PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

Nos. 21-3167, 21-3379

SANOFI AVENTIS U.S. LLC,
Appellant in No. 21-3167

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; GENERAL COUNSEL, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; HEALTH RESOURCES SERVICES ADMINISTRATION; ADMINISTRATOR OF THE HEALTH RESOURCES SERVICES ADMINISTRATION,
Appellants in No. 21-3379

On Appeal from the United States District Court
for the District of New Jersey
(D.C. No. 3:21-cv-00634)
Chief District Judge: Honorable Freda L. Wolfson

Nos. 21-3168, 21-3380

NOVO NORDISK INC.; NOVO NORDISK PHARMA, INC.
Appellants in No. 21-3168

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; GENERAL COUNSEL, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; HEALTH RESOURCES SERVICES ADMINISTRATION; ADMINISTRATOR OF THE HEALTH RESOURCES SERVICES ADMINISTRATION,
Appellants in No. 21-3380

On Appeal from the United States District Court
for the District of New Jersey
(D.C. No. 3:21-cv-00806)
Chief District Judge: Honorable Freda L. Wolfson

No. 22-1676

ASTRAZENECA PHARMACEUTICALS LP

v.

SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; GENERAL COUNSEL, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ADMINISTRATOR OF THE HEALTH RESOURCES AND SERVICES ADMINISTRATION; UNITED STATES DEPARTMENT OF HEALTH

AND HUMAN SERVICES; HEALTH RESOURCES AND SERVICES ADMINISTRATION,
Appellants.

On Appeal from the United States District Court
for the District of Delaware
(D.C. No. 1:21-cv-00027)
District Judge: Honorable Leonard P. Stark

Argued: November 15, 2022

Before: AMBRO, KRAUSE, and BIBAS, *Circuit Judges*

(Filed: January 30, 2023)

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OPINION OF THE COURT

BIBAS, *Circuit Judge*.

Statutory silences, like awkward silences, tempt speech. But courts must resist the urge to fill in words that Congress left out. The Department of Health and Human Services claims that drug makers must deliver certain discounted drugs wherever and to whomever a buyer demands. But the relevant law says nothing about such duties. So HHS's efforts to enforce its interpretation against the drug makers here are unlawful.

I. BACKGROUND

A. Congress enacted Section 340B

The federal government dominates the healthcare market. Through Medicare and Medicaid, it pays for almost half the annual nationwide spending on prescription drugs. *See* Cong. Budget Off., *Prescription Drugs: Spending, Use, and Prices* 8 (2022). It uses that market power to get drug makers to subsidize healthcare. Under Section 340B, drug makers that want to take part in Medicare or Medicaid must offer their drugs at a discount to certain healthcare providers. 42 U.S.C. §§256b, 1396r-8(a)(1), (5). These providers, called "covered entities," typically care for low-income and rural persons. Section 340B helps providers do that. First, it gives them extra revenue from serving insured patients: they turn a profit when insurance companies reimburse them at full price for drugs that they bought at the 340B discount. Second, it enables them to give

uninsured patients drugs at little or no cost. *See* Gov't Accountability Off., *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement* 17–18 (GAO-11-836, Sept. 2011).

Congress enacted Section 340B as part of the Veterans Health Care Act of 1992 and amended it in 2010 as part of the Affordable Care Act. Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967; Pub. L. No. 111-148, tit. VII.B, §§ 7101–02, 124 Stat. 119, 821–27 (both codified at 42 U.S.C. § 256b).

It has three basic parts: (1) a cap on drug makers' prices, (2) restrictions on covered entities, and (3) compliance mechanisms.

1. *Price cap on drug makers*. Central to this appeal are two provisions requiring drug makers to sell their drugs at or below a price cap. First, Section 340B directs the Secretary of HHS to sign an agreement with each drug maker capping prices "for covered outpatient drugs … purchased by a covered entity." 42 U.S.C. § 256b(a)(1). This is known as the "purchased by" requirement. The second requirement is the "shall offer" provision:

> Each such agreement … shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price.

Id.

2. *Covered-entity restrictions.* Section 340B also subjects participating covered entities to two restrictions. First, it bans duplicate discounts: covered entities cannot get the 340B

discount on drugs already subject to a Medicaid rebate. §256b(a)(5)(A)(i). Second, it bans diversion: covered entities can sell 340B drugs to only their own patients. §256b(a)(5)(B).

3. *Compliance mechanisms.* Though Section 340B's substantive requirements and restrictions are few, its compliance provisions are many. *See, e.g.*, §256b(d). For instance, drug makers and the Secretary of HHS can audit covered entities. §256b(a)(5)(C). And the statute specifies punishments for violators: drug makers and covered entities can be fined, and covered entities can be kicked out of the program. §256b(d)(1)(B)(vi), (d)(2)(B)(v)(I)–(II).

B. HHS issued guidance on contract pharmacies

When Congress first enacted Section 340B, few covered entities had pharmacies in house. So covered entities sought to contract with outside pharmacies to distribute 340B drugs for them. Covered entities using contract pharmacies would still order and pay for the drugs, but they would be shipped directly to the pharmacies. In 1996, HHS issued guidance saying that covered entities could use one contract pharmacy each. 61 Fed. Reg. 43,549 (Aug. 23, 1996). Then, in 2010, HHS issued new guidance, saying that covered entities could use an unlimited number of contract pharmacies. 75 Fed. Reg. 10,272 (Mar. 5, 2010).

After the 2010 guidance, the use of contract pharmacies skyrocketed. Their number increased twentyfold.

C. Drug makers rebelled

This explosion worried drug makers. They thought that contract pharmacies were driving up duplicate discounting and

diversion. So, in 2020, they responded, adopting policies to limit the use of contract pharmacies. Here is a summary of the three drug makers' policies at issue:

	2020 Distribution Policy
Sanofi	1. Covered entities may use an in-house pharmacy. 2. If they do not have an in-house pharmacy, they may use one contract pharmacy. 3. If they agree to provide claims data, they may use an unlimited number of contract pharmacies.
Novo Nordisk	1. Covered entities may use an in-house pharmacy. 2. If they do not have an in-house pharmacy, they may use one contract pharmacy. 3. They may use multiple contract pharmacies at Novo Nordisk's discretion.
Astra-Zeneca	1. Covered entities may use an in-house pharmacy. 2. If they do not have an in-house pharmacy, they may use one contract pharmacy.

D. HHS reacted

HHS responded with the three actions at the center of this litigation.

1. *The Advisory Opinion.* First, in December 2020, HHS released an Advisory Opinion declaring that Section 340B

unambiguously requires drug makers to deliver 340B drugs to an unlimited number of contract pharmacies. HHS Off. Gen. Couns., *Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program* (Dec. 30, 2020), https://perma.cc/L7W2-H597. HHS reasoned that 340B drugs are "purchased by" a covered entity no matter how they are distributed. *Id.* at 1–3. So, it argued, the "situs of delivery … is irrelevant." *Id.* at 3.

2. *Violation Letters.* Five months later, HHS sent Violation Letters to the drug makers. These letters said their policies were unlawful and ordered them to rescind those policies and reimburse covered entities for any overcharges.

Though the Advisory Opinion relied mainly on Section 340B's "purchased by" language, the Violation Letters relied solely on Section 340B's "shall offer" language. But their conclusions were the same: drug makers must deliver discounted drugs to an unlimited number of contract pharmacies.

3. *The Administrative Dispute Resolution Rule.* When Congress amended Section 340B back in 2010, it told HHS to set up a process through which drug makers and covered entities could resolve Section 340B–related disputes. §256b(d)(3). But HHS dawdled. It did not issue a notice of proposed rulemaking until 2016. 81 Fed. Reg. 53,381 (Aug. 12, 2016). And after accepting comments on the proposed Administrative Dispute Resolution (ADR) Rule, HHS seemed to abandon it. In 2017, in a regulatory publication called the Unified Agenda, it listed the proposed rule as withdrawn. 340B Drug Pricing Program; Administrative Dispute Resolution Process, RIN 0906-AA90 (Spring 2017), https://perma.cc/ADX3-QUEJ (noting "NPRM Withdrawn" on "08/01/2017").

But that would not be the last of the proposed rule. In 2020, HHS revived it. The agency said that it had just "paus[ed] action on the proposed rule" rather than withdrawing it. 85 Fed. Reg. 80,632, 80,633 (Dec. 14, 2020). It then responded to the four-year-old comments and issued a final ADR Rule. *Id.* at 80,633–42, 80,644–46.

After we heard this appeal, HHS proposed a new rule to revise the 2020 ADR Rule's procedures. 87 Fed. Reg. 73,516 (Nov. 30, 2022). But for now, the 2020 Rule remains in force.

E. Procedural history

1. *AstraZeneca won in Delaware*. Not long after the Advisory Opinion was issued, AstraZeneca sued in the District of Delaware to invalidate it. That Court held that the Advisory Opinion was arbitrary and capricious because it wrongly called Section 340B unambiguous. *AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47, 58–62 (D. Del. 2021). Unsure of "the precise relief to be granted," the Court asked for the parties' views. *Id.* at 62. Instead, HHS rescinded the Advisory Opinion. Finding that rescission did not moot the issue, the Court vacated the Advisory Opinion. *AstraZeneca Pharms. LP v. Becerra*, 2021 U.S. Dist. LEXIS 122049, at *3–5 (D. Del. June 30, 2021).

During the lawsuit, HHS also sent AstraZeneca a Violation Letter, ordering it to stop restricting delivery to contract pharmacies. *AstraZeneca Pharms. LP v. Becerra*, 2022 WL 484587, at *3 (D. Del. Feb. 16, 2022). The Court likewise vacated the Violation Letter because it rested on the same flawed premise that Section 340B was unambiguous and wrongly

called HHS's position consistent between 1996 and 2010. *Id.* at *5–6, 9.

2. *But the government won in New Jersey*. Things played out differently for Sanofi and Novo Nordisk in the District of New Jersey. That Court held that their challenge to the Advisory Opinion was moot. *Sanofi-Aventis U.S., LLC v. HHS*, 570 F. Supp. 3d 129, 159 n.31 (D.N.J. 2021). And although it agreed with the District of Delaware that Section 340B was ambiguous, it mostly upheld the Violation Letters. Relying largely on the statute's purpose and legislative history, it concluded that Section 340B requires delivery to at least one contract pharmacy. *Id.* at 193–202. Yet rather than decide whether it also requires delivery to an unlimited number of contract pharmacies, the Court remanded to the agency for further consideration. *Id.* at 203–06. Finally, it upheld the ADR Rule, rejecting a challenge to the agency's notice-and-comment process. *Id.* at 161–67.

A flurry of appeals from both District Court proceedings is now before us. From the District of Delaware, HHS has appealed. From the District of New Jersey, Sanofi and Novo Nordisk have appealed and HHS has cross-appealed.

We review the District Courts' rulings de novo. *See Eid v. Thompson*, 740 F.3d 118, 122 (3d Cir. 2014). And we review the underlying agency actions for whether they were "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Id.* (quoting 5 U.S.C. § 706(2)(A)).

II. THE GOVERNMENT MAY NOT ENFORCE ITS READING OF THE STATUTE AGAINST THESE DRUG MAKERS

A. The drug makers' challenge to the Advisory Opinion is not moot

We start with the government's half-hearted suggestion that the dispute over the Advisory Opinion is moot. It is not. Though HHS rescinded the Opinion after it lost in Delaware, it has "not altered its position" on the use of contract pharmacies. *Solar Turbines Inc. v. Seif*, 879 F.2d 1073, 1079 (3d Cir. 1989). It still says that drug makers must deliver their drugs to an unlimited number of contract pharmacies. And it still takes enforcement actions in line with that view. "We will understandably be skeptical of a claim of mootness when a defendant yields in the face of a court [ruling] and assures us that the case is moot because the injury will not recur, yet maintains that its conduct was lawful all along." *Hartnett v. Pa. State Educ. Ass'n*, 963 F.3d 301, 306 (3d Cir. 2020). That is what happened here.

True, by rescinding the Advisory Opinion, HHS obviated vacating it. *Cf. United States v. Texas*, No. 22-58 (U.S. argued Nov. 29, 2022) (considering vacatur as a remedy under the APA). But we can still enjoin HHS from reverting to the Advisory Opinion's interpretation of Section 340B. *United States v. W. T. Grant Co.*, 345 U.S. 629, 633 (1953) ("[T]he court's power to grant injunctive relief survives discontinuance of the illegal conduct."). Thus, the dispute is not moot.

B. Section 340B does not require delivery to an unlimited number of contract pharmacies

Both the Advisory Opinion and the Violation Letters say Section 340B requires drug makers to deliver drugs to an unlimited number of contract pharmacies. As the parties agree, HHS lacks rulemaking authority here, so its reading does not merit *Chevron* deference. *See Christensen v. Harris Cnty.*, 529 U.S. 576, 587 (2000). Nor does it merit *Skidmore* deference. The agency's reading is "entitled to respect …, but only to the extent that" it has "the power to persuade." *Id.* (internal quotation marks omitted). As we explain below, "we find unpersuasive the agency's interpretation of the statute." *Id.* So it deserves no deference.

1. *The text is silent about delivery*. We turn to the statutory text. The parties focus on Section 340B's "shall offer" provision. If drug makers make drugs available to anyone at any price, they must "offer" those drugs to "covered entities" at a discount. 42 U.S.C. § 256b(a)(1). Nowhere does Section 340B mention contract pharmacies.

Nor does the word "offer" imply that the offeror must deliver goods wherever and to whomever the buyer demands. "Offer" means to "present[ ] something for acceptance." *Offer*, *Black's Law Dictionary* (11th ed. 2019). Even if drug makers limit where they will deliver drugs, they still present the drugs for covered entities' acceptance. And the drug makers' delivery conditions do not prevent any covered entity from accepting these offers. Each can still buy and dispense unlimited discounted drugs by having them delivered to an in-house or contract pharmacy.

By contrast, one could argue that if a drug maker barred all use of contract pharmacies, it would not "present" discounted drugs "for acceptance" by all covered entities. A covered entity that lacks an in-house pharmacy and cannot use a contract pharmacy might have no way to dispense the drugs and so could not in practice "accept" them. But that situation is not before us. Under the three drug makers' policies at issue, all covered entities can still use the Section 340B program. Though the covered entities cannot squeeze as much revenue out of it as they once could, drug makers need not help them maximize their 340B profits.

Section 340B's "purchased by" language likewise says nothing about delivery. § 256b(a)(1). HHS reasoned that because discounted drugs are "purchased by" a covered entity no matter where they are delivered, drug makers must deliver them wherever a covered entity demands, whether that be "a neighborhood pharmacy" or "the lunar surface." HHS Off. Gen. Couns., *Advisory Opinion* 2–3. But that is one giant leap from the text. The "purchased by" provision imposes only a price term for drug sales to covered entities, leaving all other terms blank. *See* § 256b(a)(1). HHS suggests that covered entities get to fill in those blanks so long as they foot the bill. But when Congress's words run out, covered entities may not pick up the pen. Plus, Congress's use of the singular "covered entity" in the "purchased by" language suggests that it had in mind one-to-one transactions between a covered entity and a drug maker without mixing in a plethora of pharmacies.

No other language in Section 340B requires delivery to an unlimited number of contract pharmacies. Still, HHS says that the drug makers' policies are "not permit[ted]" just because

Section 340B does not "expressly prohibit[ ]" them. HHS Resp. Br. 33 (internal quotation marks omitted). But that logic is "exactly backwards." *Christensen*, 529 U.S. at 588. Unless Section 340B "*prohibits*" drug makers from adopting their policies, HHS cannot show that they have violated Section 340B. *Id.* (emphasis in original). Because Section 340B "contains no such prohibition," the drug makers' policies are lawful. *Id.*

2. *Structural clues confirm that the statute does not require unlimited delivery*. Several structural clues confirm our reading of Section 340B. To start, "Congress knew how to" grant covered entities permission to contract with third parties for distribution. *State Farm Fire & Cas. Co. v. United States ex rel. Rigsby*, 580 U.S. 26, 36 (2016); *Rotkiske v. Klemm*, 140 S. Ct. 355, 361 (2019). A subsection elsewhere in Section 340B instructs HHS to set up a program under which "covered entities may enter into contracts with prime vendors for the distribution of covered outpatient drugs." §256b(a)(8). Congress could have included similar language for contract pharmacies but did not.

Congress also knew how to impose delivery-related requirements. That same subsection provides that if covered entities "obtain[ ] drugs directly from a manufacturer, the manufacturer shall be responsible for the costs of distribution." *Id.* Again, Congress could have similarly required drug makers to deliver their drugs to certain places. And again, it chose not to.

What is more, Section 340B's statutory neighbor includes language along the lines of what the government asks us to insert into Section 340B. Pub. L. No. 102-585, §603(a)(1), 106 Stat. 4943, 4971 (codified at 38 U.S.C. §8126). That

neighboring provision was enacted as part of the same Veterans Health Care Act of 1992, and it started on the very page of the Act where Section 340B ended. It regulates the prices that federal agencies pay for drugs. Like Section 340B, it directs the Secretary of HHS to enter agreements with drug makers to sell "covered drug[s]" at discounted prices. 38 U.S.C. §8126(a)(2). But unlike Section 340B, it expressly contemplates drug makers selling discounted drugs through contract pharmacies. *Id.* §8126(a)(2), (h)(3)(A)(ii). Discounts apply to drugs "purchased under depot contracting systems," including those delivered through "a commercial entity operating under contract with [the] agency." *Id.* Congress added that specific language there but not here. We presume that it did so intentionally. *Barnhart v. Sigmon Coal Co.*, 534 U.S. 438, 452 (2002).

The government's reading would also put drug makers in a legal bind. Some drugs are so risky that the Food and Drug Administration requires drug makers to develop programs for their safe use. *See, e.g.*, 21 U.S.C. §355-1. Drug makers often comply by limiting distribution to a few pharmacies that are specially trained to educate and monitor patients. The government now says that such limits are illegal under Section 340B. Perhaps there is a costly, complex way to comply with both requirements, but this tension is another strike against the government's reading. Leaving drug makers discretion on delivery is not only more consistent with Section 340B's text, but also more consistent with this other statutory requirement.

Finally, Section 340B's compliance measures do not implicitly preclude delivery limits. Recall that the drug makers say their restrictions were driven by concerns about contract

pharmacies' compliance. In response, the government correctly notes that Section 340B already has extensive compliance measures. *See, e.g.*, § 256b(a)(5)(C)–(D), (d)(2). So, it reasons, drug makers may not tack on measures of their own. That misses the mark. The statute directs its compliance provisions at covered entities, not contract pharmacies. For instance, it authorizes audits of only "covered entit[ies]." *See* § 256b(a)(5)(C). So the government's inference that drug makers cannot limit the use of contract pharmacies "go[es] beyond the category to which the negative implication pertains." Antonin Scalia & Bryan A. Garner, *Reading Law* 108 (2012) (negative-implication canon). In short, the statutory structure supports the drug makers, not the government.

3. *Neither drafting history nor legislative purpose compels a different result*. With no textual or structural hook for its position, the government grasps at drafting history and legislative purpose. Neither calls for a different outcome.

Take drafting history. When enacting Section 340B, Congress also considered a bill that would have required discounts on drugs "purchased and dispensed by, or under a contract entered into for on-site pharmacy services with," a covered entity. S. Rep. No. 102-259, at 2 (1992). Section 340B kept the "purchased by" language but dropped the rest. § 256b(a)(1). So, the government reasons, Congress must have meant for drug makers to give discounts on all drugs "purchased by" covered entities, no matter how they are dispensed.

But drawing inferences from unenacted drafting history is "perilous." *District of Columbia v. Heller*, 554 U.S. 570, 590 (2008); *see Ramos v. Louisiana*, 140 S. Ct. 1390, 1400 (2020).

Just so here. Congress could have omitted the language about on-site pharmacies because it did not want *any* contract pharmacy involved in the 340B program. With that language gone, it might have thought that the language letting a covered entity dispense 340B drugs was unnecessary: of course covered entities are allowed to dispense drugs that they buy. In other words, the same cutting-room scrap can support "opposite inference[s]." *Ramos*, 140 S. Ct. at 1400.

Finally, the government argues that letting drug makers limit the use of contract pharmacies would thwart Congress's purpose in enacting Section 340B. When it was passed, few covered entities had in-house pharmacies, so most could not have accessed the discounted drugs without contract pharmacies. But this argument does not get the government where it needs to go. Congress might have expected that a covered entity without its own in-house pharmacy could instead use one contract pharmacy. But that is a far cry from the government's current position that covered entities may use an unlimited number of contract pharmacies.

So the Violation Letters and Advisory Opinion are unlawful. These three drug makers' restrictions on delivery to contract pharmacies do not violate Section 340B. And we will enjoin HHS from enforcing against them its reading of Section 340B as requiring delivery of discounted drugs to an unlimited number of contract pharmacies. That will give them complete relief. We conclude by considering the ADR Rule.

III. THE ADR RULE IS LAWFUL

Only Sanofi challenges the ADR Rule. It says the Rule violated the APA's notice and comment requirements because it

rested on a proposed rule that, in a 2017 publication, HHS listed as withdrawn. The government responds that it never withdrew the rule, but just "paus[ed] action on" it. 85 Fed. Reg. at 80,633.

The APA does not mention withdrawing proposed rules. Nor has the Supreme Court. So we are reluctant to give withdrawal separate legal significance under the APA. Rather, marking a rule as withdrawn seems to be just a message about an agency's intent.

Sanofi argues that if an agency later changes its mind, it must start over. But nothing in the APA says that. Instead, all the APA requires of an agency before publishing a final rule is (1) putting a notice of proposed rulemaking in the Federal Register, (2) accepting comments on that proposal, and (3) considering those comments. *See* 5 U.S.C. § 553(b)–(c). Though HHS listed the rule as withdrawn, that did not negate that HHS had taken the required steps: the public knew about the proposed rule and had a chance to comment on it, and the agency considered those comments. The APA prescribes the "maximum procedural requirements that an agency must follow in order to promulgate a rule." *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 2385 (2020) (internal quotation marks omitted). No more was needed.

Still, Sanofi complains that it was caught off guard by the ADR Rule's promulgation. Our dissenting colleague echoes this concern. But the APA already accounts for blindsiding. For instance, it requires an agency to publish a final rule thirty days before it takes effect. 5 U.S.C. § 553(d). Again, HHS did that. We cannot require something more.

Even if an agency had the power to effectively nullify the prior notice and comments, we think it would require something more than what happened here. The proposed rule was marked as withdrawn in the Unified Agenda, which is published semiannually by the Office of Information and Regulatory Affairs to lay out the executive branch's plans. But that publication was not created as part of the APA. Instead, its express purpose is to "help[ ] agencies comply with their obligations" under various other statutes and executive orders. *See* 86 Fed. Reg. 41,166, 41,167-68. It would be odd if agencies could nullify past steps taken to comply with the APA in a publication that has little if anything to do with the APA.

Plus, the Unified Agenda says it does "not create a legal obligation on agencies … to confine their regulatory activities to those regulations that appear within it." *See id.* at 41,167. This disclaimer should have put the drug makers on notice that the agency was not binding itself simply by listing the rule as withdrawn there. And though there was a long delay between the notice of proposed rulemaking and finalizing the rule, such delays do happen. *See, e.g.*, 85 Fed. Reg. 49,240, 49,243 (Aug. 13, 2020) (promulgation nearly five years after notice of proposed rulemaking); 85 Fed. Reg. 13,312, 13,314 (Mar. 6, 2020) (promulgation nearly four years after notice of proposed rulemaking). Ultimately, Sanofi's complaints ring hollow.

* * * * *

Legal duties do not spring from silence. Congress never said that drug makers must deliver discounted Section 340B drugs to an unlimited number of contract pharmacies. So by trying to enforce that supposed requirement, the government

overstepped the statute's bounds. And HHS did not violate the APA by purporting to withdraw the proposed ADR Rule before later finalizing it.

Sanofi Aventis US LCC v. United States HHS, et al.

Case Nos. 21-3167, 21-3168, 21-3379, 21-3380, 22-1676

AMBRO, Circuit Judge, dissenting in part.

I join my colleagues in all but Part III. Because HHS took multiple actions alerting the public it had withdrawn its notice of proposed rulemaking ("NPRM") outlining an administrative dispute resolution ("ADR") process, I would vacate the final ADR Rule and remand for HHS to issue a new NPRM.

The usual process by which an agency promulgates a binding final rule is as follows. It publishes an NPRM in the Federal Register that includes "the terms or substance of the proposed rule or a description of the subjects and issues involved." 5 U.S.C. § 553(b)(3). It then allows for comments by "giv[ing] interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments." *Id.* § 553(c). Finally, and only after considering the comments submitted, the agency may publish the final rule. *Id.*

The process for deciding *not* to promulgate a final rule after it is proposed is less clear. Neither the APA nor the Supreme Court has set out procedures for withdrawing an NPRM. Usual practice is to publish a notice of withdrawal in the Federal Register. *See, e.g.*, 83 Fed. Reg. 60,804 (Nov. 27, 2018) (HHS withdrawal of proposed rule); 84 Fed. Reg. 37,821 (Aug. 2, 2019) (same). That said, because the APA's notice-

and-comment requirements are meant to "ensure fairness to affected parties," *Council Tree Commc'ns, Inc. v. F.C.C.*, 619 F.3d 235, 250 (3d Cir. 2010) (quoting *Int'l Union, United Mine Workers v. Mine Safety & Health Admin.*, 407 F.3d 1250, 1259-60 (D.C. Cir. 2005)), I propose a practical rule: Some agency actions short of formal notice in the Federal Register should constitute withdrawal because they make any reasonable person believe the proposed rule would not take effect.

Here, HHS took multiple actions indicating it had withdrawn the NPRM for the ADR process. To start, HHS removed it from the Unified Agenda. More specifically, the website of the Office of Information and Regulatory Affairs ("OIRA") displays the NPRM as "Withdrawn" as of August 1, 2017, and identifies the stage of rulemaking as "Completed Action," which is a term used to describe "rulemakings that are being [w]ithdrawn or ending their lifecycle with a regulatory action that completes the rulemaking." OIRA, *About the Unified Agenda*, https://bit.ly/2OYh3FZ (last visited Oct. 26, 2022). Further, in March 2020 an official from the Health Resources and Services Administration, an agency within HHS that operates the 340B program, stated that it did "not plan to move forward on issuing [an ADR] regulation due to the challenges with enforcement of guidance." SJA 788. And ultimately, when HHS issued the final ADR Rule in December 2020, it did so under a new Regulatory Identification Number ("RIN"). *Compare* 85 Fed. Reg. 80,632 (RIN 0906-AB26), *with* 81 Fed. Reg. 53,381 (RIN 0906-AA90). Even if HHS thought it paused consideration of the proposed ADR Rule temporarily, the agency's words and actions put the public on notice that it withdrew the proposal.

Any one of these facts alone may not be sufficient to constitute a withdrawal of the NPRM. But when an agency consistently takes the position for *three years* that it will not turn that proposed rule into a final rule, the public should be able to take what the agency says at face value.

As a result, I respectfully dissent in part. I would vacate the final ADR Rule and remand to allow HHS to publish a new NPRM, which HHS has done since we heard argument in this appeal. *See* 87 Fed. Reg. 73,516 (Nov. 30, 2022).