Nos. 21-3167, 21-3379 (cross-appeal)

IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

SANOFI-AVENTIS U.S., LLC,
Plaintiff-Appellant-Cross-Appellee,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; GENERAL COUNSEL, U.S. DEPARTMENT OF HEALTH HUMAN SERVICES; HEALTH RESOURCES SERVICES ADMINISTRATION; ADMINISTRATOR OF THE HEALTH RESOURCES SERVICES ADMINISTRATION,
Defendants-Appellees-Cross-Appellants.

On Appeal from the United States District Court for the District of New Jersey (No. 3:21-cv-00634)

REPLY AND RESPONSE BRIEF FOR APPELLANT/CROSS-APPELLEE SANOFI-AVENTIS U.S., LLC

Toni-Ann Citera
Rajeev Muttreja
JONES DAY
250 Vesey Street
New York, New York 10281
(212) 326-3939
tcitera@jonesday.com
rmuttreja@jonesday.com

Noel J. Francisco
Brett A. Shumate
JONES DAY
51 Louisiana Ave. NW
Washington, DC 20001
(202) 879-3939
njfrancisco@jonesday.com
bshumate@jonesday.com

Counsel for Appellant/Cross-Appellee Sanofi-Aventis U.S., LLC

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INTRODUCTION

The government concedes that Section 340B says not a word about the role of contract pharmacies in the 340B Program. Nor does the government dispute that, for almost all of the 340B Program's 30-year history, HHS openly understood that it *lacked* the authority to require manufacturers to provide discounted drugs to contract pharmacies. But in now arguing the exact opposite—and urging that Section 340B unambiguously compels manufacturers to provide discounted drugs to contract pharmacies—the government has virtually nothing to say about the text of the statute, and instead rests almost entirely on policy-driven arguments about legislative history and statutory purpose.

None of the government's arguments can overcome the plain text of Section 340B—which, by saying nothing about contract pharmacies, does not create the purported rule that the government seeks to enforce. Nor, for that matter, does the legislative history or statutory purpose support the government's argument that Sanofi must unconditionally provide discounted drugs to an unlimited number of contract pharmacies. Section 340B requires manufacturers to make a bona fide "offer" of the discounted drugs to covered entities, but it does not require

manufacturers to deliver the drugs wherever and to whomever the covered entities wish. And the government conspicuously never argues that Sanofi's conditions on delivery to contract pharmacies somehow nullify the offer. Nor could it, because Sanofi offers to provide 340B-priced drugs to covered entities in three ways: (1) directly to the covered entity, if it has an in-house pharmacy; (2) to a single contract pharmacy, if the covered entity lacks its own pharmacy; and (3) to an unlimited number of contract pharmacies, if the covered entity submits minimal claims data. *See* Opening Br. 19. This is more generous than what HHS itself permitted for almost two decades.

Moreover, even if the government's interpretation were a plausible one—and it is not—the government never disputes (and thus concedes by forfeiture) that HHS acted arbitrarily and capriciously by ignoring the agency's inconsistent positions as well as the fact that Section 340B is—at most—ambiguous. Nor does the government dispute that HHS violated the Administrative Procedure Act ("APA") if the agency withdrew the ADR Rule—which HHS explicitly stated it did. The Violation Letter, the similar Advisory Opinion, and the ADR Rule should thus all be vacated.

As for the cross-appeal, the government argues that the District Court erred by partially vacating and remanding the Violation Letter because HHS lacks power to regulate contract-pharmacy arrangements under Section 340B. That only underscores Sanofi's point that the statutory silence gives HHS no authority in this area. But even if the District Court and government were somehow correct that Section 340B silently mandated billions of dollars of drug sales through contract pharmacies, it is well-settled that HHS needed to fully explain its interpretation of Section 340B. That means HHS needed to adequately address the problematic and widely recognized consequences of the unlimited use of contract pharmacies—a topic the agency instead avoided entirely. The government's cross-appeal is thus meritless.

ARGUMENT

I. HHS Exceeded Its Statutory Authority By Requiring Sanofi to Unconditionally Provide Discounted Drugs to Contract Pharmacies.

The government admits the key premises of Sanofi's argument. First, the government concedes that "the statute *alone* dictates the manufacturers' substantive obligations with respect to covered entities"—and thus the "enforcement actions at issue here" must be

"based on [Section 340B] alone." Gov't Br. 48-49 (emphasis added). Second, the government further agrees that Section 340B does not "explicit[ly]" address covered entities' use of contract pharmacies. *Id.* at 37; *see also* D.Ct.ECF.93 at 22. The question for this Court, then, is whether Section 340B's undisputed "*silence*" about contract pharmacies, Gov't Br. 36 (emphasis added), must be understood—as the government contends—as a *requirement* that manufacturers provide discounted drugs to an unlimited number of contract pharmacies without conditions. As Sanofi's opening brief explained, Section 340B requires no such thing, and none of the government's arguments demonstrate otherwise.

A. The Government Fails to Demonstrate That Section 340B Requires Sanofi to Unconditionally Provide Discounted Drugs to an Unlimited Number of Contract Pharmacies.

All the tools of statutory construction demonstrate that Section 340B does not mandate unconditionally providing discounted drugs to an unlimited number of contract pharmacies.

1. The Government Concedes That Section 340B Is Silent About Contract Pharmacies.

Statutory interpretation of course "starts with [the] text," *Milner v. Dep't of Navy*, 562 U.S. 562, 569 (2011), and "ends there as well" when

the statute is clear, *Nat'l Ass'n of Mfrs. v. Dep't of Def.*, 138 S. Ct. 617, 631 (2018). All parties—and all courts that have considered the question, including the District Court—agree that Section 340B says nothing about any role for contract pharmacies in the 340B Program. *See* Gov't Br. 36-37; D.Ct.ECF.93 at 22; JA88 (Op.78); Opening Br. 37 (collecting cases).

That should be the end of the matter. Yet the government argues, repeating the District Court's error, that Section 340B's silence as to contract pharmacies is insufficient to "permit" or "authorize" manufacturers to limit the use of contract pharmacies. Gov't Br. 36-37, 39-40; *see* JA103-04 (Op.93-94). As the opening brief explained, however, this argument is "exactly backwards," because it is the *government*—not Sanofi—that requires statutory permission to act. *Christensen v. Harris Cnty.*, 529 U.S. 576, 588 (2000).

A manufacturer can produce and sell goods as it wishes absent a "prohibition" authorized by law. *See id.*; *City of Philadelphia v. Att'y Gen.*, 916 F.3d 276, 284 (3d Cir. 2019); Opening Br. 42-43. HHS, on the other hand, is a "creature[] of statute" that "possess[es] only the authority that Congress has provided," *NFIB v. OHSA*, 142 S. Ct. 661, 665 (2022);

accord FEC v. Cruz, 142 S. Ct. 1638, 1649 (2022)—and, as the government concedes, lacks rulemaking power "to fill a gap in" Section 340B, *Novartis Pharms. Corp. v. Espinosa*, No. 21-cv-1479, 2021 WL 5161783, at *8 (D.D.C. Nov. 5, 2021); *see* Gov't Br. 2-3. The government disputes none of these principles—even though they together underscore that Section 340B's silence about contract pharmacies deprives HHS of the authority to require the unconditional delivery of discounted drugs to contract pharmacies.

Instead, the government urges the Court not to draw "inference[s] … from congressional silence" that are "contrary to all other textual and contextual evidence of congressional intent." Gov't Br. 36 (quoting *Burns v. United States*, 501 U.S. 129, 136 (1991)). But "[i]t is at best treacherous to find in congressional silence alone the adoption of a controlling rule of law." *United States v. Wells*, 519 U.S. 482, 496 (1997); *see also, e.g.*, *Corrigan v. Haaland*, 12 F.4th 901, 910 (9th Cir. 2021) ("[W]e avoid reading in [to congressional silence] unstated statutory requirements." (quotation marks omitted)). And this principle rings especially true here, where the rule that the government seeks to extract from statutory

silence would undisputedly mandate *billions* of dollars of drug sales. *See* Gov't Br. 18.

Indeed, the government posits that its interpretation of the statute would have cost Sanofi $47 million in just one month alone. *See id.* But as Sanofi explained in its opening brief, "Congress … does not … hide elephants in mouseholes." *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001). Instead, "when authorizing an agency to exercise powers of vast economic and political significance," courts expect Congress not only to speak explicitly, but "to speak clearly." *NFIB*, 142 S. Ct. at 665 (quoting *Ala. Ass'n of Realtors v. HHS*, 141 S. Ct. 2485, 2489 (2021) (per curiam)). So too, if Congress wishes to subject private parties to an obligation backed by massive financial sanctions—such as Section 340B's threat of civil monetary penalties—the "words of the statute" must "plainly impose" the rule. *Commissioner v. Acker*, 361 U.S. 87, 91 (1959).

Here, however, the government's position is a matter about which Section 340B not only lacks the requisite clear statement but literally says nothing. And even if, as the government contends, one should not interpret "congressional silence" in a manner "contrary to *all* other textual and contextual evidence of congressional intent" (*e.g.*, in a way

that would "render what Congress has *expressly* said absurd"), *Burns*, 501 U.S. at 136-37 (first emphasis added), here Section 340B's "textual and contextual" clues cut squarely against the government—and certainly do not "all" point in the government's favor.

2. Section 340B's Text Refutes the Government's Interpretation.

Beyond conceding the statutory silence about contract pharmacies, the government has very little to say about the text that Congress *did* enact in Section 340B. Spending just a page on the issue, the government notes that Section 340B requires manufacturers to "offer" discounted drugs to covered entities. Gov't Br. 32 (quoting 42 U.S.C. § 256b(a)(1)). But the government does not explain how this mandatory "offer" of a discounted price supports HHS's novel command that manufacturers "must sell" (Gov't Br. 33) their products on whatever *non-price* terms covered entities demand.

Indeed, Section 340B's text does not specify any of the mandatory offer's terms other than the price—and, thus, does not require how or where the drugs must be *delivered*, much less that they must be delivered *without condition* to third parties such as contract pharmacies. *See Novartis*, 2021 WL 5161783, at *6-7, *9. Instead, as Sanofi explained,

Section 340B's "offer" provision simply requires manufacturers to make bona fide, good-faith offers of discounted drugs—meaning that Sanofi cannot impose conditions that would essentially make the offer an illusory one. *See* Opening Br. 48, 51-53. And there can be no dispute that Sanofi's program easily meets this requirement. Sanofi makes discounted drugs readily available to covered entities in multiple ways: (1) directly to any covered entity's in-house pharmacy, (2) to a single contract pharmacy if the covered entity lacks an in-house pharmacy, and (3) to an *unlimited* number of contract pharmacies, if the covered entity merely provides minimal claims data—a reasonable condition that the government does not even argue is burdensome. *See id.* at 18-21.

The government does not even acknowledge this straightforward argument that Section 340B requires merely a bona fide "offer" of the discounted price. To the contrary, it admits that Section 340B does not "explicitly" or "directly" prohibit 340B offers from including other conditions of delivery. Gov't Br. 37, 48. That, of course, should end the matter; if the statutory text does not prohibit Sanofi from imposing reasonable non-price conditions on its offer, then it plainly does not

prohibit the reasonable conditions at issue in this case. The government offers no meaningful response.

Nor can the government derive a rule mandating unconditional offers of the discounted price from Section 340B's provision that HHS must enter into PPAs "under which the amount required to be paid … to the manufacturer for covered outpatient drugs … purchased by a covered entity … does not exceed" the ceiling price. Gov't Br. 32-33 (quoting 42 U.S.C. § 256b(a)(1)). This provision—which was not even invoked by and thus cannot sustain the Violation Letter, *see DHS v. Regents of Univ. of Cal.*, 140 S. Ct. 1891, 1907 (2020)—merely mandates the *price* of the drugs. And it is undisputed here that the "amount required to be paid" to Sanofi from covered entities "does not exceed" the ceiling price. But nothing in this provision requires Sanofi to provide its drugs at that price anywhere and to whomever a covered entity wishes.

This is reinforced, moreover, by how Section 340B expressly defines "covered entity," which "means" only 15 categories of entities and prohibits the "diversion" of discounted drugs to any third parties (except patients). 42 U.S.C. § 256b(a)(4), (a)(5)(B), (d)(2)(A); *see* Opening Br. 39. The definite and exclusive nature of this list makes it "hard to believe

that Congress" also "intended to include contract pharmacies as a 16th option by implication." *AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47, 60 (D. Del. 2021) ("*AstraZeneca I*"); *see Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 162 (2012). Yet the government says not a word about this or any of Sanofi's other textual arguments.

3. Section 340B's Context and Structure Rebut the Government's Position.

The government likewise ignores Sanofi's arguments about statutory context and structure. Although Section 340B is silent about contract pharmacies, the statute explicitly addresses numerous *other* types of third parties—including wholesalers, distributors, associations, and entities representing covered entities. *See* Opening Br. 39-40; 42 U.S.C. § 256b(d)(1)(B)(v), (d)(2)(B)(iv), (d)(3)(B)(iii), (d)(3)(B)(vi). Because these provisions were all enacted contemporaneously with an expansion of the list of covered entities, the "presum[ption] that Congress acts intentionally and purposely in the disparate inclusion or exclusion" of statutory language is particularly strong. *Russello v. United States*, 464 U.S. 16, 23 (1983); *see* Pub. L. No. 111-148, §§ 7101, 7102, 124 Stat. 119, 822, 823 (2010); *see also, e.g.*, *Salinas v. U.S. R.R. Ret. Bd.*, 141 S. Ct. 691, 698 (2021). This confirms that Congress deliberately chose where to

include third parties in Section 340B—and declined to include contract pharmacies.

Indeed, in *the very next section* of the law that initially enacted Section 340B in 1992, Congress addressed drugs purchased by federal agencies and "delivered through … a commercial entity"—in other words, delivered to a for-profit third party like a contract pharmacy. Veteran's Health Care Act of 1992, Pub. L. No. 102-585, § 603(a)(1), 106 Stat. 4943, 4974, *codified at* 38 U.S.C. § 8126(h)(3)(a). Thus, Congress plainly knew how to require that drugs be delivered through a contract pharmacy if it wanted to, yet omitted any similar reference to contract pharmacies from Section 340B. This Court should presume that Congress acted "intentionally," *Russello*, 464 U.S. at 23—and that is especially so in light of the government's argument that "Congress knew of [contract] pharmacy arrangements when it enacted the 340B statute," Gov't Br. 35.

Instead of responding to these points, the government (like the District Court) asserts that "Congress's failure to speak directly to a specific case … that falls within a more general statutory rule" does not "create[] a tacit exception" to that rule. Gov't Br. 33 (quoting JA104 (Op.94) (quoting *Bostock v. Clayton Cnty.*, 140 S. Ct. 1731, 1747 (2020))).

As the government sees it, manufacturers thus cannot limit the use of contract pharmacies "just because those actions are not expressly prohibited" by Section 340B. *Id.* The fatal flaw in this argument, of course, is that the "general rule" the government relies on simply does not exist, and Sanofi therefore seeks no "exception" to it. The government also does not explain how this so-called canon against "donut holes" applies where, as discussed above, the text and context of Section 340B clearly show that Congress did *not* intend to include contract pharmacies in Section 340B.

The government also argues that Section 340B prohibits conditions on the use of contract pharmacies by providing tools "to prevent diversion and duplicative discounts"—namely, audits of covered entities and penalties for Section 340B violations. Gov't Br. 38-39 (citing 42 U.S.C. § 256b(a)(5)(A)-(D), (d)(2)(B)(i)-(v)). The government sees these means as exclusive, arguing that Congress has not "implicitly authorize[d]" manufacturers to otherwise attempt to prevent practices prohibited under Section 340B. *Id.* at 39-40. But the government again gets things "exactly backwards." *Christensen*, 529 U.S. at 588. Manufacturers like Sanofi do not *need* statutory authority in order to attempt to prevent

diversion and duplicate discounts. *See id.*; *City of Philadelphia*, 916 F.3d at 284. And Section 340B has no language directing that the process through which HHS can *penalize* statutory violations precludes manufacturers from attempting to *prevent* such violations in the first place.

Indeed, even the government is forced to acknowledge that manufacturers may permissibly impose some conditions under Section 340B. *See Novartis*, 2021 WL 5161783, at *7. In particular, HHS has long maintained—and the government now admits—that manufacturers may permissibly condition their offers of discounted drugs on a covered entity's provision of "standard information" and agreement to "the manufacturer's normal business policies." JA168-70 (59 Fed. Reg. 25,110, 25,112-14 (May 13, 1994) (VLTR.83-85)); *see* Gov't Br. 42. But the government offers no statutory basis to distinguish these conditions from the other reasonable conditions at issue here.

Falling back, the government contends that Sanofi's interpretation of Section 340B would empower it to demand that a covered entity purchase only Sanofi drugs where possible, not those of Sanofi's competitors. *See* Gov't Br. 37. But such a demand obviously would

render the offer illusory and hence not be a bona fide one and, indeed, might well violate antitrust or consumer-protection laws. The government's strawman hypothetical, therefore, cannot possibly support its position that Sanofi's program—which, it bears emphasizing, allows (among other things) covered entities who simply provide Sanofi with minimal claims data to use an unlimited number of contract pharmacies—somehow is not, in fact, an "offer" under the plain text of Section 340B.

The government further argues that Section 340B "must be construed to ensure that 'everything necessary to making [the statute] effectual, or requisite to attaining the end, is implied'"—which, as the government sees it, "precludes manufacturers" from placing any conditions on the use of contract pharmacies. Gov't Br. 34 (quoting A. Scalia & B. Garner, *Reading Law: The Interpretation of Legal Texts* 193 (2012)). But the government omits key language from *Reading Law*—which, in full, states that, "*whenever a power is given by a statute,* everything necessary to making it effectual or requisite to attaining the end is implied." *Reading Law*, *supra*, at 192-93 (emphasis added). For instance, "permission to harvest the wheat on one's land implies

permission to enter on the land for that purpose." *PennEast Pipeline Co., LLC v. New Jersey*, 141 S. Ct. 2244, 2260 (2021) (quoting *Reading Law*, *supra*, at 192). By contrast, Section 340B merely requires manufacturers to "offer" discounted drugs to covered entities. 42 U.S.C. § 256b(a)(1). Sanofi does not need to unconditionally provide discounted drugs to contract pharmacies in order to give full effect to that statutory requirement. *See supra* at 8-11; Opening Br. 37-42.

Moreover, this interpretive principle applies only where the means in question are truly "necessary" to achieving the statutory ends and not "conjectural." *Reading Law*, *supra*, at 193. Here, however, the unconditional use of contract pharmacies is not "necessary to making [Section 340B] effectual," *id.*, given that—as the government does not dispute—the vast majority of covered entities do not even use contract pharmacies. *See* Opening Br. 17; Gov't Br. 13 (acknowledging "that, as of 2017, about one-third of the covered entities in the 340B Program used contract pharmacies"). Justice Scalia emphasized in *Reading Law* that this interpretive canon "must be applied with caution, lest the tail of what is implied wag the dog of what is expressly conferred." *Reading Law*, *supra*, at 192. The government fails to heed this warning.

4. Legislative History Only Hurts the Government.

The government also places great weight on a single piece of legislative history—namely, the unenacted statutory language that would have required 340B discounts not merely on drugs "purchased by a covered entity," 42 U.S.C. § 256b(a)(1), but more broadly on drugs "purchased and dispensed by, *or under a contract entered into for on-site pharmacy services with*," a covered entity. S. 1729, at 9, 102d Cong. (1992) (emphasis added). But as *AstraZeneca I* recognized, this legislative history "suggests that Congress did *not* clearly intend to require manufacturers to deliver 340B drugs to an unlimited number of contract pharmacies"—and *a fortiori* Congress did not require *unconditional* delivery to contract pharmacies. 543 F. Supp. 3d at 60-61 (emphasis added). This legislative history thus *supports* Sanofi's position by showing that Congress chose to *omit* a requirement that discounted drugs be provided to certain contract pharmacies. *See* Opening Br. 46.

The government nevertheless asserts that this legislative history shows that Congress "knew of these pharmacy arrangements when it enacted the 340B statute" and declined to "enact [any] limit" on such

pharmacies. Gov't Br. 35-36. As explained above, that is wrong. But it also does not matter. After all, legislative history may be considered only as a "last resort," *In re Trump Ent. Resorts*, 810 F.3d 161, 168 (3d Cir. 2016), and even then it "never" "override[s]" other evidence establishing a statute's plain meaning, *S.H. ex rel. Durrell v. Lower Merion Sch. Dist.*, 729 F.3d 248, 259 (3d Cir. 2013). Indeed, a "failed legislative proposal[]" is "a particularly dangerous ground on which to rest an interpretation of a … statute." *Cent. Bank of Denver, N.A. v. First Interstate Bank of Denver, N.A.*, 511 U.S. 164, 187 (1994). And while Sanofi's understanding of the legislative history is consistent with the text and context of the statute, the government's view is not.

Remarkably, the government does not even acknowledge the other way in which this legislative history can be read—namely, the correct reading adopted by Judge Stark in *AstraZeneca I*, 543 F. Supp. 3d at 60. But because the legislative history is, at minimum, susceptible to another reasonable interpretation, it cannot help the government. When legislative history is ambiguous, this Court should decline to consult it. *See Milner*, 562 U.S. at 574; *see Abraham v. St. Croix Renaissance Grp., L.L.L.P.*, 719 F.3d 270, 279 n.8 (3d Cir. 2013) (legislative history "sheds

little light on Congress's true intent" if "either party … can cite [it] as authority for their respective interpretations").

Nor can the government's reliance on legislative history be squared with its insistence that Section 340B *unambiguously* compels its interpretation. Previously, the government has "contend[ed] that if the statutory text is unambiguous, it is inappropriate and unnecessary to inquire into the legislative history," and that "the plain and literal language of the statute" should control. *United States v. Geiser*, 527 F.3d 288, 292, 294 (3d Cir. 2008) (quotation marks omitted). Sanofi agrees—but the government cannot prevail on this basis, when Section 340B is undisputedly silent about contract pharmacies. The government's proposed use of the legislative history simply attempts to "muddy the meaning of clear statutory language." *Food Mktg. Inst. v. Argus Leader Media*, 139 S. Ct. 2356, 2364 (2019) (quotation marks omitted); *see also Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1814 (2019).

5. The Government Cannot Rely on Section 340B's General Purpose to Rewrite the Statute's Text.

The government also argues—without citation—that Congress must have authorized any and all means necessary "to provide covered entities with drugs at a discounted price," because that is why "Congress

established the 340B Program." Gov't Br. 34-35. But it "frustrates rather than effectuates legislative intent simplistically to assume that *whatever* furthers the statute's primary objective must be the law," because "no legislation pursues its purposes at all costs." *Rodriguez v. United States*, 480 U.S. 522, 525-26 (1987) (per curiam). Instead, "pretty much everything Congress does"—Section 340B included—is a "result of compromise." *Abramski v. United States*, 573 U.S. 169, 186 (2014). To look past the legislative text in favor of legislative purpose ignores that fundamental fact. *See Henson v. Santander Consumer USA Inc.*, 137 S. Ct. 1718, 1725 (2017) ("[I]t is quite mistaken to assume, as [the government] would have us, that whatever might appear to further the statute's primary objective must be the law." (alterations and quotation marks omitted)).

Instead, as Sanofi has explained, *see* Opening Br. 34-36, 46-47, "[w]here the intent of Congress has been expressed in reasonably plain terms, that language must ordinarily be regarded as conclusive." *Donovan ex rel. Donovan v. Punxsutawney Area Sch. Bd.*, 336 F.3d 211, 222 (3d Cir. 2003) (quotation marks omitted); *see also In re Pro. Ins. Mgmt.*, 130 F.3d 1122, 1127 (3d Cir. 1997). And although courts "avoid

rendering what Congress has plainly done … devoid of reason and effect," Gov't Br. 35 (quoting *Great-W. Life & Annuity Ins. Co. v. Knudson*, 534 U.S. 204, 217-18 (2002)), this principle applies only to "plain[]" statutory requirements "embodied in the text that Congress has adopted." *Great-W. Life*, 534 U.S. at 217-18, 221. "[V]ague notions of a statute's 'basic purpose'"—exactly what the government offers here—"are … inadequate to overcome the words of its text regarding the specific issue under consideration." *Id.* at 220-21. Thus, because the text of Section 340B does not require manufacturers to unconditionally provide discounted drugs to contract pharmacies, that requirement cannot be layered atop the text based on the government's asserted statutory purpose.

In any event, the government offers no response to the fact that Sanofi's interpretation obviously does, in fact, further the statutory purpose of ensuring that covered entities "obtain lower prices on the drugs that they provide to their patients." H.R. Rep. No. 102-384, pt. 2, at 7 (1992); *see* S. Rep. No. 102-259, at 6 (1992) (JA243); *see also* Opening Br. 57-58; *Novartis*, 2021 WL 5161783, at *6-7. On the one hand, Sanofi's program offers its drugs at the mandated discounts to *all* covered entities, allowing *all* such entities to use an in-house pharmacy or a

single contract pharmacy without condition or to use an *unlimited* number of contract pharmacies if they merely provide Sanofi with minimal data that helps prevent program abuses. On the other hand, the government accepts the fact that contract pharmacies siphon revenue away from covered entities with high fees. *See* JA490-93 (GAO, Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement, GAO-18-480, at 24-27 (June 2018)). And the government does not even suggest—nor could it, given that HHS did not even *permit* the use of contract pharmacies for four years after the statute's enactment—that Congress intended for Section 340B to provide the windfall that contract pharmacies are now reaping from HHS's interpretation. *See* Opening Br. 14-15. It is impossible to understand—and the government never explains—how Sanofi's program somehow nullifies Section 340B's purposes, much less violates its clear text, which, as explained, merely requires that Sanofi "offer" its drugs to covered entities at the ceiling price.

6. Sanofi's Interpretation Would Not Turn Section 340B Into a "Dead Letter."

The government also contends that, under Sanofi's reading of the statute, "Section 340B would have been a dead letter … from the very moment of its enactment," because most covered entities lacked in-house pharmacies at that time. Gov't Br. 35 (quotation marks omitted). The government never specifies this argument's legal basis but appears to be invoking the canons of construction that a statute should not receive an absurd construction, or should not negate its purpose. Under those canons, the government must show that Sanofi's interpretation either "defies rationality or renders [Section 340B] nonsensical and superfluous," *Riccio v. Sentry Credit, Inc.*, 954 F.3d 582, 588 (3d Cir. 2020) (en banc) (absurdity), or makes Section 340B "nugatory" or otherwise deprives it of any meaningful effect, *Reading Law*, *supra*, at 64-65 (quoting *The Emily*, 22 U.S. 381, 389 (1824)); *see In re Davis*, 960 F.3d 346, 354 (6th Cir. 2020); *cf. United States v. Hartley*, No. 22-3010, 2022 WL 1548483, at *6, *9 (10th Cir. May 17, 2022) (rejecting interpretation that would have rendered the statute a "nullity"). Notably, courts assessing this question will consider the "current" operation and "reach" of the statute. *N.Y. State Dep't of Soc. Servs. v.*

Dublino, 413 U.S. 405, 418-21 & nn.22, 25 (1973); *see also, e.g.*, *Vooys v. Bentley*, 901 F.3d 172, 174, 192-94 & nn.125-26 (3d Cir. 2018) (analyzing whether statutory interpretation was absurd based on current circumstances); *United States v. Fontaine*, 697 F.3d 221, 230, 232 (3d Cir. 2012) (similar).

The government does not come close to satisfying this demanding burden, because it does not (and cannot) dispute that the overwhelming majority of covered entities *do not even use* contract pharmacies today. Opening Br. 16-19. Indeed, the government offers no response to the fact that Congress would have achieved the widespread distribution of discounted drugs to covered entities even without the interpretation the government has recently announced. Moreover, even if some covered entities do lack an in-house pharmacy, the government does not explain why it is essential that *all* covered entities be *unconditionally* allowed to use *unlimited* contract pharmacies. Interpreting Section 340B merely to require bona fide offers of the discounted price, as the statutory text states, thus would not remotely render the statute a "dead letter."

The same is true even if one attempts to divine what Congress may have intended in 1992, when Section 340B was enacted. Even if fewer

covered entities had in-house pharmacies at that moment in time, that would not suggest Congress intended to mandate unconditional delivery to unlimited contract pharmacies. Again, in 1996, HHS guidance merely stated that covered entities were *permitted* to use *just one* contract pharmacy. JA171-72, 177 (61 Fed. Reg. 43,549, 43,549-50, 43,555 (Aug. 23, 1996) (VLTR.88-89, 94)). It was not until 2010 that HHS even *allowed* the use of unlimited contract pharmacies. JA180 (75 Fed. Reg. 10,272, 10,273 (Mar. 5, 2010) (VLTR.101)); *see City of Philadelphia*, 916 F.3d at 290 (agency practice is an "important interpretive tool"). HHS's argument, therefore, reduces to the assertion that *its own past interpretations* of Section 340B were "absurd" and "nugatory." It makes no attempt to explain this disconnect.

Moreover, the government has not supplied any reason to think that Congress even knew how many covered entities operated in-house pharmacies when it enacted Section 340B in 1992. *See, e.g.*, *NBD Bank, N.A. v. Bennett*, 67 F.3d 629, 633 (7th Cir. 1995) ("Congress is not omniscient."); *BP P.L.C. v. Mayor & City Council of Balt.*, 141 S. Ct. 1532, 1541 (2021) (explaining courts decline to presume Congress is aware even of judicial interpretations unless the judicial consensus is "broad and

unquestioned"). For that matter, the government has not cited any evidence that any covered entity even *used* contract pharmacies before 1996, when HHS first purported to permit the practice.

Indeed, in 1994, when advising that a covered entity could "use a purchasing agent without forfeiting its right to" 340B pricing, HHS emphasized that all 340B drugs must still be "distribut[ed] *to the [covered] entity*" before being dispensed to patients. JA169 (59 Fed. Reg. at 25,113 (VLTR.84)). This requirement would make no sense if, as the government now suggests, contract pharmacies were always essential to the program's design.

In addition, in 1996, when HHS issued its first non-binding guidance about contract pharmacies, the agency explained that, "[d]uring the early period of program implementation, it *became apparent* that only a very small number of the 11,500 covered entities used in-house pharmacies." JA172 (61 Fed. Reg. at 43,550 (VLTR.89)) (emphasis added). If the government were right that even "Congress knew" that contract pharmacies were purportedly necessary when Section 340B was enacted, Gov't Br. 35, then this fact would not have "bec[o]me apparent"

to HHS years *after* the program began. It would have been known from day one.

Instead, however, there is good reason to think that Congress was focused on the availability of discounted drugs to covered entities' in-house pharmacies. When enacting Section 340B, Congress expressed concern with rising "[p]rices paid for outpatient drugs by . . . Federally-funded clinics and public hospitals"—*i.e.*, providers paying more to fill their *own* pharmacies' shelves. H.R. Rep. No. 102-384, pt. 2, at 11. Thus, even if few covered entities operated in-house pharmacies at the time of the statute's enactment, it was those covered entities that appear to have been the statute's principal concern.

At bottom, though, only the statutes enacted by Congress are the law; presumptions about whether Congress wanted a particular result do not control. *See Cooper Indus., Inc. v. Aviall Servs., Inc.*, 543 U.S. 157, 167 (2004) ("[I]t is ultimately the provisions of our laws rather than the principal concerns of our legislators by which we are governed."). And here, as discussed, the enacted statute did not require that discounted drugs must be unconditionally provided to contract pharmacies.

Moreover, it is hardly inconceivable that Congress would have wanted manufacturers to provide their discounted drugs only to covered entities that serve patients in need, rather than for-profit contract pharmacies that may pocket the discounts. *See* Opening Br. 14-15 (discussing problems caused by contract pharmacies). Nor is it absurd to think that Congress would have expected covered entities seeking the benefit of deeply discounted prices to establish an in-house pharmacy, or at least comply with good-faith offer terms. If anything is absurd, it is the government's suggestion that Congress intended manufacturers to deliver discounted drugs even to the "lunar surface" or "low-earth orbit," if that is what covered entities ask. JA213 (ADVOP.3). That is plainly incompatible with the statutory requirement of a "meaningful, *bona fide* offer[]" by manufacturers. *Novartis*, 2021 WL 5151783, at *6.

B. The Government Fails to Show That Sanofi Violated Section 340B.

When properly understood as set forth above, Section 340B does not prohibit Sanofi's integrity initiative. The government does not show that Sanofi failed to make bona fide, good faith "offers" of discounted drugs, which is what Section 340B requires.

1. Sanofi Makes a Bona Fide Offer of the 340B Price.

As explained, Sanofi makes a bona fide offer to covered entities by offering to provide 340B-priced drugs in three ways: (1) directly to the covered entity, if it has an in-house pharmacy; (2) to a single contract pharmacy, if the covered entity lacks its own pharmacy; or (3) to an unlimited number of contract pharmacies, if the covered entity submits minimal claims data. *See* Opening Br. 19. These terms do not come close to nullifying Sanofi's offers or rendering them illusory.

Tellingly, the government barely even engages with the features of Sanofi's integrity initiative. The government has no response to the undisputed fact that Sanofi's terms are *more generous* than what HHS permitted for the 340B Program's first eighteen years. *See id.* at 55. In the *AstraZeneca* case, the government tried to bury HHS's past, longstanding practices as "not consistent with the agency's understanding of the statute" today—but that smacks of litigation-driven revisionism, particularly when the government has never explained how or why HHS supposedly had things wrong for so long. *See* Oral Arg. Tr. 67:6-12, *AstraZeneca Pharms. LP*, No. 21-cv-0027 (D. Del. May 28, 2021), ECF No. 76.

Moreover, the government never once argues that Sanofi's conditions are unduly burdensome, let alone that they nullify the offer. The government does cite three complaints from covered entities about Sanofi's program, but none demonstrates any burden from Sanofi's initiative.[1] The first covered entity (North Country HealthCare) reported that its patients can "no longer access" Sanofi's medications at contract pharmacies and "have to travel" long distances to reach in-house pharmacies. Gov't Br. 17 (citing JA1170, 1172 (VLTR.7303, 7305)). But the cited declaration does not complain that Sanofi's request for claims data is burdensome; indeed, the declaration does not even explain why the covered entity chose not to provide the requested information and, instead, decided to forego access to Sanofi's drugs at the 340B price. *See* JA1169-73 (VLTR.7302-06).

Similarly, the second covered entity (Medical Associates Plus) does not suggest that it ever even considered participating in Sanofi's integrity

[1] The government also cites a "similar complaint" against Novo "from Presence St. Francis Hospital." Gov't Br. 16. As Sanofi explained below, this covered entity has not purchased Sanofi drugs at a price above the 340B ceiling price. *See* JA989-90 & n.3 (Declaration of Scott Bray (D.Ct.ECF.94-2, ¶ 12 & n.3)).

initiative, let alone that it concluded the program was too burdensome. *See* Gov't Br. 16-17 (citing JA1179-82 (VLTR.7255-58)). And although the third covered entity (AIDS Response Effort) reported being unable to obtain Sanofi's cancer drugs at the 340B price, *id.* at 16-17 (citing JA1095-1162 (VLTR.173-240)), this covered entity is excluded from Sanofi's initiative, as are Sanofi's cancer medicines, and thus it is free to use an unlimited number of contract pharmacies. *See* JA988-89 & n.2 (Declaration of Scott Bray ("Bray Declaration") (D.Ct.ECF.94-2, ¶ 11 & n.2 (citing JA1108 (VLTR.186)))). Thus, for all the "thousands of pages from covered entities" HRSA compiled in the Administrative Record, Gov't Br. 18, the government has failed to direct the Court to any evidence that Sanofi's integrity initiative is not a bona fide "offer" to covered entities to purchase Sanofi's drugs at the 340B price.

Instead, the government argues that manufacturers' policies on contract pharmacies are *collectively* burdensome on covered entities, because the manufacturers' policies are not identical, and covered entities would need to "accommodate a web of restrictive manufacturer conditions." *Id.* at 43. Even if that were true, it would not matter; all Section 340B requires is that each manufacturer offer their drugs at the

340B price, which Sanofi plainly does. Nothing in Section 340B adopts the government's theory of collective action. But regardless, the government's assertion finds no support in the administrative record, which has no evidence of covered entities struggling to comply with purportedly disparate policies on contract pharmacies. Nor can this argument even be squared with the government's own position that certain conditions (*e.g.*, a request for "standard information") are permissible—as nothing requires manufacturers to impose those conditions identically. One manufacturer's "standard information" may be different from another's (just as payors' requirements are often different); manufacturers may ask for information in different formats; the submissions' timing might differ; and so on. The government's purported concern about inconsistency is thus effectively an argument that no conditions at all should be allowed—which even the government has rightly declined to embrace. *See supra* at 14.

2. The Government's Other Objections to Sanofi's Program Are Meritless.

Unable to show that Sanofi's integrity initiative nullifies Sanofi's offers of the 340B price, the government tries to dismiss Sanofi's program as impermissible "self-help," arguing that Sanofi is not allowed to

penalize covered entities for diversion or duplicate discounting. Gov't Br. 40-41. But, as explained, that is not a rule found in Section 340B. *See supra* at 13-14. And regardless, the government misunderstands Sanofi's program—which merely requests claims data that allows Sanofi to identify impermissible duplicate discounts. With this data, Sanofi does not cut off any covered entities, but instead can decide whether to request an audit of a covered entity under Section 340B. *See* Opening Br. 20-21. Sanofi also uses the data to ensure that it does not improperly pay duplicative Medicaid rebates to state agencies. *See id.* As a result, even if the government were right that manufacturers cannot themselves police covered entities' compliance with Section 340B, Gov't Br. 39-40, Sanofi does no such thing.

The government also argues that Sanofi's request for limited claims data—a mere subset of the information covered entities already submit to insurers—violates HHS guidance that prohibits manufacturers from asking covered entities to provide "assurance of compliance with section 340B provisions." *Id.* at 42 (quoting JA165 (58 Fed. Reg. 68,922, 68,925 (Dec. 29, 1993))). But the government offers no statutory basis for (or even further explanation of) this supposed rule, which HHS announced

only in non-binding guidance. And in any event, Sanofi's initiative does not ask covered entities to provide "assurance of compliance" with Section 340B, *id.*; instead, Sanofi merely requests minimal data that can later be compared to Medicaid payor data. *See* Opening Br. 19-21.

The government likewise argues that Sanofi may not request this data in light of HHS guidance that prevents manufacturers from seeking information "related to drug acquisition, purchase, and inventory systems." Gov't Br. 42 (quoting JA165 (58 Fed. Reg. at 68,925)). But the government never explains the statutory basis for this non-binding guidance. Nor does the government explain why Sanofi's request for limited claims data is somehow impermissibly "related to drug acquisition, purchase, and inventory systems." *Id.* (quoting JA165 (58 Fed. Reg. at 68,925)).

The government also insinuates that Sanofi's data-collection program has "unknown privacy protections." *Id.* But the record establishes that Sanofi's program has been certified as HIPAA-compliant. *See* JA996 (Bray Declaration (D.Ct.ECF.94-2, ¶ 25)). If the government is attempting to imply confidentiality concerns with Sanofi's program, that is pure conjecture that should be rejected out of hand.

At any rate, there is no basis for the Court to conclude that Sanofi's data requests nullify 340B offers—or even impose burdens on covered entities—when the Violation Letter itself reached no such conclusions. As the opening brief explained, and as the government does not dispute, this Court can uphold the Violation Letter only on the grounds stated by the letter itself—namely, that Section 340B unambiguously prohibits any and all conditions on 340B offers. *See* Opening Br. 55-56; *Regents*, 140 S. Ct. at 1907.

* * *

According to the government, Congress has required private parties to underwrite the metamorphosis of a cost-savings program for safety-net providers into the second-largest federal drug program, at the cost of billions annually, subject to administrative enforcement and punitive fines—all *sub silentio*. This argument flouts bedrock principles of statutory construction and administrative law. Private parties are not *required* to act absent Congressional command; federal agencies are not *authorized* to act absent Congressional command; and courts expect Congress to speak—indeed, to speak clearly—when imposing

requirements concerning multi-billion-dollar questions. Section 340B thus does not authorize the Violation Letter.

II. The Government Fails to Rebut Sanofi's Argument That HHS Also Acted Arbitrarily and Capriciously.

Even if the Violation Letter were consistent with HHS's legal authority, it should be vacated as arbitrary and capricious for the two reasons Sanofi explained in its opening brief. *See* Opening Br. 59-62. *First*, HHS treated Section 340B as unambiguous even though the statute is, at best for the government, ambiguous about the rule the government seeks to enforce. *See id.* at 59-60. *Second*, HHS failed to address the changes in its statutory interpretation over time. *See id.* at 61. The government offers no response to these points and thus concedes them. *See Beazer E., Inc. v. Mead Corp.*, 412 F.3d 429, 437 n.11 (3d Cir. 2005) ("[T]he appellee waives, as a practical matter anyway, any objections not obvious to the court to specific points urged by the [appellant]." (quotation marks omitted)).

Although not addressing whether the Violation Letter was arbitrary and capricious, the government does argue that any possible ambiguity in Section 340B is "beside the point" because HHS does not seek *Chevron* deference. Gov't Br. 48. But the government's *Chevron*

argument is beside the point. If Section 340B is ambiguous with respect to contract pharmacies, the Violation Letter's failure to grapple with that purported ambiguity requires vacatur even if the government could offer an interpretation that is ultimately justifiable (which it cannot). *Regents of Univ. of Cal. v. DHS*, 908 F.3d 476, 505 (9th Cir. 2018) (citing *SEC v. Chenery Corp.*, 318 U.S. 80, 94 (1943)), *rev'd in part, vacated in part sub nom. Regents*, 140 S. Ct. 1891; *Peter Pan Bus Lines, Inc v. Fed. Motor Carrier Safety Admin.*, 471 F.3d 1350, 1354 (D.C. Cir. 2006).

The government next invites this Court to make the same mistake as the District Court by "resolv[ing] the ambiguity," if the Court rejects HHS's view that Section 340B is unambiguous. Gov't Br. 48. But again, this Court cannot sustain the Violation Letter based on a new theory of statutory ambiguity that HHS never mentioned in the Letter. Opening Br. 60-61.

The government also suggests that HHS's change in positions need not be explained because the Violation Letter is based on "the statute's requirements alone." Gov't Br. 48-49. But the government cites no authority for this position, which flouts the well-settled rule of administrative law that an agency must "display awareness" of changes

in its position and provide a "reasoned explanation" for those changes. *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221-22 (2016).

III. This Court Should Address the Flawed Advisory Opinion.

Sanofi is also entitled to relief from the Advisory Opinion, which suffers from the same legal flaws discussed above. *See* Opening Br. 63-64. Rather than defending the Advisory Opinion on the merits, the government asserts that this dispute is "academic," and that "[i]t is unclear what relief [Sanofi] seek[s]" given that "HHS has already withdrawn the [A]dvisory [O]pinion." Gov't Br. 49*; see id*. at 28 n.5.

But Sanofi has made perfectly clear what relief it seeks: vacatur of the Advisory Opinion, an injunction barring HHS from enforcing the position announced in the Advisory Opinion against Sanofi, and a declaration concerning Sanofi's statutory obligations and the unlawfulness of the Advisory Opinion. JA981-82 (Sanofi Compl. at 60-61); *see* Opening Br. 64. Tellingly, the government never actually argues that Sanofi's claims about the Advisory Opinion are moot, nor does the government respond to Sanofi's arguments on why these claims are *not* moot. *See* Opening Br. 64-65. The government's strategic withdrawal thus does not shield the Advisory Opinion from judicial review, as

multiple courts have held. *See Eli Lilly & Co. v. HHS*, No. 21-cv-0081, 2021 WL 5039566, at *12 (S.D. Ind. Oct. 29, 2021); ECF No. 83 at 2, *AstraZeneca Pharms. LP*, No. 21-cv-0027 (D. Del. June 30, 2021).

Nor is this just some "academic" dispute. HHS contends that Sanofi is subject to massive civil monetary penalties for operating the integrity initiative—but such penalties can be appropriate only for a "knowing[] and intentional[]" violation of Section 340B. 42 C.F.R. § 10.11(a). Granting Sanofi's requests for relief regarding the Advisory Opinion will confirm that Sanofi did not receive proper notice of the agency's purported rule about contract pharmacies in advance of the Violation Letter—which, in turn, is one of the reasons why civil monetary penalties are not appropriate. This Court thus should not hesitate to resolve the validity of the Advisory Opinion. *See* Opening Br. 66.

IV. HHS Violated the APA When Promulgating the ADR Rule.

Like the Violation Letter and Advisory Opinion, the ADR Rule is unlawful, too. HHS violated the APA's notice-and-comment requirement by promulgating the ADR Rule based on a notice of proposed rulemaking ("NPRM") that had been withdrawn years earlier. *See* Opening Br. 66-

69; *Eli Lilly & Co. v. Cochran*, 526 F. Supp. 3d 393, 407-08 (S.D. Ind. 2021) ("*Lilly I*").

The government does not dispute that an agency may not issue a final rule based on a withdrawn NPRM. According to the government, though, the 2016 NPRM was not actually withdrawn but merely "omit[ed]" or "removed" from the Unified Agenda. Gov't Br. 51-53. This ignores that the Executive Branch *expressly announced* that the NPRM was "*Withdrawn*" as of 2017 and even identified the rulemaking as a "Completed Action[]," JA195 (OIRA, RIN 0906-AA90 (2017), https://tinyurl.com/5y66nkjp ("Unified Agenda")) (emphasis added)—a status reserved for "completed or withdrawn" rulemakings, JA721 (86 Fed. Reg. 41,166, 41,168 (July 30, 2021)); *see* JA28 (Op.18). That announcement is dispositive, particularly when coupled with HHS's public statements—also ignored by the government—confirming that the rulemaking had been terminated. *See* Opening Br. 21-23, 66-67.

Regulated entities and the public are entitled to "reliability in their dealings with their Government." *Heckler v. Cmty. Health Servs. of Crawford Cnty., Inc.*, 467 U.S. 51, 61 & n.13 (1984). "If [they] must turn square corners when they deal with the government, it cannot be too

much to expect the government to turn square corners when it deals with them." *Niz-Chavez v. Garland*, 141 S. Ct. 1474, 1486 (2021); *see Regents*, 140 S. Ct. at 1909. At minimum, affected parties should be able to take the Executive Branch at its word when it announces that an NPRM is "Withdrawn."

The government tries to recharacterize this withdrawal as a mere regulatory "paus[e]" pursuant to a memorandum issued by the President's Chief of Staff in January 2017. Gov't Br. 52 (quoting JA197 (85 Fed. Reg. 80,632, 80,633 (Dec. 14, 2020) (ADR.13)); *see* JA381 (Regulatory Freeze Pending Review, 82 Fed. Reg. 8346 (Jan. 24, 2017) (ADR.527)). But the timeline belies the government's revisionist history. The withdrawal occurred more than half a year later in August 2017, demonstrating that it was not a ministerial pause driven by the memorandum but rather a discretionary decision by the agency. *See* JA195 (Unified Agenda). That is presumably why the Unified Agenda stated that the rulemaking was "Completed" and the NPRM was "Withdrawn"—not paused. *Id.*; *cf. Regents*, 140 S. Ct. at 1909 (an agency must defend its actions based on the "contemporaneous explanations" it gave "when it acted").

According to the government, the Unified Agenda deserves little weight because it merely "'predict[s]'" an agency's "anticipated" activities "'over the next 12 months.'" Gov't Br. 52 (quoting JA40 (Op.30) (quoting JA720 (86 Fed. Reg. at 41,167))). But the Unified Agenda "*also* show[s] actions … *withdrawn* since the last Unified Agenda." JA720 (86 Fed. Reg. at 41,167) (emphasis added).

The government additionally remarks that withdrawing an NPRM through the Unified Agenda "without further explanation" would be "odd," because "such a withdrawal might be challenged as final agency action." Gov't Br. 53. "Odd" or not, an unexplained withdrawal remains a withdrawal—and the fact that a withdrawal might be prone to attack hardly shows the withdrawal never occurred.

Similarly, in asserting that agencies "*ordinarily*" withdraw NPRMs through the Federal Register "*often* accompanied by an explanation," *id.* at 52-53 (emphasis added), the government admits that agencies do not *always* do so. And the government cites no case holding that withdrawals in the Federal Register are the only ones that count. *See Lilly I*, 526 F. Supp. 3d at 406-07 (finding "no evidence" or "case law" supporting that a Federal Register notice "is required to effectuate withdrawal"). For these

reasons, even the District Court rejected as "incorrect" the notion that HHS "did not terminate rulemaking simply because it did not publish notice in the Federal Register." JA39-40 (Op.29-30).

The government also misunderstands the significance of the four-year delay between the 2016 NPRM and the ADR Rule. Sanofi does not argue that "the mere passage of time" violated the APA here. Gov't Br. 53. Rather, Sanofi argues that the "years of agency silence" "buttress[es] the conclusion that the NPRM had been terminated." *Lilly I*, 526 F. Supp. 3d at 407; *see* Opening Br. 67. After all, four years of inaction confirm that HHS itself believed—consistent with its public statements as late as 2020—that the rulemaking had ended. *See Lilly I*, 526 F. Supp. 3d at 407.

Like the District Court, the government further contends that Section 340B itself provided "fair notice" by requiring an ADR rule "at some point, sooner or later." Gov't Br. 54-55 (quoting JA42 (Op.32)). As Sanofi explained, however, the notice required by the APA must come from the agency, not a statute. Opening Br. 68. Indeed, this argument would create an extraordinary exception to the APA's notice-and-comment requirement, eliminating agencies' obligation to comply with

that requirement whenever they engage in rulemaking mandated by Congress.[2] That is not and cannot be the law.

Last, the government suggests that the APA violation should be overlooked because no "relevant" changes occurred between the comment period and the ADR Rule. Gov't. Br. 55. But the government cites no authority supporting that an agency may issue a rule based on a withdrawn NPRM so long as the circumstances remain static. Moreover, the circumstances were *not* static. Before the ADR Rule issued, for

[2] There are many examples of rulemaking mandated by Congress—all of which, under the government's argument, would be exempt from the APA's notice-and-comment requirement. *See, e.g.*, 21 U.S.C. §355b (HHS, labelling rules); *id.* § 360a (HHS, medical device registration standards); *id.* § 387a-1 (HHS, tobacco product rules); 42 U.S.C. § 273 (HHS, criteria for qualified organ procurement organizations); *id.* § 290ii-2 (HHS, in-patient mental health facilities rules); *id.* § 300gg-17 (HHS, group health plan reimbursement criteria); *id.* § 1395*l*(f) (HHS, maximum payment rates for visits to rural health clinics); *id.* § 1395*l*(t)(18)(B) (HHS, cancer hospital cost differential adjustments); *id.* § 1396t(k) (HHS, rules governing facilities for the care of disabled elderly individuals); *id.* § 6103 (HHS, nondiscrimination rules); *see also, e.g.*, 15 U.S.C. § 2506(b) (Department of Energy, electric vehicle performance standards); *id.* § 7712 (FTC, consumer protection standards); 21 U.S.C. § 350h (FDA, produce safety regulations); 38 U.S.C. § 3707A(d) (Department of Veterans Affairs, loan underwriting standards); 42 U.S.C. § 1758(a)(4)(B) (Department of Agriculture, nutritional standards for national school lunch program); 47 U.S.C. § 262(c)(1)(B) (FCC, service quality standards); 49 U.S.C. § 30129(a) (Department of Transportation, crash avoidance technology standards).

example, manufacturers sought to present HHS with "significant new evidence" that the dramatic growth in contract pharmacy arrangements after 2017 had precipitated extensive abuses. JA829, 838 (PhRMA, Petition for Rulemaking (Nov. 24, 2020) ("Petition") (ADVOP.1379, 1388)); *see* JA832-38 (Petition (ADVOP.1382-88)) (detailing abuses). Such evidence and other industry developments between 2017 and 2021 were plainly relevant to a rulemaking obligated to ensure that manufacturers and covered entities can resolve disputes over abuses and pricing "fairly, efficiently, and expeditiously." JA839 (Petition (ADVOP.1389)) (quoting 42 U.S.C. § 256b(d)(3)(B)(ii)). As the manufacturers explained, for instance, the new evidence was relevant to crafting adequate audit and investigation procedures as part of the rulemaking: Without an up-to-date understanding of the problems of diversion and duplicate discounting, HHS was not equipped to develop a process for identifying those abuses through covered-entity audits—a "critical" prerequisite to manufacturers' ADR claims. JA830, 839-40, 846 (Petition (ADVOP.1380, 1389-90, 1396)). Nor was HHS equipped to determine whether manufacturers needed more robust investigatory tools before and during ADR proceedings, such as the ability to seek

discovery from covered entities and contract pharmacies rather than rely on the more limited options that the agency hastily adopted. *See* 42 C.F.R. § 10.22; *see also* JA201, 204 (85 Fed. Reg. at 80,637, 80,640 (ADR.17, 20)). Yet HHS nevertheless ignored these developments.

V. The Government's Cross-Appeal Is Meritless.

Finally, the government has separately cross-appealed the District Court's decision to partially vacate the Violation Letter and remand to HHS for a fuller consideration of whether Section 340B requires manufacturers to recognize one, multiple, or unlimited contract pharmacy arrangements. Gov't Br. 45-49; JA6 (Notice of Cross-Appeal); *see* JA9-10, 105-109, 132 (Order 2-3; Op.95-99, 122). The government contends that "there was no basis for a remand" because "Congress did not delegate general authority to HHS to make substantive rules regarding the 340B Program." Gov't Br. 47. Thus, as the government sees it, HHS "has no statutory authority to restrict covered entities' use of contract pharmacies." *Id.* at 48.

But the parties all agree that, when issuing the Violation Letter, HHS was operating in an area of statutory silence. Even if this silence somehow authorizes the agency's enforcement action, it is fundamental

that an agency must adequately explain *all* of its final "agency action[s]"—not just acts of formal rulemaking. 5 U.S.C. § 706(2)(A); *see, e.g.*, *Regents*, 140 S. Ct. at 1905, 1910, 1916 (explaining that a court should vacate agency action when the agency fails to examine the "relevant factors," address an "important aspect[] of the problem," or articulate a satisfactory "reasoned explanation" for its action). Here, even accepting the government's erroneous assessment that Section 340B requires manufacturers to provide their drugs to contract pharmacies, it was still imperative that HHS have explained why this principle required delivery to unlimited contract pharmacies—as opposed to just one or multiple contract pharmacies.

That is an exceedingly important question because, as the District Court explained, "[a] limitless number of contract pharmacies (or perhaps even a lesser number) may render the *overall* statutory scheme unworkable, undermine how Congress intended *all* of § 340B's provisions to work together, or otherwise affect how HHS can lawfully exercise its enforcement authority." JA105-06 (Op.95-96). For instance, because "contract pharmacy arrangements increase the rate of fraud in the 340B Program," their unlimited use may "undermine[]" "statutory priorities"

such as "preventing fraud and abuse." JA106-08 (Op.96-98) (citing GAO-18-480). And given that different types of covered entities have different "needs and characteristics," "there may be a point" at which a "one-size-fits-all" contract pharmacy requirement "ceases to advance Program goals." JA108 (Op.98). Yet the Violation Letter failed to grapple with any of these considerations—and the District Court was accordingly correct to partially vacate and remand the letter, if the District Court's decision was otherwise correct. *See Regents*, 140 S. Ct. at 1905, 1910, 1916; *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42-43 (1983); *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 744 (1985); *W.R. Grace & Co. v. EPA*, 261 F.3d 330, 333, 338 (3d Cir. 2001).

The government does not dispute that HHS failed to address these issues. Instead, the government claims that HHS properly ignored them because the agency had no "statutory authority" or "discretion" under *Chevron* to "restrict covered entities' use of contract pharmacies." Gov't Br. 46-48. But that is the government's argument now. It is not what HHS said in the Violation Letter, and it is accordingly not a proper basis to uphold the Letter.

Moreover, even if Section 340B requires manufacturers to provide discounted drugs to an unlimited number of contract pharmacies, HHS was still obligated to explain its decision to enforce that requirement against Sanofi. After all, HHS need not enforce Section 340B to the hilt in all circumstances. Rather, HHS retains discretion to decide whether to enforce the statutory requirements—and "an agency must cogently explain why it has exercised its discretion in a given manner." *State Farm*, 463 U.S. at 48-49; *see also, e.g.*, *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 516-22 (2009) (subjecting agency enforcement decisions to reasoned decisionmaking requirements); *Michigan v. EPA*, 576 U.S. 743, 753 (2015) ("[R]easonable regulation ordinarily requires paying attention to the advantages *and* the disadvantages of agency decisions.").

Due to these errors on the agency's part, even assuming the District Court was correct in finding that Sanofi's integrity program violated 340B in any way (and it was not), the District Court nonetheless properly granted the default remedies for an APA violation: vacatur in relevant part and remand for further consideration. *See State Farm*, 463 U.S. at

43*; Fla. Power & Light Co.*, 470 U.S. at 744. Thus, if it reaches the issue, this Court should affirm this aspect of the District Court's judgment.[3]

CONCLUSION

The Court should set aside the Violation Letter, the Advisory Opinion, and the ADR Rule; declare that Section 340B does not require Sanofi to provide discounted drugs to contract pharmacies; declare that Sanofi's integrity initiative complies with Section 340B; enjoin further enforcement action against Sanofi's integrity initiative; and affirm the District Court's partial vacatur and remand of the Violation Letter.

[3] The government has forfeited any argument that the District Court should have remanded *without* vacatur. *See, e.g.*, *In re LTC Holdings, Inc.*, 10 F.4th 177, 181 n.1 (3d Cir. 2021).

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Respectfully submitted,

s/ Brett A. Shumate

Toni-Ann Citera
Rajeev Muttreja
JONES DAY
250 Vesey Street
New York, New York 10281
(212) 326-3939
tcitera@jonesday.com
rmuttreja@jonesday.com

Noel J. Francisco
Brett A. Shumate
JONES DAY
51 Louisiana Ave. NW
Washington, DC 20001
(202) 879-3939
njfrancisco@jonesday.com
bshumate@jonesday.com

Counsel for Appellant/Cross-Appellee Sanofi-Aventis U.S., LLC

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I hereby certify that, on July 14, 2022, I filed the foregoing brief using this Court's CM/ECF system, which effected service on all parties.

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