that as Attorney General of California (and the intended nominee for Secretary of Health and Human Services), he urged the *last* Secretary of Health and Human Services to take the same action against drug companies he is now pursuing.[99]

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In sum, HRSA's May 17 letter falls far short of the basic requirement that agency action be reasonable and reasonably explained. Its determination contradicts the statute, exceeds the agency's rulemaking authority, fails to explain the agency's position—let alone its changes in position over time—and fails to support that position with reasoned explanation and evidence after considering the unique features of Sanofi's integrity initiative. HRSA's letter is a classic example of arbitrary and capricious agency decision-making.

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[97] *See* Ex. 2, Letter from A. Gluck to Secretary Azar (Aug. 13, 2020).

[98] Tom Mirga, *Breaking: Becerra, on 340B Pricing Denials, Tells House Panel, "Everyone Has to Follow the Law,"* 340B Report (May 12, 2021), *available at* Dkt. 95-4, *Eli Lilly & Co. v. Becerra*, No. 21-cv-0081 (S.D. Ind. May 20, 2021).

[99] *See* Ex. 9, Letter from Attorney General Becerra et al. to Secretary Azar (Dec. 14, 2020).

IV. Civil Monetary Penalties Would Be Inappropriate on Multiple Grounds.

Based on the conclusion set out in HRSA's letter that Sanofi has violated Section 340B, HRSA declared that HHS "will determine whether CMPs are warranted" sometime after June 1, in light of Sanofi's response.[100] There would be no basis for such penalties because, as explained, Sanofi's integrity initiative complies with the unambiguous requirement in Section 340B that manufacturers "offer" 340B-discounted drugs to covered entities. But that is far from the only reason that CMPs would be improper. HRSA has provided no evidence to support the conclusion that any overcharges have actually taken place—a statutory prerequisite to the imposition of CMPs. And even if Sanofi *had* overcharged covered entities, HRSA has provided no basis whatsoever for concluding that such overcharges were "knowing" and "intentional," as the statute requires before the agency can impose CMPs. Nor would penalties be appropriate given how the unique features of Sanofi's integrity initiative advance Congress's goal of preventing duplicate discounting while still providing 340B-priced drugs to all covered entities. Finally, any CMPs would also be constitutionally suspect for multiple reasons.

A. Sanofi's Integrity Initiative Is Fully Consistent with Section 340B.

Most importantly, there would be no basis for HHS to impose CMPs on Sanofi because, as explained, its integrity initiative complies with Section 340B. Section 340B authorizes CMPs for a manufacturer who "knowingly and intentionally charges a covered entity a price for purchase of a drug that exceeds" the 340B-discounted price.[101] But as explained, the statutory term "covered entity" does not include contract pharmacies, and the statute does not otherwise require manufacturers to deliver 340B-discounted drugs to contract pharmacies without condition. Because Sanofi's integrity initiative complies with Section 340B, there is no statutory basis for the agency to impose CMPs.

B. HRSA Has Not Identified Any Evidence That Sanofi's Integrity Initiative Has Caused Covered Entities To Be Overcharged.

Nor has HRSA identified evidence of overcharges relating to Sanofi's integrity initiative. Again, the statute authorizes CMPs for a manufacturer who "knowingly and intentionally charges a covered entity a price" exceeding the 340B-discounted price.[102]

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[100] Letter at 2.
[101] 42 U.S.C. § 256b(d)(1)(B)(vi)(III).
[102] *Id.*

But HRSA has not identified any covered entity that has been overcharged or any overcharges to which covered entities have been subjected. This is unsurprising, given that Sanofi continues to provide drugs to covered entities through an unlimited number of contract pharmacy arrangements so long as the covered entity provides Sanofi with minimal, de-identified claims data. Indeed, the one association of covered entities that has filed a complaint against Sanofi under HHS's Administrative Dispute Resolution ("ADR") regulation has likewise presented no evidence that Sanofi has overcharged its member covered entities, complaining instead that Sanofi's conditions on the delivery of 340B-discounted drugs violate the statute.[103] Moreover, as explained above and as Sanofi has also explained in litigation, under the standard replenishment model contract pharmacies use to process 340B discounts, a covered entity is typically not charged at all—let alone "overcharged"—when a manufacturer declines to provide a 340B discount (and instead charges standard commercial prices) for drugs shipped to a contract pharmacy. Only the pharmacy is charged, and because contract pharmacies are not covered entities, no covered entity is overcharged.

HRSA's regulation governing the imposition of civil monetary penalties, moreover, provides that "[a]n instance of overcharging may occur at the time of initial purchase or [because of] subsequent ceiling price recalculations due to pricing data submitted to CMS or new drug price estimations." 42 C.F.R. § 10.11(b)(4). But HRSA does not contend that any overcharges resulted from recalculations or new drug price estimations. And HRSA likewise has not identified any instance of overcharging that happened at the time of an "initial purchase." *Id.* Under the prevalent replenishment model, no overcharge happens at the time of "initial purchase"; instead, a contract pharmacy "replenish[es] [drugs sold at commercial prices] with 340B drugs [at 340B prices] once 340B patient eligibility is confirmed and can be documented through auditable records."[104]

Finally, even if HRSA's May 17 letter had rested on the agency theory of contract pharmacy use that the agency appears to have jettisoned, available public information tends to undercut any conclusion that contract pharmacies operate as agents of covered

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[103] *See* Ex. 10, ADR Complaint filed by Nat'l Ass'n of Community Health Centers, at ¶ 32.

[104] HRSA, Statutory Prohibition on Group Purchasing Organization Participation, 340B Drug Pricing Program Release No. 2013-1, *supra* n.17 at 3.

entities[105]—such that a purported "overcharge" paid by the contract pharmacy would not constitute an "overcharge" paid by the covered entity. As a result, any order for CMPs would fail to satisfy the statute's requirement that a manufacturer has "charge[d] a covered entity a price" exceeding the 340B ceiling price.

C. HRSA Could Not Prove That Sanofi Knowingly or Intentionally Violated Section 340B.

Even if Sanofi *had* somehow overcharged covered entities, HRSA has provided no basis for concluding, as the statute requires, that such overcharges were "knowing[]" and "intentional[]."[106]

The only conceivable basis for such a conclusion would be HRSA's reliance on its own interpretation of the statute. But HRSA has previously maintained that Section 340B has "many gaps" and "is silent as to permissible drug distribution systems."[107] This recognition precludes the agency from determining that Sanofi's reliance on its own reasonable interpretation of the statute—even if that interpretation ultimately proves to have been erroneous—constitutes "knowing" and "intentional" misconduct.[108] Such a position would be especially inappropriate when HRSA lacks "substantive rulemaking authority" under Section 340B,[109] and when HRSA *itself* (in the 1996 guidance) previously understood Section 340B to permit Sanofi's current approach. Although Sanofi and HRSA obviously now disagree on what Section 340B requires, there is not and could not be any suggestion that Sanofi has adopted its understanding in bad faith.

Nor could HRSA have "warned [Sanofi] away"[110] from its integrity initiative in light of the many changes in HRSA's position over time. As Sanofi has explained, *see supra* pp.

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[105] *See, e.g.*, Servs. Agreement, *supra* ("Independent Contractor" provision disclaiming "any relationship between the parties hereto other than that of independent entities contracting").

[106] 42 U.S.C. § 256b(d)(1)(B)(vi)(III).

[107] 61 Fed. Reg. at 43,549–51, 43,555.

[108] *See Safeco Ins. Co. of Am. v. Burr*, 551 U.S. 47, 70 (2007).

[109] *Id.* (holding an interpretation that was "not objectively unreasonable" fell "well short" of recklessness where the agency offering a competing interpretation lacked substantive rulemaking authority); *Pharm. Rsch. & Mfrs. of Am.*, 43 F. Supp. 3d at 35, 42 (explaining HHS lacks general rulemaking authority under Section 340B).

[110] *Safeco*, 551 U.S. at 70.

17-18, HRSA's 1996 guidance is inconsistent with its 2010 guidance, and its May 17 letter is inconsistent with its Advisory Opinion. HRSA cannot claim to have issued authoritative guidance sufficient to warn parties that consequences for knowing and intentional misconduct might follow when HRSA itself has failed to provide regulated parties with a clear and consistent statement of their legal obligations. An agency's position can only be authoritative if it is consistent, because "[a]n agency interpretation of a relevant provision which conflicts with the agency's earlier interpretation is 'entitled to considerably less deference' than a consistently held agency view."'[111] Here, moreover, HRSA acknowledged as recently as last year that it *lacked* the ability to set enforceable rules in this area. Nothing has changed that would somehow now give rise to HRSA having that ability.

HRSA's conclusion that Sanofi's integrity initiative violates Section 340B also creates unfair surprise, given the agency's shifting statutory interpretation and its recent concession in litigation that its 1996 guidance is incorrect. "To defer to the agency's interpretation in this circumstance would seriously undermine the principle that agencies should provide regulated parties 'fair warning of the conduct [a regulation] prohibits or requires.'"[112] HRSA cannot prove that Sanofi has knowingly and intentionally violated Section 340B in light of the agency's own shifting interpretations.

D. The Unique Features of—and Lawful Purpose Motivating—Sanofi's Integrity Initiative Should Preclude Civil Monetary Penalties.

Nor would CMPs be warranted in light of the significant steps Sanofi has taken to limit the burdens on covered entities and patients while still attempting to prevent the unlawful waste and abuse that have become widespread at contract pharmacies. For example, Sanofi is *not* flatly refusing to provide 340B-priced drugs to contract pharmacies. Instead, as explained, Sanofi's integrity initiative is unique because Sanofi makes 340B-priced drugs available to all covered entities in three ways: (i) through the covered entity's own in-house pharmacy; (ii) through a single, designated contract pharmacy, if the covered entity has no in-house pharmacy; and (iii) through multiple contract pharmacies, if the covered entity provides the data Sanofi requests. Because of these features, Sanofi's integrity

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[111] *INS v. Cardoza–Fonseca*, 480 U.S. 421, 446 n.30 (1987); *see also King Broad. Co. v. FCC*, 860 F.2d 465, 470 (D.C. Cir. 1988) (holding that "result reached by the agency is impermissible under the second prong of Chevron ... [because it] is inconsistent with its prior analysis in similar situations without any acknowledgement of the fact, or cogent explanation as to why").

[112] *Christopher*, 567 U.S. at 158-59.

initiative is "designed to facilitate program participation for those eligible covered entities that do not have access to appropriate 'in-house' pharmacy services."[113]

Moreover, Sanofi's initiative is designed to address the problem of duplicate discounting in the 340B Program attributable to the explosive growth of contract pharmacies. Section 340B squarely prohibits duplicate discounting. Although HRSA may believe that the integrity initiative is not an appropriate way to address manufacturer concerns about duplicate discounting,[114] HRSA cannot dispute that Sanofi designed its unique program to advance Congress's goal of preventing duplicate discounting in the 340B Program. This further underscores that Sanofi certainly did not engage in knowing and intentional misconduct, as the imposition of CMPs would require.

E. Civil Monetary Penalties Would Be Unconstitutional.

Even if Sanofi had not just overcharged covered entities but done so *knowingly and intentionally*—none of which HRSA has demonstrated—the CMPs HHS might impose would be unconstitutional for several reasons.

For one thing, those CMPs would violate the Excessive Fines Clause of the Eighth Amendment. That clause provides: "Excessive bail shall not be required, nor excessive fines imposed, nor cruel and unusual punishments inflicted."[115] The Excessive Fines Clause "limits the government's power to extract payments, whether in cash or in kind, 'as punishment for some offense.'"[116] HRSA's letter notes that the inflation-adjusted civil monetary penalty HRSA stands to impose for *each instance* of overcharging nears $6,000.[117] And as the letter explains, "[a]ssessed CMPs would be *in addition to* repayment for an instance of overcharging."[118] These fines are thus designed to punish manufacturers.[119] They are also grossly disproportionate to the purported statutory violation the government has

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[113] 61 Fed. Reg. at 43,551, 43,555.

[114] Letter at 2.

[115] U.S. Const. amend. VIII.

[116] *Austin v. United States*, 509 U.S. 602, 609–10 (1993).

[117] *See* Letter at 2 n.3.

[118] *Id.* at 2 (emphasis added).

[119] *See Vt. Agency of Nat. Res. v. U.S. ex rel. Stevens*, 529 U.S. 765, 784 (2000) (observing that treble damages under the False Claims Act are "essentially punitive in nature"); *U.S. ex rel. Drakeford v. Tuomey*, 792 F.3d 364, 389 (4th Cir. 2015) (analyzing False Claims Act damages under the Eighth and Fifth Amendments as punitive).

identified—particularly where the government has offered no evidence whatsoever that Sanofi has actually overcharged any covered entity and in light of the fact that Sanofi continues to offer 340B-discounted drugs to all covered entities, as it has explained.[120] As a result, any order imposing such CMPs would be improper under the Excessive Fines Clause.

The CMPs HHS is considering would similarly violate the Due Process Clause. "The Due Process Clause of the Fourteenth Amendment prohibits the imposition of grossly excessive or arbitrary punishments on a tortfeasor."[121] The CMPs authorized under Section 340B are, again, "essentially punitive in nature."[122] And HRSA threatens to impose these penalties on an extraordinary scale—penalizing Sanofi in an amount nearing $6,000 for *each instance* of supposed overcharging. These CMPs exceed any constitutionally permissible ratio between the punitive fine and the amount by which any covered entities have actually been overcharged—if they have been overcharged at all. The Supreme Court has observed that "few awards exceeding a single-digit ratio between punitive and compensatory damages, to a significant degree, will satisfy due process."[123] Here, where Sanofi faces CMPs in an untold amount—with no evidence of any *actual* overcharges to balance that ratio—an order for CMPs would violate the protections of due process.

HRSA's demand that Sanofi comply with its incorrect statutory interpretation on threat of CMPs also violates the Takings Clause of the Fifth Amendment. That clause protects private property from being taken for public use without just compensation.[124] And as relevant here, it prevents the government from taking private property to "confer[] a private benefit on a particular private party."[125] Such private takings are always unconstitutional, because "[n]o amount of compensation can authorize such action."[126] Yet that is exactly what HRSA now commands Sanofi to do: Provide its drugs to private

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[120] *See United States v. Bajakajian*, 524 U.S. 321, 327–28, 334 (1998); *Hudson v. United States*, 522 U.S. 93, 103 (1997).

[121] *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 416 (2003).

[122] *Vt. Agency of Nat. Res.*, 529 U.S. at 784.

[123] *Campbell*, 538 U.S. at 425; *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 581 (1996) (noting a ratio of four-to-one would approach, but not cross, the line of constitutional impropriety).

[124] *See Horne v. Dep't of Agric.*, 576 U.S. 350, 358 (2015).

[125] *Kelo v. City of New London*, 545 U.S. 469, 477 (2005).

[126] *Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528, 543 (2005).

entities—contract pharmacies—on threat of CMPs, where Section 340B does not even require it.

Relatedly, any CMPs issued as a result of HRSA's determination that Sanofi must convey its property to other private parties would impose an unconstitutional condition of Sanofi's participation in Medicare Part B and Medicaid. The unconstitutional conditions doctrine "vindicates the Constitution's enumerated rights by preventing the government from coercing people into giving them up."[127] The ability simply to reject the government's offer is irrelevant, including where it would "force[]" Sanofi to "choose between" Medicare Part B and Medicaid participation and its "right under the Fifth Amendment to just compensation."[128] Here, the government has put Sanofi to an "[e]xtortionate demand[]"[129]—to provide its drugs at a significant loss where Congress has not required it, or forfeit the ability to participate in Medicare Part B and Medicaid and suffer crippling CMPs. The unconstitutional conditions doctrine prohibits this.

V. Conclusion

Sanofi reiterates its commitment to comply with its 340B obligations. The scope of Sanofi's legal obligations under Section 340B is currently being litigated in court as part of Sanofi's good-faith disagreement with HRSA's legal position. If HRSA's legal position is ultimately upheld in the litigation, Sanofi will of course comply with its obligations under Section 340B as finally adjudicated at the conclusion of the pending litigation. In the meantime, HRSA should not penalize Sanofi for asking the court to clarify the scope of its legal obligations.

Sanofi objects to HRSA's conclusion that its integrity initiative violates Section 340B and urges HRSA in the strongest possible terms not to take any further enforcement action—particularly while the litigation involving Sanofi's integrity initiative remains pending. As we have explained, Sanofi's integrity initiative is fully consistent with Section 340B, and HRSA's contrary determination is arbitrary and capricious. Any order imposing CMPs would be baseless, inappropriate, unconstitutional, and unjustified in light of the unique features of Sanofi's integrity initiative. Sanofi has been—and remains—open to

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[127] *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 604 (2013).
[128] *Dolan v. City of Tigard*, 512 U.S. 374, 385–86 (1994).
[129] *Koontz*, 570 U.S. at 605.

meeting with HRSA to explain why its unique integrity initiative fully complies with Section 340B and why CMPs would be inappropriate.

Very truly yours,

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