UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SANOFI-AVENTIS U.S., LLC,

Plaintiff,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,

Defendants.

Civil Action No. 3:21-cv-634

PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT ON COUNTS X-XII, OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT ON COUNTS X-XII, AND REPLY IN SUPPORT OF CROSS-MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

The Department of Health & Human Services ("HHS") has now taken a trio of unlawful actions seeking to compel Sanofi-Aventis U.S. LLC ("Sanofi") to comply with new extra-statutory requirements that exceed the agency's authority under Section 340B. In early December 2020, HHS rushed out the Alternative Dispute Resolution ("ADR") Rule without complying with its obligation to give notice and provide an opportunity to comment. *See Eli Lilly & Co. v. Cochran*, No. 21-cv-00081, 2021 WL 981350, at *7–10 (S.D. Ind. Mar. 16, 2021). Later that month, HHS's general counsel issued an Advisory Opinion announcing—again without notice and comment—a new rule that, breaking with decades of agency guidance, requires drug manufacturers to deliver 340B-priced drugs to an unlimited number of contract pharmacies without condition. And then in May 2021, while Sanofi's challenges to the first two actions were pending, the Health Resources and Services Administration ("HRSA," an agency within HHS) sidestepped its own ADR Rule to find that Sanofi had violated the agency's new contract pharmacy rule—based on ex parte complaints from covered entities that HRSA never shared with Sanofi. These unlawful agency actions are the antithesis of the reasoned decision-making required by the Administrative Procedure Act ("APA"), not to mention violations of Section 340B and the U.S. Constitution.

Chief Judge Stark recognized some of these problems when he held that the

Advisory Opinion misread Section 340B. *See AstraZeneca Pharms. LP v. Becerra*, No. 21-cv-27-LPS, 2021 WL 2458063, at *11 (D. Del. June 16, 2021). In response, HHS swiftly withdrew the Advisory Opinion—with the government now asking this Court to focus on HRSA's May 17 enforcement letter (the "May 17 Letter") instead. But this game of whack-a-mole is nothing more than a distraction, when the government continues to press the same interpretation of Section 340B in this Court.

In all events, the parties agree that the Court can and should decide the validity of Sanofi's integrity initiative. Under the correct reading of Section 340B, Sanofi's integrity initiative fully complies with the statute—which neither obligates manufacturers to deliver 340B-priced drugs to contract pharmacies, nor prohibits reasonable conditions on the delivery of those drugs.

But even if Sanofi were wrong about the statute, the agency's actions must still be set aside as arbitrary and capricious. By enforcing the procedurally defective contract pharmacy rule first announced in the Advisory Opinion, HRSA repeated the same mistakes recognized by Chief Judge Stark. And HRSA committed a fundamental error by never providing Sanofi with an opportunity to respond to covered entities' complaints about the integrity initiative, despite Congress and HHS both having recognized (consistent with basic principles of due process) that such complaints cannot automatically be accepted at face value. Had HRSA given Sanofi an opportunity to respond to these complaints—as would have occurred under a

proper adjudicative process—Sanofi would have demonstrated that the complaints frequently misrepresent Sanofi's program and do not establish that Sanofi has overcharged covered entities under the statute.

Yet the agency's ADR Rule cannot provide Sanofi with a lawful adjudicative process in which to defend the integrity initiative. The Supreme Court's recent decision in *Arthrex* confirms that the ADR Rule violates Article II because ADR panelists are principal officers who have not been properly appointed. The government fumbles to answer why *Arthrex* is not controlling here, and it fails to rebut Sanofi's claim that the ADR Rule also violates Article III and the APA (as Judge Barker recognized in *Eli Lilly*). For all of these reasons, the Court should grant declaratory and injunctive relief to stop HHS's misguided attempts to interpret and enforce Section 340B, and the Court should confirm the legality of Sanofi's integrity initiative.

BACKGROUND

Much has transpired since Sanofi opposed the government's motion to dismiss and filed its motion for summary judgment. On May 17, 2021, HRSA announced its determination that Sanofi's integrity initiative violates Section 340B—the very question at issue in this case. On June 16, 2021, Chief Judge Stark held that the Advisory Opinion is invalid in the parallel *AstraZeneca* lawsuit. HHS withdrew the Advisory Opinion on June 18, 2021, and Chief Judge Stark issued a further order

vacating the Advisory Opinion on June 30, 2021. All of these developments are material to this case.

I. HRSA's May 17 Letter

Months after Sanofi filed this suit challenging the Advisory Opinion and seeking to uphold the validity of its integrity initiative, HRSA sent a letter to Sanofi baldly asserting that Sanofi's integrity initiative is "in direct violation of the 340B statute." *See* VLTR_000009 (the "May 17 Letter"). This was the first time HRSA had contacted Sanofi with *any* concerns about its integrity initiative.

The May 17 Letter enforces the rule that HHS first articulated in the Advisory Opinion. According to the May 17 Letter, Section 340B "requires" Sanofi to deliver 340B-priced drugs to contract pharmacies and "does not permit manufacturers to impose conditions on covered entities' access to 340B pricing, including the production of claims data." *Id.* Moreover, the May 17 Letter determines that "Sanofi's actions have resulted in overcharges" and threatens Sanofi with civil monetary penalties for continuing to operate its integrity initiative. VLTR_000009–10. Sanofi responded by explaining to HRSA that its integrity initiative complies with Section 340B, as it has explained in this litigation. *See* Ex. 1 at 8–13.

The administrative record for the May 17 Letter discloses everything that HRSA purportedly considered when deciding that Sanofi had violated Section 340B. One of the documents HRSA considered was the now-withdrawn and vacated

Advisory Opinion. VLTR_008048–55. But for the most part, the administrative record contains short, boilerplate complaints from covered entities. *See* ECF 85. HRSA never shared these complaints with Sanofi or asked Sanofi for its response.

Many covered entities submitted complaints without even attempting to understand or participate in Sanofi's integrity initiative. For example, many of the complaints—approximately 20%, on preliminary review—came from covered entities that are *exempt* from Sanofi's integrity initiative. *See* Ex. 2, Bray Decl. ¶ 11. Many complaints similarly reported that 340B prices were unavailable for drugs that are exempted from Sanofi's integrity initiative or not even eligible for 340B discounts, like vaccines. *See id.* ¶¶ 13, 15. Relatedly, some complaints list Sanofi's entire product list as unavailable at 340B prices, even though those entities had never previously purchased many of Sanofi's products and would have no reason to do so—for example, because the drugs treat diseases outside the clinics' purview. *See id.* ¶ 16.

Sanofi has begun taking steps to address these issues unrelated to its integrity initiative—and would have done so sooner if HRSA had provided it with this information previously. *See id.* ¶¶ 11, 14. For example, the government cites a complaint from Niles Community Health Center ("Niles"), which operates its own in-house pharmacy, noting that Niles "reported that it … was charged $410.42 for one of Sanofi's drugs—far above the applicable 340B price." Reply 7 (citing VLTR_003291). Niles contacted Sanofi the same day it complained to HRSA. *See*

Bray Decl. ¶ 14. Sanofi responded the next day and worked with the distributor to quickly resolve the issue, with Niles thanking Sanofi for its efforts. *See id.*

Notably, almost all of the covered entity complaints in the administrative record appear on the same form prepared by Apexus, HRSA's "340B Prime Vendor." The National Association of Community Health Centers ("NACHC")—which filed a formal complaint against Sanofi under the ADR Rule—appears to have helped orchestrate the coordinated submission of these complaints to HRSA. *See* VLTR_002272; VLTR_004929 (providing complaints "pre-populated with the drugs that are impacted by the actions taken by the three drug companies").[1] Indeed, the forms almost all recite the same complaint verbatim: "I am forced to pay WAC [wholesale acquisition cost] for [the drugs] for my contract pharmacies." *See* Reply 26.

The administrative record is also notable for what it does not contain. The complaints do not show (nor does the government contend) that covered entities maintain title to drugs shipped to contract pharmacies under the standard replenishment model. The administrative record does not contain any evidence demonstrating that contract pharmacies function as agents of covered entities. And a covered entity's submission of one of these generally boilerplate complaints does not

[1] A significant number (approximately 30) of the covered entities that submitted complaints to HRSA are also parties to NACHC's pending ADR proceeding against Sanofi.

demonstrate that it ever actually purchased eligible outpatient drugs at above-ceiling prices as a result of Sanofi's integrity initiative.

II. The *AstraZeneca* Opinion

On June 16, in AstraZeneca's case in Delaware, Chief Judge Stark issued an opinion holding—just as Sanofi has alleged in this case—that the Advisory Opinion is arbitrary and capricious in violation of the APA. *See AstraZeneca*, 2021 WL 2458063, at *1. Rejecting the same procedural defenses asserted by the government in this case, the court held that AstraZeneca had mounted a timely challenge to final agency action because the Advisory Opinion was "[m]aterially [d]ifferent [f]rom [HHS's] 1996 and 2010 guidance" and was "the first document in which HHS explicitly concluded that ***drug manufacturers*** are required ***by statute*** to provide 340B drugs to ***multiple*** contract pharmacies." *See id.* at *5–6 (emphasis in original).

Chief Judge Stark then rejected the Advisory Opinion on the merits, holding that HHS wrongly believed that "unambiguous statutory language mandates its conclusion" that manufacturers must deliver 340B-priced drugs to contract pharmacies—when, in fact, Section 340B "says nothing of the permissible role (if any) of contract pharmacies," and when a variety of statutory indicia "militate against the view set out in the Opinion" and "cut against HHS's position." *Id.* at *8–10.

III. HHS Withdraws the Advisory Opinion

In response to the *AstraZeneca* ruling, HHS simply withdrew the Advisory

Opinion outright, just two days after Chief Judge Stark issued his decision. *See* ECF 90. In its notice of withdrawal in this case, the government stated that it "disagree[s]" with the *AstraZeneca* opinion and asserted that Sanofi's challenge to the Advisory Opinion is "moot." ECF 90-1 at 2. But in its subsequent reply brief (to which Sanofi now responds), the government says not a word about mootness, nor does it otherwise address Sanofi's challenge to the Advisory Opinion. Instead, the government now insists that the May 17 Letter alone should be the Court's focus, along with the ADR Rule. *See* Reply 11.

In *AstraZeneca*, on June 30, 2021, after the parties submitted briefs addressing the proper remedy, Chief Judge Stark held that AstraZeneca's claims were not moot, entered summary judgment in AstraZeneca's favor on its APA claim that the Advisory Opinion is arbitrary and capricious, and vacated the Advisory Opinion. *See* Dkt. 83, *AstraZeneca Pharms. LP v. Becerra*, No. 21-cv-00027 (D. Del. June 30, 2021).

ARGUMENT

I. The Government Unlawfully Enforced Section 340B Against Sanofi.

The government's attempts to enforce Section 340B against Sanofi—through both the Advisory Opinion and the May 17 Letter—are contrary to law and arbitrary and capricious. Sanofi's integrity initiative complies with Section 340B, which neither mandates the provision of discounted drugs to contract pharmacies nor prohibits conditions on such transactions. Moreover, HRSA's determination that Sanofi's

integrity initiative violates Section 340B is arbitrary and capricious: HRSA concluded that Section 340B is unambiguous (it is not), asserted that the May 17 Letter extends a long-held and consistent agency position (it does not), and resolved claims that covered entities have been overcharged without ever hearing from Sanofi. And the May 17 Letter improperly enforces the new contract pharmacy rule announced in the since-withdrawn and vacated Advisory Opinion, even though HHS did not comply with the APA's notice-and-comment requirement when issuing that rule. Each of these defects independently precludes the government's attempt to take enforcement action against Sanofi.

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

Sanofi's integrity initiative is fully consistent with Section 340B. The government's contrary view—set forth first in the Advisory Opinion and then in the May 17 Letter—is wrong.

1. Section 340B Does Not Require Sanofi to Provide Discounted Drugs to Contract Pharmacies.

Section 340B requires drug manufacturers to "offer each covered entity covered outpatient drugs for purchase at or below" the 340B-discounted price. 42 U.S.C. § 256b(a)(1). Sanofi's integrity initiative complies with the statute because Sanofi offers 340B-priced drugs to all covered entities, Sanofi Mot. 24–29, and nothing in the statute "requires" Sanofi to provide 340B-priced drugs to contract pharmacies, VLTR_000009—as the Advisory Opinion and May 17 Letter both

erroneously concluded.

As Chief Judge Stark explained, several textual "clues … militate against the view set out in the Opinion." *AstraZeneca*, 2021 WL 2458063, at *10.[2] First, "[i]t is hard to believe that Congress enumerated 15 types of covered entities with a high degree of precision and intended to include contract pharmacies as a 16th option by implication." *Id.* Indeed, the statutory list of covered entities entitled to 340B discounts is specific and comprehensive—and it does not include contract pharmacies. *See* Sanofi Mot. 25–27.

Second, other provisions of the statute "cut against HHS's position." *AstraZeneca*, 2021 WL 2458063, at *10. Congress addressed agency and agency-type relationships elsewhere in Section 340B and related statutes—yet did not address the provision of 340B-priced drugs to contract pharmacies. *See id.*; Sanofi Mot. 27. This shows that "Congress knows how to write statutes that cover agents and contractors, but it did not do so in the 340B statute." *AstraZeneca*, 2021 WL 2458063, at *10.

Third, "legislative history is of no greater assistance to the government." *Id.* When Congress "specifically contemplated"—but decided against—"including

[2] The statute's "silen[ce] as to the role that contract pharmacies may play in connection with covered entities' purchases of 340B drugs," *AstraZeneca*, 2021 WL 2458063, at *9, does not make it *ambiguous* on that point in light of the remaining textual evidence. *See Coffelt v. Fawkes*, 765 F.3d 197, 202, 204 (3d Cir. 2014) (holding that statutory silence was not ambiguous because silence is not the same as "an ambiguity tied up with the provisions of the statute" (quotation omitted)).

language referring to drugs 'purchased and dispensed by, or ***under a contract entered into for on-site pharmacy services with***'" covered entities, that "suggests that Congress did not clearly intend to require manufacturers to deliver 340B drugs to an unlimited number of contract pharmacies." *Id.* (quoting S. Rep. No. 102-259, at 2 (1992)). Indeed, the fact that Congress did not allow the "unlimited" use of contract pharmacies, *id.*, makes perfect sense when, among other things, contract pharmacies can be thousands of miles away from the covered entities they nominally serve—hardly just "neighborhood" pharmacies as the government now tries to label them. Reply 5.[3]

In addition to identifying these interpretive signals, Chief Judge Stark rejected the government's contention that the "purchased by" language in Section 340B compels HHS's interpretation. As Chief Judge Stark explained, "[t]his provision does not directly act on covered entities and, in any event, says nothing of the permissible role (if any) of contract pharmacies." *AstraZeneca*, 2021 WL 2458063, at *9. Instead, the provision "is directed to the Secretary of HHS, requiring him to 'enter into an agreement with each manufacturer … under which the amount to be paid [for drugs] … ***purchased by*** a covered entity … does not exceed'" the ceiling price. *Id.* (quoting

[3] *See* U.S. Government Accountability Office ("GAO"), Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement, GAO-18-480, at 22 (June 2018), https://www.gao.gov/assets/700/692697.pdf.

42 U.S.C. § 256b(a)(1)). Because the provision "only indirectly imposes obligations on manufacturers," it "simply cannot bear the weight that the government places on it" as the linchpin for a purported statutory obligation to provide 340B-priced drugs to contract pharmacies. *Id.*

But even if the government were correct that manufacturers must provide to contract pharmacies all 340B-priced drugs that are "purchased by" covered entities, the government's theory collapses on its own terms. In the government's own view, covered entities must "maintain title to the drug[s]" they order. 75 Fed. Reg. 10,272, 10,277 (Mar. 5, 2010). Under the replenishment model, however, covered entities do *not* "maintain title" over 340B-priced drugs when contract pharmacies are involved. Instead, as the government itself concedes, the drugs ordered by covered entities "become[] 'neutral inventory,' and may be dispensed to any subsequent patient" that visits the contract pharmacy. ECF 93-2, Pedley Decl. ¶ 11; *id.* ¶ 5 (explaining that every drug dispensed by a contract pharmacy, whether to a covered entity's patient or not, "comes from the contract pharmacy's own inventory"); *see also* VLTR_005072 (covered entity's statement that "[w]e have put the *replenishment* of Sanofi NDCs to our contract pharmacies on hold").[4] Thus, even under HHS's own understanding of

[4] It is thus puzzling that the government criticizes Sanofi for the purported "mischaracterization" that HRSA would require "manufacturers to provide 340B-priced drugs to contract pharmacies," Reply 23, when this is exactly how the replenishment model works, as HRSA's own leadership attests. *See* Pedley Decl. ¶ 5.

when drugs are "purchased by" covered entities, manufacturers are not obligated to provide 340B-priced drugs to contract pharmacies—because covered entities do not maintain title to the drugs under the replenishment model.

The government's attempt to find support for its statutory interpretation in HHS's "duly promulgated regulations" regarding civil monetary penalties ("CMPs") is equally unpersuasive. *See* Reply 13. HHS's CMP regulations address when and how statutory violations can be penalized; using these regulations to define what violates Section 340B in the first place puts the cart before the horse. Nor, as the government belatedly argues, Reply 14, does Sanofi's integrity initiative run afoul of any prohibition on discrimination. HHS's regulatory provision that "[m]anufacturers have an obligation to ensure that the 340B discount is provided through distribution arrangements *made by the manufacturer*" does not force manufacturers to honor covered entities' side agreements with contract pharmacies. 42 C.F.R. § 10.11(b)(2) (emphasis added).

The government also cannot find support for its position in the definition of "overcharging." Reply 13. Section 340B contemplates that an "overcharge" will be accompanied by a "refund," which indicates that an "overcharge" requires a sale above the 340B ceiling price. 42 U.S.C. § 256b(d)(1)(B)(ii)(I). To that end, under HHS's regulations, an "overcharge" requires an "*actual sale* of the covered outpatient drug above the 340B ceiling price" to the covered entity. 82 Fed. Reg. 1,210, 1,224

(Jan. 5, 2017) (emphasis added); 42 C.F.R. § 10.11(b) (defining "[a]n instance of overcharging" as "any order for a covered outpatient drug … which results in a covered entity paying more than the ceiling price"). Tellingly, the government's declaration describing the replenishment model does not address what happens when a manufacturer *denies* a 340B price. As Sanofi has explained, in that circumstance, a covered entity is not charged for the drug. *See* Sanofi Mot. 28. Complaints that covered entities merely have been unable to access 340B prices thus do not support a determination that an "overcharge" has occurred.

The government's policy arguments fare no better. According to the government, Sanofi's interpretation cannot be correct because most covered entities lack an in-house pharmacy and thus need contract pharmacies in order to serve their patients. *See* Reply 15. But this policy concern rings hollow when HHS *itself* did not permit covered entities to use an unlimited number of contract pharmacies until 2010. *See AstraZeneca*, 2021 WL 2458063, at *3, 7. And the fact that Sanofi and other drug manufacturers "have historically complied with" HRSA's contract pharmacy guidance is immaterial, because Sanofi "has neither waived nor forfeited any rights to pursue its legal challenges" to the Advisory Opinion and May 17 Letter, *id.* at *8 n.13, and because Sanofi enacted the integrity initiative in response to HRSA's failure to control the explosive growth of contract pharmacy arrangements after issuing its 2010 guidance, *see* Bray Decl. ¶¶ 4–7.

At bottom, Sanofi's integrity initiative complies with the statute because Section 340B does not require manufacturers to provide 340B-priced drugs to contract pharmacies. Because the government's interpretation of Section 340B is wrong, the Court should set aside the Advisory Opinion and May 17 Letter.

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

Even if Section 340B does require providing 340B-priced drugs to all contract pharmacies, Sanofi continues to do *exactly* that—so long as covered entities provide the minimal information requested through the integrity initiative. Nothing in Section 340B prevents Sanofi from imposing this condition, which does not affect covered entities' ability to have 340B-priced drugs provided to their in-house pharmacies or, if a covered entity lacks such a pharmacy, to a contract pharmacy of its choice.

The government fails to identify *any* statutory text prohibiting conditions on an offer of 340B pricing—especially when those conditions apply only to drugs provided to contract pharmacies, *i.e.*, entities which are never mentioned in the statute. Indeed, HHS has long *permitted* manufacturers to impose conditions (such as the provision of "standard information") on offers of 340B-discounted drugs. *See* Sanofi Mot. 44–45.

Conceding (as it must) that at least some conditions are permissible—which the government tries to categorize as "ministerial" requests—the government says that "non-statutory data demands" cannot be a basis to "deny purchases by covered

entities." Reply 17. But *all* conditions are "non-statutory." *Id.* And by definition, *all* conditions can provide reason to "deny purchases," *id.*—as otherwise they would not be conditions. The government's argument thus lacks a statutory basis and cannot even be squared with itself.

Even under the government's view, Sanofi's request for minimal claims data is precisely the sort of "ministerial" condition that the government admits would be permissible. Contrary to the government's argument, *id.* at 10, the administrative record does not show that Sanofi's request imposes burdens on covered entities. The government cites a covered entity's report that Sanofi estimated its "claims upload process will take approximately five minutes" bi-weekly—hardly a heavy lift. *See* VLTR_001548.[5] And though this covered entity speculated that data manipulation would be required, that assumption was wrong—as the government would have learned had it simply asked Sanofi how the integrity initiative works. *See* Bray Decl. ¶ 20. Moreover, the fact that data submitted to Sanofi's program is de-identified and certified as HIPAA-compliant by an independent third party, *see id.* ¶ 27, resolves any risk that submission would disclose information protected under HIPAA or

[5] Another cited covered entity, *see* Reply 10, baldly described Sanofi's reporting platform as "burdensome" without further explanation. But that covered entity never attests that it actually attempted to use the reporting platform—making its assessment of the burden entirely speculative. *See* VLTR_007324.

otherwise, *see* VLTR_001546–47.[6]

The government is also wrong to describe Sanofi as requiring "an entity's *assurance of compliance with section 340B provisions*." Reply 18 (quoting 59 Fed. Reg. 25,110, 25,113–14 (May 13, 1994)). Sanofi merely asks for minimal claims data that is just a small subset of what covered entities already submit to their third-party administrators as well as to insurance companies or government payors for reimbursement. *See* Bray Decl. ¶ 19. And Sanofi uses the information only to cross-check rebates later requested by third-party payors—not to deny anything requested by the covered entities themselves. *See id.* ¶ 24. Far from undermining Section 340B's purposes, Reply 19, Sanofi's request *advances* the statutory goal of preventing duplicate discounting. In short, Sanofi's request for minimal claims data is the sort of reasonable condition that Section 340B permits.

3. The Government's Position Is Not Entitled to Deference.

The government's plea that the Court should defer to HRSA's May 17 Letter under *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944), is meritless. *See* Reply 21.[7]

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[6] Any concern that provision of this data would contravene the terms of covered entities' side agreements with contract pharmacies is purely speculative based on this administrative record and, in any event, irrelevant to what Section 340B requires of manufacturers. *See* Reply 10.

[7] The government does not claim that HHS's interpretation of Section 340B—in either the Advisory Opinion or HRSA's May 17 Letter—is entitled to deference under *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). And for good reason. As Sanofi explained, Sanofi Mot. 25, HHS is not entitled to *Chevron* deference because Congress has not delegated HHS authority to make rules

Skidmore embodies a particularly weak form of deference, under which an agency's legal interpretation is "entitled to respect" "only to the extent that" it has the "power to persuade." *Christensen v. Harris Cnty.*, 529 U.S. 576, 587 (2000). For example, the Third Circuit has deferred to the government's view under *Skidmore* when there was "[n]o clearer alternative[]" interpretation. *United States v. Miller*, 833 F.3d 274, 281 (3d Cir. 2016); *see also, e.g.*, *Dodge v. Comptroller of Currency*, 744 F.3d 148, 155–56 (D.C. Cir. 2014). As a result, even if the Court sees the government's understanding as a potentially "permissible" interpretation of Section 340B, Reply 20, the government's interpretation is nonetheless not entitled to any persuasive weight under *Skidmore* because Sanofi offers the best reading of the statute.

But even if Sanofi did not offer the best reading of Section 340B, the government's interpretation is still not entitled to deference under the factors that courts consider when deciding how much weight (if any) to accord to an agency's interpretation under *Skidmore*—which include "the thoroughness evident in [the agency's] consideration, the validity of its reasoning, its consistency with earlier and

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"to carry out all the provisions of the 340B program." *Pharm. Rsch. & Mfrs. of Am. v. HHS*, 43 F. Supp. 3d 28, 42 (D.D.C. 2014); *see also United States v. Mead Corp.*, 533 U.S. 218, 226–27 (2001). Nor would *Chevron* deference be appropriate in light of the government's erroneous conclusion that Section 340B is unambiguous. Reply 21; VLTR_000009; *AstraZeneca*, 2021 WL 2458063, at *8; *Peter Pan Bus Lines, Inc. v. Fed. Motor Carrier Safety Admin.*, 471 F.3d 1350, 1354 (D.C. Cir. 2006) ("*Chevron* step 2 deference" is reserved only "for those instances when an agency recognizes that the Congress's intent is not plain from the statute's face").

later pronouncements," and any other "factors which give it the power to persuade." *Mercy Cath. Med. Ctr. v. Thompson*, 380 F.3d 142, 155 (3d Cir. 2004). Here, the May 17 Letter's *ipse dixit* reasoning suggests no "thoroughness." *Id.* at 155; *see also, e.g.*, *Packard v. Pittsburgh Transp. Co.*, 418 F.3d 246, 253 (3d Cir. 2005) (affording a brief letter no deference under *Skidmore*); *Fox v. Clinton*, 684 F.3d 67, 80 (D.C. Cir. 2012) (finding persuasive power to be "virtually nil" where letter was "neither adequately explained … nor supported by agency precedent"). And as Chief Judge Stark noted, the government's interpretation "has not remained constant but has, instead, evolved over time," *AstraZeneca*, 2021 WL 2458063, at *6, which "militate[s] against affording [*Skidmore*] deference," *Mercy Cath. Med. Ctr.*, 380 F.3d at 155; *see Hornbeck Offshore Transp., LLC v. U.S. Coast Guard*, 424 F. Supp. 2d 37, 50 (D.D.C. 2006) (holding inconsistency in agency rationale "defeats any claim to *Skidmore* deference").

Indeed, the government cites *no* case crediting an agency's inconsistent statutory interpretation with deference. *See* Reply 21–22. Every case cited by the government instead deferred to a longstanding agency interpretation that had never changed. *See Hagans v. Comm'r of Soc. Sec.*, 694 F.3d 287, 305 (3d Cir. 2012) (deferring to ruling where agency had "consistently applied this policy during the past 20 years"); *Hayes v. Harvey*, 903 F.3d 32, 47 (3d Cir. 2018) (en banc) (deferring to "longstanding" and "consistent" agency position "adopted contemporaneously" with relevant statutory language); *Dep't of Lab. v. Am. Future Sys., Inc.* 873 F.3d 420, 428–29 (3d Cir.

2017) (deferring to "longstanding and unchanging" agency rule that had been ratified by Congress). *Skidmore* deference thus cannot help the government.

At bottom, the government advances a view that it may have come to believe is good policy, but that simply is not supported by the text of the statute that Congress enacted, nor even by HHS's past, non-binding guidance. This Court should enforce Section 340B as written and reject the government's position.

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

Even if the government's reading of Section 340B were correct, HRSA's May 17 letter should still be set aside because it is arbitrary and capricious in several respects—including for reasons identified by Chief Judge Stark in *AstraZeneca*.

1. HRSA Erroneously Concluded That Section 340B Unambiguously Prohibits Sanofi's Integrity Initiative.

Just as Chief Judge Stark explained with respect to the Advisory Opinion, the May 17 Letter is "legally flawed" because HRSA "wrongly determine[d] that purportedly unambiguous statutory language mandates its conclusion regarding covered entities' permissible use of an unlimited number of contract pharmacies." *AstraZeneca*, 2021 WL 2458063, at *8. The May 17 Letter also incorrectly concluded that Section 340B unambiguously prohibits Sanofi from placing reasonable conditions on the provision of 340B-priced drugs to contract pharmacies. Because "deference to an agency's interpretation of a statute is not appropriate when the agency wrongly

believes that interpretation is compelled by Congress," *id.* at *11 (quoting *Peter Pan Bus Lines, Inc. v. Fed. Motor Carrier Safety Admin.*, 471 F.3d 1350, 1354 (D.C. Cir. 2006)), the May 17 Letter—just like the Advisory Opinion—is arbitrary and capricious, *id.* (citing *Am. Lung Ass'n v. EPA*, 985 F.3d 914, 944 (D.C. Cir. 2021)).

To be sure, the May 17 Letter is not as explicit as the Advisory Opinion was in concluding that Section 340B unambiguously prohibits Sanofi's program. But the letter's language nonetheless makes clear that HRSA sees no statutory ambiguity. Just as the Advisory Opinion "asserts that its conclusions are compelled by the 'plain meaning' of the 340B statute," *id.* at *4, HRSA's May 17 Letter determined that "Sanofi's actions … are in direct violation of the 340B statute" without providing any analysis beyond a recitation of the statutory text. Moreover, the letter stated—without analysis—that Sanofi's statutory obligation to offer the 340B price to covered entities "is not qualified" or "restricted" in any way, that "[n]othing in the 340B statute" supports conditions on 340B pricing, and that it is "plain" "that the 340B statute requires manufacturers to honor such purchases regardless of the dispensing mechanism." May 17 Letter at 1. None of this language evinces even a hint of recognition that Section 340B is, at best for the government, ambiguous about these issues. Lest there be any doubt on the matter, the government now defends HRSA's

view that Section 340B lacks any "ambiguity regarding" these matters. Reply 21.[8]

Nor should HRSA's misunderstanding of Section 340B come as a surprise. When HRSA issued the May 17 Letter, the Advisory Opinion—issued by the general counsel of HHS, who provides legal advice to HRSA—was still on the books and spelled out the agency's view that Section 340B was unambiguous. Although the agency quickly jettisoned the Advisory Opinion after Chief Judge Stark rejected its analysis, the same misunderstanding of the statutory text unquestionably served as the basis for the May 17 Letter. Indeed, the Advisory Opinion is part of the May 17 Letter's Administrative Record. *See* VLTR_008048–55 (citing Advisory Opinion). Because HRSA's May 17 Letter "is based on the 'unjustified assumption' that Congress imposed [its] interpretation as a statutory requirement," *AstraZeneca*, 2021 WL 2458063, at *11, the May 17 Letter should be set aside as arbitrary and capricious.

2. HRSA Erroneously Concluded That Its Interpretation of Section 340B Has Been Consistent.

HRSA also repeated the Advisory Opinion's legal error by failing to acknowledge that "the government's interpretation of manufacturers' obligations under the 340B Program has not remained constant but has, instead, evolved over time." *AstraZeneca*, 2021 WL 2458063, at *6. This "'[u]nexplained inconsistency' in

[8] If HRSA's May 17 Letter actually treated Section 340B as *ambiguous* (despite saying no such thing), that would have been yet another unacknowledged departure from the Advisory Opinion. *See infra* Part II.B.2.

agency policy is 'a reason for holding an interpretation to be an arbitrary and capricious change from agency practice.'" *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016).

As Chief Judge Stark held, the Advisory Opinion violated this APA requirement by concluding that "the government's interpretation of the statute has been consistent throughout the past 25 years." *AstraZeneca*, 2021 WL 2458063, at *4 (citing Advisory Opinion 4–5); *see also* Sanofi Mot. 39. In fact, the Advisory Opinion is "[m]aterially [d]ifferent" from HHS's 1996 and 2010 guidance, because "Congress did not codify the 'must offer' requirement until … after HRSA issued the 2010 Guidance;" "the focus of the Opinion is different from the focus of the 1996 and 2010 Guidance;" and "the mode of analysis in the Opinion is different from the mode of analysis employed in the 1996 and 2010 Guidance." *AstraZeneca*, 2021 WL 2458063, at *5–6. The government has even conceded that its 1996 guidance is "wrong." *Id.* at *6 n.10. Chief Judge Stark thus concluded "that the Opinion is the first document in which HHS explicitly concluded that **drug manufacturers** are required **by statute** to provide 340B drugs to multiple contract pharmacies." *Id.* at *6.[9] The government's "failure to accept th[e] reality" that its current interpretation

[9] As Chief Judge Stark observed, the fact that AstraZeneca's program—like Sanofi's, *see* Sanofi Mot. 32—would have *complied* with the 1996 guidance illustrates that the government's position has changed over time. *See AstraZeneca*, 2021 WL 2458063, at *6.

of Section 340B differs from prior agency guidance does not "change the fact that the government's interpretation of the statutory obligations of drug manufacturers has actually changed." *Id.* at *6 n.11 (citing *Encino Motorcars*, 136 S. Ct. at 2126).

HRSA's May 17 Letter committed the same error. That letter stated that HRSA "has made plain, *consistently since the issuance of its 1996 contract pharmacy guidance*, that the 340B statute requires manufacturers to honor [340B] purchases regardless of the dispensing mechanism." May 17 Letter at 1 (emphasis added). As Chief Judge Stark explained, however, HRSA's position "has not remained constant but has, instead, evolved over time." *AstraZeneca*, 2021 WL 2458063, at *6. Chief Judge Stark also rejected HRSA's reliance on isolated statements in its earlier guidance, explaining "that, throughout the past 25 years, the government has dramatically expanded how covered entities may purchase 340B drugs." *Id.* at *7. The court thus held that "it is inaccurate to insist that manufacturers' duties have never changed" under HRSA's understanding of the statute. *Id.* The government's belated argument that its interpretation has actually been consistent since 1994, *see* Reply 18–19, only underscores how, in light of its narrower 1996 guidance, the government's interpretation of the statute has changed over time.

The government's insistence that Chief Judge Stark improperly analyzed whether it has previously permitted covered entities to use multiple contract pharmacies, as opposed to whether it has always required manufacturers to deliver to

them, is a distinction without difference. *See id.* at 20 n.9, 22 n.11. As Chief Judge Stark explained, when the government now contends—but previously did not—that manufacturers must provide drugs anywhere covered entities wish to receive them, the government's understanding of manufacturers' obligations has necessarily varied over time as HHS's guidance has evolved. *AstraZeneca*, 2021 WL 2458063, at *7.

HRSA's May 17 Letter also departed from the Advisory Opinion's requirement that manufacturers must deliver 340B-priced drugs to contract pharmacies only "to the extent contract pharmacies are acting as agents of a covered entity." Advisory Opinion at 1, 6. The May 17 Letter does not even *mention* whether the supposedly "overcharge[d]" covered entities have agency relationships with contract pharmacies. May 17 Letter at 1. Although the government now tries to downplay the Advisory Opinion's "reference to an agency relationship" as "merely an example," Reply 28, it was in fact the Advisory Opinion's core reasoning "that the covered entity and contract pharmacy are not distinct, but function as principal-agent." Advisory Opinion at 6. HRSA's abandonment of the Advisory Opinion's agency requirement is little surprise—none of the administrative records include any evidence demonstrating an agency relationship between covered entities and contract pharmacies—but the agency's failure to acknowledge and explain this shift is further reason that the May 17 Letter is arbitrary and capricious and should be vacated.

3. HRSA Erroneously Adjudicated Covered Entity Complaints Against Sanofi Ex Parte.

HRSA also acted arbitrarily and capriciously by adjudicating covered entity complaints against Sanofi ex parte, without ever providing Sanofi with an opportunity to see or rebut those complaints. Covered entities' complaints cannot be accepted at face value, because it was critical that the agency at least *hear* from Sanofi before the agency "determined that Sanofi's actions . . . are in direct violation of the 340B statute." VLTR_000009.

This much is clear from Section 340B itself, which directs that HHS create "an *administrative process* for the resolution of claims by covered entities that they have been overcharged." 42 U.S.C. § 256b(d)(3)(A) (emphasis added); *see also id.* § 256(b)(d)(1)(B)(ii) (providing for "procedures for manufacturers to issue refunds to covered entities in the event that there is an overcharge … including … an explanation of why and how the overcharge occurred"). Similarly, HHS has long been clear—both in the ADR Rule and in earlier guidance—that a manufacturer must be given an opportunity to respond to a covered entity's complaint. 42 C.F.R. § 10.21(a) (requiring service on "opposing party"), *id.* § 10.21(f) (allowing for "written response to the Petition"); *see also* Manufacturer Audit Guidelines and Dispute Resolution Process 0905-ZA-19, 61 Fed. Reg. 65406-01 (Dec. 12, 1996) (providing "for a response to or rebuttal of the allegations"). Anything less would raise serious due process concerns. *See, e.g.*, *Reeve Aleutian Airways, Inc. v. United States*, 982 F.2d 594,

599 (D.C. Cir. 1993) ("Due process requires notice reasonably calculated … to apprise interested parties of the pendency of the action *and afford them an opportunity to present their objections*") (internal quotation marks and citation omitted); *U.S. Lines, Inc. v. Fed. Mar. Comm'n*, 584 F.2d 519, 539 (D.C. Cir. 1978) ("The inconsistency of secret [e]x parte contacts with the notion of a fair hearing and with the principles of fairness implicit in due process has long been recognized."). It would also be arbitrary and capricious for an agency to "fail[] to consider an important aspect" of a complaint by refusing to consider the manufacturer's response. *Motor Vehicles Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

With the May 17 Letter, however, HRSA deprived Sanofi of a fair process by determining ex parte—based exclusively on "the complaints HRSA has received from covered entities"—"that Sanofi's actions have resulted in overcharges." VLTR_000009–10. As per the government, HRSA concluded that the covered entities who had complained to the agency "were, in fact, forced to pay higher prices as a result of Sanofi's policy." Reply 4–11, 24, 26. Assuming that a manufacturer's decision not to provide drugs to contract pharmacies at 340B prices could *ever* result in an "overcharge" under the statute—and it cannot, for the reasons Sanofi has explained—complaints that a covered entity has been overcharged should not be automatically accepted at face value, as HRSA has done here. If the statutory requirement for an administrative dispute resolution process stands for anything, it is

that such complaints must be subjected to adversarial testing—not accepted blindly in an enforcement proceeding.

HRSA's failure to give Sanofi an opportunity to see and rebut the overcharge complaints was thus arbitrary and capricious. *See Kelly v. R.R. Ret. Bd.*, 625 F.2d 486, 491–92 (3d Cir. 1980) (holding agency action that "failed to adhere to [the agency's] own regulations … [was] illegal and of no effect."). The agency has itself recognized the importance of hearing manufacturers' responses to covered entities' complaints—going so far in the ADR Rule as even to subject those complaints to the Federal Rules of Civil Procedure and Evidence. *See* 42 C.F.R. § 10.23(b), (c). And HRSA would have benefited from adversarial testing of the covered entities' complaints here. *See Jicarilla Apache Nation v. U.S. Dep't of Interior*, 613 F.3d 1112, 1119 (D.C. Cir. 2010) (holding agency action arbitrary and capricious for "fail[ure] to consider an important aspect of the problem") (quoting *State Farm*, 463 U.S. at 43).

Had it been given the opportunity, Sanofi would have explained why HRSA should not have credited the complaints in the administrative record. For example, the vast majority of the covered entities that submitted complaints to HRSA do not allege having *actually* purchased drugs at prices above the 340B ceiling price as a result of Sanofi's integrity initiative. These complaints, even if true, could not establish that an overcharge has occurred. Instead, as the government recounts, the forms generally report verbatim: "I am forced to pay WAC [wholesale acquisition cost] for these

products for my contract pharmacies." Reply 5. But a report that a covered entity could not purchase a drug at the 340B price is not the same as confirmation that it *has* purchased the drug above the ceiling price.[10]

The complaints highlighted by the government illustrate this problem. For example, Blue Ridge Medical Center's complaint that it is "forced to pay [wholesale acquisition cost]" for 340B drugs delivered to its contract pharmacies, Reply 4, is unaccompanied by any evidence that Blue Ridge Medical Center actually purchased 340B-eligible drugs at wholesale acquisition cost. *See* VLTR_001602–05. The same is true of complaints submitted by Lancaster Health Center, Reply 4, and Windrose Health Network, Reply 5. *See* VLTR_003302–05, 6649–52.

Indeed, at least some of the covered entities that submitted complaints to HRSA have *not* purchased drugs at wholesale acquisition cost. Sanofi itself is not informed when a purchase is made at wholesale acquisition cost without 340B pricing.

[10] Nor do the handful of reports in the administrative record alleging that a covered entity actually has paid more than the 340B ceiling price demonstrate that an overcharge has occurred. An overcharge occurs only when Section 340B requires a drug to be provided at a discounted price; but Section 340B does not require manufacturers to offer 340B discounts for drugs provided to contract pharmacies. The government's examples—from Beverly Hospital and Kearney County Health Services, Reply 4—again illustrate its failure of proof. Far from showing that covered entities purchased drugs that should have received a 340B discount, those complaints leave open the possibility—and in some cases, *demonstrate*—that the covered entities simply ordered drugs that replenished the stocks of contract pharmacies, with the covered entity never even taking title to the drug. *See* VLTR_003159.

See Bray Decl. ¶ 12.[11] But Sanofi has confirmed with the distributor that 26 Health, Alliance for Living, Presence St. Francis Hospital, Presence St. Mary's Hospital, Presence Sts. Mary & Elizabeth Medical, and Columbia St. Mary's (Milwaukee Campus)—all of which submitted complaints that the government highlights in its brief[12]—*have not* purchased 340B-eligible Sanofi drugs at wholesale acquisition cost. *See id.* HRSA's determination that Sanofi has "overcharged" these entities thus rests on the fiction—inconsistent with basic English as well as the government's own regulatory interpretation—that an entity is "overcharged" any time 340B pricing is unavailable, regardless of whether a higher price is charged.

In light of these facts, Sanofi was significantly prejudiced by HRSA's determination that all of the complaining covered entities have been overcharged and are entitled to monetary relief. Not only did HRSA order Sanofi to "credit or refund

[11] Although the government contends that "Sanofi's arbitrary-and-capricious claim should be decided on the basis of the administrative record," Reply 24 n.13, the government filed its own extra-record declaration purportedly in response to an amicus brief. This Court can consider Mr. Bray's declaration, not only because the government has opened the door to it, but also because the "record may be supplemented to provide, for example, background information or evidence of whether all relevant factors were examined by an agency." *AT&T Info. Sys., Inc. v. GSA*, 810 F.2d 1233, 1236 (D.C. Cir. 1987) (per curiam); *see also Esch v. Yeutter*, 876 F.2d 976, 991–992, 993 (D.C. Cir. 1989) ("Consideration of all relevant factors includes at least an effort to get both sides of the story").

[12] *See* Reply 5 (citing VLTR_000139 (26 Health); 321 (Alliance for Living); 405 (Presence St. Francis Hospital); 443 (Presence St. Mary's Hospital); 473 (Presence Sts. Mary & Elizabeth Medical); 848 (Columbia St. Mary's—Milwaukee Campus)).

all covered entities for overcharges that have resulted from Sanofi's policy," VLTR_000010, HRSA also threatened Sanofi with civil monetary penalties of nearly $6,000 for each supposed overcharge, *id.*—even though Sanofi never had a chance to rebut the covered entity complaints on the merits.[13]

In addition, HRSA sanctioned Sanofi based on complaints filed before Sanofi had received fair notice of the rule enforced in its May 17 Letter—namely, that manufacturers must provide 340B-priced drugs to an unlimited number of contract pharmacies without condition, and that "not allowing covered entities to reap the benefits of the 340B statute" amounts to an "overcharge" even if the covered entities are *never even charged*. Reply 26. "It is a basic principle of administrative law that an agency cannot sanction an individual for violating the agency's rules unless the individual had 'fair notice' of those rules. *SNR Wireless LicenseCo, LLC v. FCC*, 868 F.3d 1021, 1043 (D.C. Cir. 2017); *see also FTC v. Wyndham Worldwide Corp.*, 799 F.3d 236, 251 (3d Cir. 2015); *Gen. Elec. Co. v. EPA*, 53 F.3d 1324, 1334 (D.C. Cir. 1995); *Trinity Broadcasting of Fla., Inc. v. FCC*, 211 F.3d 618, 632 (D.C. Cir. 2000).

But here, before the Advisory Opinion was issued in December 2020, there

[13] The government does not dispute that the May 17 Letter is final agency action, or that HRSA has finally "determin[ed]," VLTR_000009, that Sanofi "has, in fact, overcharged covered entities," Reply 27. The only question that remains, according to the May 17 Letter, is "whether CMPs are warranted," VLTR_000010—a question distinct from whether a violation has occurred.

was never any suggestion from HHS that a program like Sanofi's integrity initiative might violate Section 340B. Before then, HRSA had merely "encouraged all manufacturers to sell 340B priced drugs to covered entities directly and through contract pharmacy arrangements," ADVOP_001597-98, because HRSA lacks general rulemaking authority under Section 340B, *Pharm. Rsch. & Mfrs. of Am. v. HHS*, 43 F. Supp. 3d 28, 35 (D.D.C. 2014). Nor did Sanofi hear any specific concerns from HRSA about its particular program; although HRSA had expressed concern in advance of the Advisory Opinion about *other* manufacturers' limitations on contract pharmacies, none of those manufacturers had a program like Sanofi's. *Cf.* Reply at 3. HRSA's May 17 Letter is accordingly arbitrary and capricious because it seeks to impose liability for supposed overcharges that preceded the Advisory Opinion. *See* Bray Decl. 7 n.5 (alleged overcharges pre-dating the Advisory Opinion).

On top of this, before HRSA's May 17 letter, HRSA never expressed the view that an "overcharge" could exist when a covered entity was not charged at all, simply because the covered entity was not allowed to order 340B-priced drugs for delivery to a contract pharmacy. Again, under HHS's regulations, "it is the *actual sale* of the covered outpatient drug above the 340B ceiling price by the manufacturers *to the covered entity* that is the subject of the overcharge." 82 Fed. Reg. at 1,224 (emphases added); *see also* 42 C.F.R. § 10.11(b) (defining "[a]n instance of overcharging" as "any order for a covered outpatient drug … which results in a covered entity paying more

than the ceiling price"). When there is no sale at all, Sanofi understood that there can be no overcharge—and, until the May 17 Letter, one would have thought that HRSA must agree. For all of these reasons, the May 17 Letter is arbitrary and capricious.

Finally, the government's new arguments in this litigation cannot save the May 17 Letter, which can be "upheld, if at all, on the basis articulated by the agency itself." *State Farm*, 463 U.S. at 50. The May 17 Letter determines that Sanofi's actions "have resulted in overcharges." VLTR_000009. But it does not advance the government's novel litigation theory that an overcharge occurs even when no above-ceiling-price sale has taken place. Reply 25–26. Far less does the May 17 Letter make a complaint-by-complaint determination that Sanofi's integrity initiative has resulted in overcharges, as the government attempts to show in this litigation. Nor does anything in the May 17 Letter support the government's present contention that drugs are "purchased by" covered entities when they are nevertheless provided to contract pharmacies to become neutral inventory. *See id.* HRSA's Letter must be judged on its own terms, and, for the reasons explained, falls short of the APA's reasoned decision-making requirement.

C. HRSA Enforced a Procedurally Defective Legislative Rule That Did Not Go Through the APA's Notice-and-Comment Process.

HRSA's May 17 Letter is also procedurally flawed because it enforced a new legislative rule—the rule regarding contract pharmacies first announced in the Advisory Opinion—that was never subject to APA notice-and-comment. Because

that rule is procedurally defective, HRSA cannot lawfully enforce it against Sanofi.

As Sanofi explained, the Advisory Opinion announced a new legislative rule by imposing new obligations on drug manufacturers with the force and effect of law. Sanofi Mot. 40–44; *see also AstraZeneca*, 2021 WL 2458063, at *7 (explaining that the Advisory Opinion "has legal consequences for" drug manufacturers). As per the Advisory Opinion, "pharmaceutical manufacturers are 'obligated' and cannot 'refuse' to provide 340B drugs to multiple pharmacies who contract with covered entities." *Id.* "That language is mandatory and conveys at least the impression that HHS expects 'immediate compliance.'" *Id.* HHS's use of this "mandatory language" when announcing its rule about contract pharmacies reflects the agency's intent to adopt a "binding" legislative rule. *Gen. Elec. Co. v. EPA*, 290 F.3d 377, 383 (D.C. Cir. 2002). As a result, this rule needed to go through notice-and-comment process in order to comply with the APA. *See* Sanofi Mot. 40–43.

Although the Advisory Opinion has now been withdrawn by the agency and judicially vacated, HRSA's May 17 Letter nonetheless still enforces the Advisory Opinion's new legislative rule against Sanofi. Just as the Advisory Opinion opined that manufacturers are "obligated to deliver its covered outpatient drugs to [] contract pharmacies and to charge the covered entity no more than the 340B ceiling price for those drugs," and to do so without "condition," Advisory Opinion at 1, 5, the May 17 Letter concluded that "Sanofi must immediately begin offering its covered outpatient

drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements" and could not "place conditions" on such sales. VLTR_000009–10.

The fact that the Advisory Opinion is now technically off the books is beside the point. The Advisory Opinion was still in effect when HRSA issued the May 17 Letter, and HRSA's letter plainly enforced the Advisory Opinion when Section 340B itself is "silent as to the role that contract pharmacies may play in connection with covered entities' purchases of 340B drugs." *AstraZeneca*, 2021 WL 2458063, at *9. The fact that HRSA began collecting complaints from covered entities before the Advisory Opinion, Reply at 11, is meaningless when the May 17 Letter was issued afterwards. And even though the May 17 Letter does not mention the Advisory Opinion, HRSA nonetheless relied upon the Advisory Opinion when formulating the letter, which adopted the same erroneous interpretation of Section 340B. *See* VLTR_008048–55. Moreover, HRSA's May 17 Letter warns "that failure to conform [to this interpretation] will bring adverse consequences." *Gen. Elec.*, 290 F.3d at 383. The government's contention that HRSA's Letter "does not 'enforce' the AO," Reply 29, thus would require the Court to "exhibit a naiveté from which ordinary citizens are free," *Dep't of Com. v. New York*, 139 S. Ct. 2551, 2575 (2019).

The Court thus should set aside the May 17 Letter because HRSA cannot lawfully enforce against Sanofi a legislative rule that was promulgated without following the APA's notice-and-comment requirement. *See Nat'l Mining Ass'n v.*

McCarthy, 758 F.3d 243, 252 (D.C. Cir. 2014) (explaining that the government cannot "impose legally binding obligations … on regulated parties … that would be the basis for an enforcement action" without notice-and-comment rulemaking); *Jones v. Espy*, No. 90-cv-2831, 1993 WL 102641, at *10 (D.D.C. Mar. 17, 1993) (holding that a rule "cannot be enforced against plaintiffs without first being subject to notice and comment.").[14]

II. The ADR Rule Is Substantively and Procedurally Unlawful.

In addition to setting aside the May 17 Letter and Advisory Opinion, the Court should also set aside the ADR Rule as a violation of the Constitution and the APA.

A. The ADR Rule Violates Article II.

Sanofi demonstrated in its opening brief that "[t]he finality of ADR panelists' decisions makes them principal officers" whose appointments violate Article II. Sanofi Mot. 64. Any doubt on that score was eliminated by the Supreme Court's recent decision in *United States v. Arthrex, Inc.*, 141 S. Ct. 1970 (2021).

Arthrex held that administrative patent judges ("APJs") are principal officers under Article II, who thus must be presidentially appointed and Senate-confirmed, because they had "'power to render a final decision on behalf of the United States'"—

[14] To be clear, Sanofi does not argue that the May 17 Letter is *itself* a legislative rule subject to the APA's notice-and-comment requirement—but instead that the letter enforces the legislative rule announced in the Advisory Opinion, which never went through notice and comment. *Bimini Superfast Operations LLC v. Winkowski*, 994 F. Supp. 2d 106 (D.D.C. 2014), which the government cites, is thus inapposite.

specifically, decisions reconsidering patents—without "review by a superior executive officer." *Id.* at 1976–77, 1980–81 (quoting *Edmond v. United States*, 520 U.S. 651, 665 (1997)). This was so even though a properly appointed principal officer (the Director of the Patent and Trademark Office) was *otherwise* "the boss" of APJs: the Director could promulgate procedural regulations and substantive guidance, designate past APJ decisions as precedential, select the APJs for each panel, decide whether to institute APJ proceedings in the first place, and stop a proceeding "if he catches wind of an unfavorable ruling on the way." *Id.* Moreover, the Director could even remove APJs from *assignments* "without cause" and thus prevent them from serving on future panels. *Id.* at 1982. Despite all these mechanisms for control over APJs, the Supreme Court nonetheless held that the APJs' appointments were unconstitutional absent a "means of countermanding [a] final decision already on the books." *Id.*

Arthrex controls this case. Here, as in *Arthrex*, ADR panelists indisputably issue significant "final decision[s] on behalf of the United States" without "review by a superior executive officer." *Id.* at 1981; *see* Sanofi Mot. 62. Section 340B and the ADR Rule both make this clear, by providing that panel decisions are "final agency decision[s]." 42 U.S.C. § 256b(d)(3)(C); 42 C.F.R. § 10.24(d). Indeed, the government has already admitted that ADR panel decisions are "final agency decisions" that are "not subject to direct review by a superior officer." DOJ Mot. 37–38. The inability of a principal officer to review ADR panel decisions is dispositive under *Arthrex*.

But the Appointments Clause problem with the ADR Rule is actually worse, because the Secretary's supervisory tools are significantly weaker than those deemed inadequate in *Arthrex*. Unlike the PTO Director, the Secretary cannot remove ADR panelists from panels without cause, *see* Sanofi Mot. 66–67; decide which ADR panel decisions are precedential; determine whether an ADR proceeding will be instituted; or stop a proceeding if he presages an unfavorable decision. So even if the Secretary might have some "tools for control[ling]" ADR panelists, DOJ Mot. 37, they are inadequate under *Arthrex* because they do not permit review of particular decisions.

Worse still, ADR panelists are more insulated than the APJs in *Arthrex* who (the Court assumed) could be removed from assignments without cause, 141 S. Ct. at 1981–82.[15] *See* Sanofi Mot. 66–67. *Arthrex* instructs that the constitutionally relevant supervision concerns when officers actually "exercis[e] … their power to issue [final] decisions." 141 S. Ct. at 1980. The government is thus wrong to focus on Board removal rather than panel removal—*i.e.*, the context in which ADR panelists actually exercise power—and to analogize to the removal of principal officers by impeachment, Reply 32. *See* Sanofi Mot. 66–67. And regardless, any removal power

[15] The government briefly asserts that the Rule does not constrain the Secretary's removal power. Reply 32, 33 n.15. But by authorizing one method for removing a panelist—for the HRSA Administrator to do so, but only for cause—the ADR Rule reserves no residual removal authority to the Secretary. *See Travelers Indem. Co. of Ill. v. DiBartolo*, 171 F.3d 168, 171–72 (3d Cir. 1999) (applying expressio unius canon to regulation).

does not enable the Secretary to "review" or "countermand[]" panel decisions "already on the books"—the issue "'significant' to the outcome" in both *Arthrex* and *Edmond*. *Arthrex*, 141 S. Ct. at 1981–82 (quoting *Edmond*, 520 U.S. at 665).

The government's contention that *Arthrex* is distinguishable because the Secretary can "overturn[] a panel decision with which he disagrees" cannot be squared with Section 340B. Reply 32. Section 340B expressly mandates that panel decisions be "*final* agency decision[s]"—meaning that ADR panels, not the Secretary, have the final word. 42 U.S.C. § 256b(d)(3)(C) (emphasis added). The statute also dictates that panel decisions "bind[]" the parties "unless invalidated by … a court," which excludes the possibility that the Secretary could invalidate them. *Id.*

Nor is the government's position consistent with the ADR Rule itself, which denies the Secretary "discretion" to review ADR panel decisions. Reply 31–32. Like Section 340B, the ADR Rule bars review by the Secretary by specifying that panel decisions are "final agency decision[s]" that are "precedential and binding on the parties involved unless invalidated by … a court." 42 C.F.R. § 10.24(d). A "precedential and binding final agency decision" is one that binds the agency, which includes the Secretary. *Id.* § 10.20; *see Nat'l Env't Dev. Ass'n Clean Air Project v. EPA*, 752 F.3d 999, 1009 (D.C. Cir. 2014). And HHS expressly rejected an agency "appeals process" in promulgating the Rule. *See* 85 Fed. Reg. 80,632, 80,641 (Dec. 14, 2020). Because "an agency is bound by its own regulations," *Nat'l Env't Dev. Ass'n*, 752 F.3d

at 1009, the Secretary cannot review panel decisions under the ADR Rule.

In short, *Arthrex* confirms that the ADR Rule contravenes Article II because ADR panelists are principal officers who have not been properly appointed.

B. The ADR Rule Violates Article III.

The ADR Rule violates Article III by granting agency bureaucrats the power to issue final judgments for money damages and equitable relief in disputes implicating manufacturers' private rights. A covered entity's claim that it has been overcharged concerns the liability of one private party to another and puts in dispute Sanofi's quintessential common-law property and contract rights. *See* Sanofi Mot. 72–76. Article III reserves the power to adjudicate these disputes to the judiciary.

The government does not dispute that Article III bars agencies from exercising judicial powers over disputes concerning private rights. *See* Reply 31–34. And, apart from a bald assertion (*id.* at 31), the government does not respond to the argument that ADR panels exercise judicial powers by resolving actions for monetary damages and equitable relief. Sanofi Mot. 69–72. That leaves only the government's claim that ADR panels do not adjudicate private rights.

But the government flouts the Third Circuit's instructions that *Thomas v. Union Carbide Agricultural Products Co.*, 473 U.S. 568 (1985), should not be read "expansively," *Beard v. Braunstein*, 914 F.2d 434, 440 (3d Cir. 1990)—and sees *Union Carbide* as permitting agency adjudication any time Congress establishes a federal scheme and

creates a cause of action deemed integral to that scheme. *See* Reply 33–34 & n.15. *Union Carbide* permits no such thing. The case approved agency adjudication only because the federal scheme did not "replace" state-law rights (which instead were "extinguished" beforehand as a matter of state law). 473 U.S. at 584; *see also Stern v. Marshall*, 564 U.S. 462, 491 (2011) (the federal scheme "did not violate Article III" because it did not "replace" a state-law right); Sanofi Mot. 75–76. Because Sanofi's core property and contract rights were not extinguished under state law, private rights are at issue, and *Union Carbide* does not control.

The government also tries to cast aside the Article III precedents limiting the powers of bankruptcy courts, remarking that proceedings "before administrative agencies often involve the adjudication of entirely new rights." Reply 34. But bankruptcy courts do not get special treatment under Article III. *Granfinanciera S.A. v. Nordberg*, 492 U.S. 33 (1989), for example, was a case about bankruptcy courts but addressed the constitutional limitations on "non-Article III tribunal[s]" or "non-Article III adjudicative bod[ies]," *id.* at 42, 50—and administrative agencies are non-Article III tribunals no less than bankruptcy courts. And the government admits that non-Article III tribunals may not resolve claims that "closely resembl[e]" common-law claims. Reply 34–35 (*Granfinanciera* "involved a private right because the statutory cause of action effectively supplanted and resembled a pre-existing common-law action"). ADR panels do just that, resolving covered entities' claims that seek to

adjudicate Sanofi's common-law property and contract rights. *See* Sanofi Mot. 73–74.[16]

C. The ADR Rule Violates the APA.

Nor can the government overcome the ADR Rule's defects under the APA.

First, the ADR Rule violates the APA's notice-and-comment requirement. The government does not dispute that an agency may not promulgate a final rule based on a withdrawn notice of proposed rulemaking ("NPRM"). Yet HHS did just that here. As the *Eli Lilly* court squarely held, the ADR NPRM was withdrawn in 2017 but HHS nevertheless proceeded to promulgate the ADR Rule, thus violating notice-and-comment requirements. 2021 WL 981350, at *10.

The government's response that the ADR NPRM was not actually withdrawn but merely "de-list[ed]" from the Unified Agenda (whatever that means), Reply 38, does not survive a glance at the Agenda, which explicitly declares the "NPRM Withdrawn" as of 2017 and identifies the NPRM as a "Completed Action[]." Sanofi Mot. 13, 58; *see Eli Lilly*, 2021 WL 981350, at *8. The government's cases holding that an agency must explain its decision to withdraw a rulemaking, Reply 37–38, show only that the withdrawal should have been explained, not that a withdrawal never occurred.

[16] Nor did the Supreme Court in *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110 (2011), authorize agency bureaucrats to wield judicial power over manufacturers' private rights. *See* Reply 36. *Astra* held merely that Section 340B did not create a private right of action to sue drug manufacturers; *Astra* did not allow for an adjudicative process that would violate Article III. *See* 563 U.S. at 113.

Similarly, in asserting that HHS's "usual practice" is to publish withdrawal notices in the Federal Register (Reply 38), the government admits that HHS does not *always* do so. And it cites no case holding that Federal Register withdrawals are the only ones that count. *See Eli Lilly*, 2021 WL 981350, at *9–10 (finding "no evidence" or "case law" supporting that a Federal Register notice "is required to effectuate withdrawal").

But even if the NPRM had not been withdrawn, the ADR Rule would still be unlawful because it was not a "logical outgrowth" of the NPRM. The government does not deny that critical provisions of the Rule were absent from the NPRM, including those addressing equitable relief, manufacturer claims, and use of the Federal Rules. *See* Sanofi Mot. 59–60.

Second, the ADR Rule is contrary to law because it exceeds the statutory authorization for an ADR process. The government responds that Congress authorized HRSA to take various "appropriate action[s]" following an ADR proceeding. Reply 39. But authorization to order refunds for overcharges and impose CMPs is *not* the same as authorization to award money damages and injunctive relief—which is authority that Congress knows how to confer but has not conferred here. *See AMG Cap. Mgmt. v. FTC*, 141 S. Ct. 1341, 1343 (2021). The ADR Rule also exceeds statutory authority by permitting panels to resolve claims other than those for "overcharge[s]." *See* Sanofi Mot. 78. In response, the government argues a manufacturer "overcharge[s]" a covered entity any time the manufacturer "denies a

covered entity the ability to purchase 340B drugs at discounted prices." Reply 40. But HHS's own regulations—not to mention the plain meaning of "overcharge"—defeat the government's argument, by defining an "overcharge" to require an "actual sale . . . above the 340B ceiling price." 82 Fed. Reg. at 1,224.

Finally, the ADR Rule is arbitrary and capricious because the government essentially admits that HHS did not consider major developments postdating the 2016 NPRM, such as growing evidence of diversion and duplicate discounting. Reply 38; *see* Sanofi Mot. 7–12, 79. Instead, the government surprisingly claims these developments "have no relevance" to the ADR Rule. Reply 40. But Section 340B itself treats duplicate discounting and diversion as important concerns. *See* 42 U.S.C. § 256b(d)(3)(A), (B)(i). HHS should not have ignored these concerns entirely, particularly given the statute's instruction that the Secretary ensure compliance with these statutory provisions. *See, e.g.*, *id.* § 256b(d)(2)(A).

III. The Court Should Award Declaratory and Injunctive Relief to Sanofi.

Consistent with the APA's command that a reviewing court "shall" "set aside" unlawful agency action, 5 U.S.C. § 706(2), the Court should vacate the Advisory Opinion, ADR Rule, and HRSA Letter. *See Council Tree Commc'ns, Inc. v. FCC*, 619 F.3d 235, 258 (3d Cir. 2010); *Sierra Club v. EPA*, 972 F.3d 290, 309 (3d Cir. 2020). In vacating the Advisory Opinion, Chief Judge Stark correctly rejected the government's argument that its "withdrawal renders claims challenging the Advisory Opinion

moot," ECF 90, Notice of Withdrawal. *See* Dkt. 83, *AstraZeneca Pharms. LP v. Becerra*, No. 21-cv-00027 (D. Del. June 30, 2021) (citing *Buckhannon Bd. & Care Home, Inc. v. W.V. Dep't of Health & Human Res.*, 532 U.S. 598 (2001)). Likewise, Sanofi's claims against the Advisory Opinion are not moot. HHS "has not altered its position on the merits" and HRSA continues to enforce the Advisory Opinion's contract pharmacy rule. *Solar Turbines, Inc. v. Seif*, 879 F.2d 1073, 1079 (3d Cir. 1989).

In addition, the Court should issue declaratory relief to lift the legal cloud over Sanofi's integrity initiative. 28 U.S.C. § 2201(a); Fed. R. Civ. P. 57. Given HRSA's erroneous conclusion that Sanofi's integrity initiative is illegal, the Court should declare that Sanofi's integrity initiative complies with Section 340B—because the statute neither requires delivering 340B-priced drugs to contract pharmacies nor prohibits imposing conditions on the provision of 340B-priced drugs to contract pharmacies. *See, e.g.*, *Christ the King Manor, Inc. v. HHS*, 730 F.3d 291, 321 (3d Cir. 2013) (remanding "with instructions to enter a declaratory judgment … that HHS's [action] was arbitrary and capricious under the APA").

CONCLUSION

For the reasons explained, the Court should vacate the Advisory Opinion, the May 17 Letter, and the ADR Rule, enter summary judgment in Sanofi's favor, and enter the declaratory and injunctive relief Sanofi has requested.

Dated: July 6, 2021

Respectfully submitted,

s/ Jennifer L. Del Medico

Jennifer L. Del Medico
Toni-Ann Citera (*pro hac vice*)
Rajeev Muttreja (*pro hac vice*)
JONES DAY
250 Vesey Street
New York, New York 10281
Telephone: (212) 326-3939
Facsimile: (212) 755-7306

Brett A. Shumate (*pro hac vice*)
Megan Lacy Owen (*pro hac vice*)
JONES DAY
51 Louisiana Avenue, N.W.
Washington, D.C. 20001
Telephone: (202) 879-3939
Facsimile: (202) 626-1700

Counsel for Plaintiff
Sanofi-Aventis U.S. LLC

CERTIFICATE OF SERVICE

I hereby certify that on July 6, 2021, a copy of the foregoing was filed with the Clerk of the Court by using the CM/ECF system. I further certify that all participants in this case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

July 6, 2021 *s/ Jennifer L. Del Medico*