UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ABBVIE INC., Plaintiff, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, Defendants.	Case No. 1:26-cv-00431 (CJN)

NOTICE OF SUPPLEMENTAL AUTHORITY

Defendants respectfully write to notify this Court of the D.C. Circuit's recent decision in *Teva Pharmaceuticals USA, Inc. v. Kennedy*, No. 25-5425 (D.C. Cir. Aug. 18, 2026) (slip opinion attached as Ex. A) ("*Teva* Op."). *Teva* involved a parallel challenge to the legality of the Medicare Drug Price Negotiation Program. As explained below, *Teva* undermines AbbVie's theory of subject-matter jurisdiction over its statutory challenge as well as the merits of its statutory and Fifth Amendment claims.

1. Under *Teva*, this Court lacks jurisdiction under 42 U.S.C. § 1320f-7(2) to review AbbVie's statutory challenge to the selection of Botox (Counts I and II). *See* ECF No. 1, Compl., ¶¶ 53-67. *Teva* held that Section 1320f-7(2) "covers CMS's drug-specific determinations, not the generally applicable legal standards that govern them." *Teva* Op. at 3. There, the D.C. Circuit reasoned that "Teva cannot ask [the Court] to overturn the selection of Austedo because Congress barred review of that determination." *Id.* at 14. It reasoned, however, that it had jurisdiction over Teva's statutory claims because "Teva [sought] prospective vacatur of the challenged legal

standards announced in CMS's Guidance, not an order reversing any particular drug determination." *Id.* at 26.

Unlike in *Teva*, the Complaint here asserts a precluded statutory challenge to a "drug-specific determination"—namely, the determination that Botox is a "qualifying single source drug" under 42 U.S.C. § 1320f-1(e). *See, e.g.*, Compl., ¶ 55 ("By selecting BOTOX for the Program, CMS acted in excess of its statutory authority."); *id*. ¶ 60 ("Because BOTOX satisfies the plasma-derived-products exclusion, CMS has no authority under the IRA to select BOTOX."); *id.* ("CMS's decision to select BOTOX thus violates the express statutory mandate of the IRA."); *id*. ¶ 66 ("This Court retains jurisdiction to set aside CMS's selection of BOTOX as *ultra vires* action."); *id*. Prayer for Relief (requesting that the Court "[v]acate and set aside CMS's selection of BOTOX under the Administrative Procedure Act (or, alternatively, as an *ultra vires* action)").

Similarly, AbbVie's briefs in support of its Motion for Summary Judgment make explicitly clear that "AbbVie's claims that Defendants exceeded their statutory authority . . . . allege that, by *selecting BOTOX* for price controls, Defendants exceeded their authority under section 1320f-1(e)." ECF No. 25 ("Pl.'s SJM Br.") at 20 (emphasis added); *see also id.* at 2 (requesting that the Court "hold unlawful and set aside Defendants' selection of BOTOX"); *id.* at 15-16 (arguing that "[t]he IRA's judicial-review bar does not prevent this Court from setting aside the selection of BOTOX as a flagrant violation of the statute's plasma-derived-products exclusion"); ECF No. 40 ("Pl.'s Reply") at 4 ("[T]his Court has jurisdiction to consider whether defendants' selection of BOTOX exceeded their authority under the IRA.").

Thus, unlike Teva, AbbVie does not challenge overarching "legal standards announced in CMS's Guidance"; it seeks "revers[al] [of] [a] particular drug determination." *Teva* Op. at 26.[1] What is more, AbbVie's failure to assert a *Teva*-like challenge was not inadvertent—it was strategic. In its Reply, AbbVie expressly distinguished its Botox-specific challenge from a broader challenge to "any upstream actions and decisions." Pl.'s Reply at 11. In doing so, AbbVie dismisses the government's invocation of the "'inextricably intertwined' rule" as "inapplicable" by presenting its statutory claims as "challenges [to] the selection of BOTOX, not just the 'means by which drugs are determined to be a [qualifying single source drug]' as a backdoor means of obtaining review of that selection." *Id.* at 10-11. Thus, in an effort to argue that "this case does not present the question of whether any upstream actions and decisions are 'inextricably intertwined' with some unreviewable decision," AbbVie made the strategic decision to challenge the "selection of BOTOX" in particular (as opposed to "the 'means by which drugs are determined to be a [qualifying single source drug]'"). *Id.* That strategic litigation choice is a "waiver" (not mere "forfeiture") of any *Teva*-like argument. *See Hamer v. Neighborhood Hous. Servs. of Chicago*, 583 U.S. 17, 20 n.1 (2017) ("[F]orfeiture is the failure to make the timely assertion of a right [;] waiver is the intentional relinquishment or abandonment of a known right." (quoting *United States v. Olano,* 507 U.S. 725, 733 (1993) (alterations in original) (internal quotations omitted)).[2]

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[1] In a passing footnote in its Reply, AbbVie states that "[t]his Court would also have jurisdiction to review challenges to CMS's recently unveiled 'policy' . . . . of identifying [qualifying single source drugs] and applying the plasma-derived-products exclusion based on products' active ingredients." Pl.'s Reply at 11 n.2. AbbVie, however, did not assert any claim with respect to any such "policy."

[2] While a "jurisdictional *defect* is not subject to waiver or forfeiture," *Hamer*, 583 U.S. at 20 (emphasis added), "arguments *in favor* of subject matter jurisdiction can be waived by

Because AbbVie's statutory challenge targets a "particular drug determination," it is precluded from review under 42 U.S.C. § 1320f-7(2) pursuant to *Teva*.

2. *Teva* also undermines AbbVie's statutory challenge on the merits. In *Teva*, the D.C. Circuit examined whether the IRA permits CMS to group together two drug products that "share the same active moiety and manufacturer" "as one 'qualifying single source drug.'" *Teva* Op. at 3. Teva objected to this approach by echoing many of AbbVie's arguments. Specifically, it argued that CMS's active-moiety analysis is inconsistent with the IRA; instead, it claimed that each drug that is approved by the FDA under a New Drug Application ("NDA") should be treated "as a separate statutory 'drug.'" *Id.* at 29.

The D.C. Circuit endorsed "CMS's active-moiety and same NDA-holder requirements" as consistent with the IRA. *Id*. Among other things, the court emphasized that the IRA directs "CMS to aggregate expenditures across dosage forms, strengths, and 'new formulations of the drug,' rather than calculate them by 'specific formulation.'" *Id.* at 28-29 (quoting 42 U.S.C. § 1320f-1(d)(3)(B)). It reasoned that "[a]pplying Teva's one-NDA, one-drug rule would therefore create substantial tension with the IRA's treatment of new formulations." *Id.* at 29. It also rejected Teva's attempt to downplay the aggregation requirement by arguing that it "operates *after* CMS identifies a qualifying single source drug." *Id.* at 28 (emphasis added). As the D.C. Circuit explained, Section 1320f-1(e) should not be read "in isolation." *Id.* "Subsection (e) supplies the conditions for qualification, while § 1320f-1(d)(3)(B) tells CMS what formulations belong to the drug whose expenditures it must calculate." *Id.*; *see also id.* at 30 ("Congress . . . carried the same aggregation principle through each stage of the process.").

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inattention or deliberate choice," *see NetworkIP, LLC v. FCC*, 548 F.3d 116, 120 (D.C. Cir. 2008) (emphasis added).

While the statutory challenge in this case is not identical to the one raised in *Teva*, the application of *Teva* to AbbVie's claim is straightforward. Whereas in *Teva*, the D.C. Circuit addressed what counts as a "drug" under Section 1320f-1(e), here, this Court must determine what counts as a "biological product" under Section 1320f-1(e). The two terms must be interpreted in tandem. After all, they merely describe the two different categories of the same thing—*i.e.*, "qualifying single source drug." *See* 42 U.S.C. § 1320f-1(e).[3] If the IRA permits CMS to adopt "active-moiety and same NDA-holder requirements" for a "drug," *Teva* Op. at 29, then it permits CMS to adopt "active-[ingredient] and same [Biologics License Application (BLA)]-holder requirements," for a "biological product."[4] *See Gustafson v. Alloyd Co.*, 513 U.S. 561, 575 (1995) (explaining that under the *noscitur a sociis* canon of construction, "a word is known by the company it keeps"). Thus, under *Teva*, CMS's application of the plasma-derived exclusion in Section 1320f-1(e)(3)(C) based on Botox's active ingredient is consistent with the IRA.

3. Finally, *Teva* straightforwardly forecloses both of AbbVie's Fifth Amendment claims (Counts III and V). *Teva* confirms that participation in Medicare (and thus the Negotiation Program) "is wholly voluntary," notwithstanding the economic pressures a manufacturer may feel to participate. *Teva* Op. at 40 (citation omitted). To be sure, "[t]he Negotiation Program sets the

[3] The IRA repeatedly groups together "biological product" and "drug." *See, e.g.*, 42 U.S.C. § 1320f-1(e)(3)(B) (referencing "[a] drug or biological product"); *id.* § 1320f-1(c)(1) (providing that "the Secretary determines at least one drug or biological product"); *id.* § 1320f-3(c)(1)(B)(ii) (referencing "a drug or biological product").

[4] For purposes of the IRA, CMS treats the "active moiety" in a "drug" as akin to the "active ingredient" in a "biological product," and an NDA for a "drug" as akin to a BLA for a "biological product." CMS, *Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028*, at 165-66 (Sept. 30, 2025), https://www.cms.gov/files/document/ipay-2028-final-guidance.pdf ("CMS Guidance").

terms on which Medicare funds may purchase selected drugs." *Id.* at 42. But a "[manufacturer] may reject those terms and forgo the funds." *Id.* Accordingly, "a manufacturer's voluntary participation in the Program creates no protected property interest in its preferred reimbursement terms." *Id*. at 40 (citing *Boehringer Ingelheim Pharms., Inc v. HHS*, 150 F.4th 76, 94 (2d Cir. 2025). And a manufacturer that chooses to participate in the Program "'suffers no deprivation of its property interests by voluntarily submitting to a price-regulated government program.'" *Id.* at 42 (quoting *Boehringer Ingelheim*, 150 F.4th at 94). That resolves AbbVie's due process claim.

As for the Takings Clause, Defendants have already explained why the voluntariness of participation in Medicare, Medicaid, and the Negotiation Program is likewise fatal to AbbVie's takings claim. *See* ECF No. 32 ("Defs.' Br.") at 30-37. In response, AbbVie argued that participation in the Negotiation Program "'forc[es] [AbbVie] to turn over physical doses of [BOTOX],'" and thus "deprives AbbVie of its fundamental right to exclude others from its property." Pl.'s Reply at 29 (*Bristol Myers Squibb Co. v. HHS*, 155 F.4th 245, 273 (3d Cir. 2025) (Hardiman, J., dissenting) (alterations in original)). But as *Teva* explained, in fact, "the Negotiation Program leaves [AbbVie's] right to exclude untouched." *Teva* Op. at 43. In all events, Teva's confirmation that participation in the Program is "wholly voluntary," *id.* at 40 (citation omitted), is fatal to whatever remains of AbbVie's takings claim, *see* ECF No. 42 ("Defs.' Reply") at 24-29 (citing *Valancourt Books, LLC v. Garland*, 82 F.4th 1222, 1232 (D.C. Cir. 2023) ("A demand for personal property would not be a taking, however, if it involved a voluntary exchange for a governmental benefit.")).

Date: August 26, 2026

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on August 26, 2026, I electronically filed this document with the Court by using the CM/ECF system, and that this document was distributed via the Court's CM/ECF system.

/s/ Pardis Gheibi

A

United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued May 5, 2026 Decided August 18, 2026

No. 25-5425

TEVA PHARMACEUTICALS USA, INC., ET AL.,
APPELLANTS

v.

ROBERT F. KENNEDY, JR., IN HIS OFFICIAL CAPACITY AS SECRETARY OF HEALTH AND HUMAN SERVICES AND MEHMET OZ, IN HIS OFFICIAL CAPACITY AS ADMINISTRATOR OF THE CENTERS FOR MEDICARE & MEDICAID SERVICES,
APPELLEES

Appeal from the United States District Court
for the District of Columbia
(No. 1:25-cv-00113)

Sean Marotta argued the cause for appellants. With him on the briefs were *Danielle Desaulniers Stempel*, *Dana A. Raphael*, and *Katherine T. McKay*.

Cesar Lopez-Morales, *Lauren Shepard*, *Clement Seth Roberts*, *Irena Royzman*, and *Andrew D. Silverman* were on the brief for *amici curiae* Bausch Health Companies Inc. et al. in support of appellants.

Brian T. Burgess was on the brief for *amicus curiae* Association for Accessible Medicines in support of appellants.

Maxwell A. Baldi, Attorney, U.S. Department of Justice, argued the cause for appellees. With him on the brief were *Eric J. Hamilton*, Deputy Assistant Attorney General, *Michael S. Raab*, Attorney, and *Kenneth R. Whitley*, Attorney, U.S. Department of Health and Human Services.

Nandan M. Joshi and *Wendy Liu* were on the brief for *amici curiae* Public Citizen, et al. in support of appellees.

Maame Gyamfi, *Kelly Bagby*, and *William Alvarado Rivera* were on the brief for *amici curiae* AARP, et al. in support of appellees.

Charles Gerstein was on the brief for *amicus curiae* Patients for Affordable Drugs in support of appellees.

Before: HENDERSON, CHILDS and PAN, *Circuit Judges*.

Opinion for the Court filed by *Circuit Judge* CHILDS.

CHILDS, *Circuit Judge*: For years, federal law kept the Centers for Medicare & Medicaid Services (CMS) out of the bargaining room. Medicare paid for prescription drugs, but CMS could not negotiate their prices. The Inflation Reduction Act of 2022 (IRA) changed that arrangement. It created the Drug Price Negotiation Program and directed CMS to identify certain high-spending drugs and negotiate the prices available under Medicare. This case concerns the line CMS has drawn between drugs brought into the Negotiation Program and those kept out, and, more importantly, whether Congress gave CMS authority to draw that line where it did.

Teva encounters those rules from both sides of the pharmaceutical market. It sells branded medicines, including Austedo and its extended-release formulation, Austedo XR. It also develops generic versions of medicines sold by others. CMS grouped Austedo and Austedo XR as one "qualifying single source drug" because they share the same active moiety and manufacturer, even though the FDA approved them under separate applications. CMS also announced that it will consider a generic as "marketed" only when the manufacturer engages in "bona fide marketing." Teva says both rules exceed CMS's statutory authority and that the Negotiation Program deprives it of a protected property interest without due process. The Government responds that the IRA bars courts from reviewing Teva's statutory claims.

We conclude that the review bar covers CMS's drug-specific determinations, not the generally applicable legal standards that govern them. On the merits, we conclude that the IRA permits CMS to treat Austedo and Austedo XR as one statutory drug, and the Negotiation Program does not deprive Teva of a protected property interest. Teva's challenge to the "bona fide" marketing requirement, however, is ripe for review. We therefore affirm in part and reverse in part the district court's grant of summary judgment in favor of the Government and remand Teva's challenge to CMS's "bona fide marketing" requirement for the district court to consider in the first instance.

I.

A.

1.

Medicare is a federally funded health-insurance program that pays for covered medical care, including prescription

drugs, for people aged 65 or older and people with disabilities. *See* 42 U.S.C. §§ 426, 426a, 426-1, 1395 *et seq.* Congress divided the program into five "Parts." *Ne. Hosp. Corp. v. Sebelius*, 657 F.3d 1, 2 (D.C. Cir. 2011). But two concern us here. Part B provides supplemental insurance and covers, among other things, certain drugs administered as part of a physician's service or furnished for use with specified durable medical equipment. *See* 42 U.S.C. §§ 1395j–1395w-6; 42 C.F.R. § 414.900(b)(1). Part D, for its part, provides beneficiaries with prescription-drug coverage. *See* 42 U.S.C. §§ 1395w-101 *et seq.*

Part D relies on private insurers to deliver that coverage. Eligible beneficiaries enroll in plans offered by those insurers, known as plan sponsors. To participate, a plan sponsor must submit a successful bid and comply with Medicare's requirements. *See Pharm. Care Mgmt. Ass'n v. Mulready*, 78 F.4th 1183, 1188 (10th Cir. 2023); 42 U.S.C. § 1395w-111. CMS, in turn, reimburses plan sponsors for covered Part D expenditures under a web of contracts and regulations. *See* 42 U.S.C. § 1395w-112(b); 42 C.F.R. §§ 423.301 *et seq.*

For years, the statute kept CMS out of the bargaining room. It prohibited the agency from "interfer[ing] with the negotiations between drug manufacturers" and plan sponsors. 42 U.S.C. § 1395w-111(i). But costs continued to climb. By 2019, Part D spending was "projected to increase faster than any other category of health spending." S. Rep. No. 116-120, at 4 (2019). Congressional reports traced much of that growth to specialty drugs facing "little or no competition," with "a relatively small number of drugs" accounting for "a disproportionately large share of Medicare costs." H.R. Rep. No. 116-324, pt. 2, at 37 (2019). In the Inflation Reduction Act of 2022, Congress changed course. It created a program through which Medicare would negotiate the prices of certain

high-cost drugs. *See* 42 U.S.C. §§ 1320f–1320f-7; 26 U.S.C. § 5000D.

2.

The IRA charges CMS with establishing a Drug Price Negotiation Program and using it to "negotiate and, if applicable, renegotiate maximum fair prices for such selected drugs." 42 U.S.C. § 1320f(a)(3). Congress stated the Program's aim plainly: to "achieve the lowest maximum fair price for each selected drug." *Id.* § 1320f-3(b)(1). That price applies when eligible beneficiaries receive selected drugs through Medicare Parts B and D. *Id.* §§ 1320f(c)(2), 1320f-2(a)(1)–(3), 1320f-3(a).

Still, the IRA does not "pursue[] its stated purpose at all costs." *Stanley v. City of Sanford,* 606 U.S. 46, 58 (2025) (quotation marks omitted). Congress instead prescribed rules for the negotiations, including a requirement that a qualifying single source drug has been approved for at least seven years. 42 U.S.C. § 1320f-1(e). Manufacturers retain a choice whether to participate, but it is not a cost-free one. A manufacturer that declines to negotiate must withdraw from Medicare and Medicaid or face an excise tax on all sales of the selected drug. *See* 26 U.S.C. § 5000D.

The Negotiation Program proceeds in calendar-year cycles. *See* 42 U.S.C. § 1320f(b)(1)–(2). Each cycle centers on an "initial price applicability year," the calendar year in which the negotiated price first applies. *Id.* § 1320f(b)(1). The corresponding "price applicability period" begins on January 1 of that year and continues through the last year in which the drug remains selected and subject to the negotiated price. *Id.* § 1320f(b)(1)–(2).

3.

Before CMS can negotiate a drug's price, it must decide which drugs enter the negotiating room. Congress prescribed a narrowing process. CMS begins with "qualifying single source drugs," identifies the highest-spending drugs among them as "negotiation-eligible drugs," and then selects a specified number for negotiation. 42 U.S.C. § 1320f-1(a), (d)–(e).

For a covered drug of the kind at issue here, three conditions govern whether it qualifies as a single source drug. First, the FDA must have approved the drug under 21 U.S.C. § 355(c), and the drug must be marketed under that approval; second, at least seven years must have passed since the approval; and third, the drug must not be the listed brand-name drug for any generic that has been "approved and marketed" under an abbreviated new drug application. 42 U.S.C. § 1320f-1(e)(1)(A).

CMS next identifies the "negotiation-eligible drugs" from that pool. *Id.* § 1320f-1(d)(1). For the 2026 and 2027 price periods, those are the 50 qualifying single source drugs with the highest total Part D expenditures during a specified 12-month period. *Id.* § 1320f-1(d)(1)(A). For later periods, CMS identifies two sets: the 50 qualifying single source drugs with the highest Part B expenditures and the 50 with the highest Part D expenditures. *Id.* § 1320f-1(d)(1). Congress excluded certain categories of drugs from both pools, but none of those exclusions concerns us here. *Id.* § 1320f-1(d)(2), (e)(3).

From the resulting pool, CMS ranks the negotiation-eligible drugs by total expenditures and, by a statutory deadline, must "select and publish" a list of the highest-ranking drugs. *Id.* § 1320f-1(a). In calculating expenditures, CMS must aggregate the data "across dosage forms and strengths of

the drug." *Id.* § 1320f-1(d)(3)(B); *see also id.* § 1320f-5(a)(2). Every drug placed on the published list becomes a "selected drug" and "shall be subject to the negotiation process." *Id.* § 1320f-1(a), (c).

The number of available slots increases over time. CMS must select 10 drugs for 2026, 15 drugs for 2027 and 2028, and 20 drugs for each year after that. *Id.* § 1320f-1(a)–(b). If fewer drugs qualify for negotiation in a given period than the statute directs CMS to select, there is no further choice to make: CMS must select them "all." *Id.* § 1320f-1(a).

4.

The IRA also restricts review at each of the three steps in this narrowing process. It provides that "[t]here shall be no administrative or judicial review of . . . [t]he selection of drugs under section 1320f-1(b) of this title, the determination of negotiation-eligible drugs under section 1320f-1(d) of this title, and the determination of qualifying single source drugs under section 1320f-1(e) of this title." 42 U.S.C. § 1320f-7(2).

5.

For a manufacturer whose drug makes the list, selection sets the next stage in motion. The manufacturer must enter into an agreement with CMS and submit pricing and other information by deadlines fixed in the statute. 42 U.S.C. §§ 1320f-2(a), 1320f-3(b)(2)(A). CMS must then make "a written initial offer" proposing a maximum fair price and providing "a concise justification" for it. *Id.* § 1320f-3(b)(2)(B). The manufacturer has thirty days to accept or counter. *Id.* § 1320f-3(b)(2)(C)(i). If it counters, CMS must respond in writing. *Id.* § 1320f-3(b)(2)(D). Throughout this exchange, CMS must consider the factors Congress specified. *Id.* § 1320f-3(e). And the bargaining cannot continue

indefinitely. For each price period, the statute fixes a date by which negotiations "shall end." *Id.* § 1320f-3(b)(2)(E).

Once the parties settle on a maximum fair price, the manufacturer must make that price available beginning on January 1 of the initial price applicability year. *See* 42 U.S.C. § 1320f-2(a)(1)–(3). The beneficiaries of that bargain include eligible Medicare recipients and the pharmacies, hospitals, physicians, and other providers that furnish them the selected drug. *Id.* The negotiated price may travel further still, affecting drug-price calculations under the 340B Drug Pricing Program and state Medicaid programs. *Id.* §§ 1320f-2(d), 1396r-8(c)(1)(C)(i)(V).

Congress attached consequences to missed deadlines. A manufacturer that fails to enter the required agreement, or that enters one but does not agree to a maximum fair price on time, enters a statutory "noncompliance period." 26 U.S.C. § 5000D(b). During that period, federal law imposes an excise tax on sales of the selected drug. *See id.* § 5000D(a)–(b).

Once established, the maximum fair price governs during the drug's price applicability period. *See* 42 U.S.C. § 1320f(b)(2). The price may later be renegotiated in specified circumstances. *Id.* § 1320f-3(f). Nor must a drug remain selected forever. Ordinarily, it ceases to be a selected drug in the first year beginning at least nine months after CMS determines that a generic version has been "approved" and "marketed." *Id.* § 1320f-1(c)(1).

B.

Congress directed CMS to implement the Program's opening years through "program instruction or other forms of program guidance." Inflation Reduction Act of 2022, Pub. L. No. 117-169, §§ 11001(c), 11002(c), 136 Stat. 1818, 1854,

1862 (codified at 42 U.S.C. §§ 1320f note, 1320f-1 note). After soliciting public comment and revising its proposals, CMS issued guidance for the 2026 and 2027 initial price applicability years. *See* CMS, *Medicare Drug Price Negotiation Program: Revised Guidance* (June 30, 2023) (2026 Guidance), https://perma.cc/J2VZ-F5BZ; CMS, *Medicare Drug Price Negotiation Program: Final Guidance* (Oct. 2, 2024) (2027 Guidance), https://perma.cc/TK33-JX9S. Teva challenges two features of that Guidance.

1.

The first concerns what counts as one qualifying single source drug. The IRA directs CMS, when calculating expenditures, to use data aggregated across a drug's dosage forms and strengths, "including new formulations of the drug." 42 U.S.C. § 1320f-1(d)(3)(B); *see* 2026 Guidance § 30.1, at 100; 2027 Guidance § 30.1, at 169. CMS says its Guidance carries that command into the process of identifying qualifying single source drugs. It groups together "all dosage forms and strengths of the drug with the same active moiety and the same holder of a New Drug Application (NDA)," even when the products are "marketed pursuant to different NDAs." 2026 Guidance § 30.1, at 99; 2027 Guidance § 30.1, at 167.

Simply put, separate NDAs do not necessarily mean separate drugs. If the products share an active moiety and an NDA holder, CMS treats them as a qualifying single source drug. CMS deemed that approach "appropriate" because manufacturers sometimes obtain approval for new dosage forms or routes of administration involving the same active moiety through different NDAs. 2027 Guidance § 30.1, at 169; *see also* 2026 Guidance § 30.1, at 100.

2.

The second provision concerns when an approved generic "is marketed." 42 U.S.C. § 1320f-1(e)(1)(A)(iii). That determination carries consequences. Once an approved generic is marketed, its brand-name counterpart no longer qualifies as a qualifying single source drug.

In CMS's view, a generic has not necessarily been "marketed" simply because it has reached the market. The Guidance instead asks whether "the totality of the circumstances" shows that the manufacturer "is engaging in bona fide marketing of that drug." 2026 Guidance § 30.1, at 102; *see also* 2027 Guidance § 30.1, at 170. To make that judgment, CMS considers Prescription Drug Event data submitted by Part D plan sponsors and Average Manufacturer Price data reported by manufacturers. *See* 2026 Guidance § 30.1, at 101–02; 2027 Guidance § 30.1, at 170–71; *see also* 2026 Guidance at 76 n.23; 2027 Guidance at 205 n.103.

But no single dataset controls. CMS describes the analysis as a "holistic inquiry" that "will not necessarily turn on any one source of data." 2027 Guidance § 30.1, at 171; *see also* 2026 Guidance § 70, at 169. Other considerations may include whether the generic remains "regularly and consistently available for purchase" and whether licensing or other agreements restrict its availability or distribution. 2027 Guidance § 30.1, at 171. The Guidance thus asks not merely whether a generic has made a sale, but whether it has entered the market in earnest.

C.

With the statutory and regulatory framework now in place, we turn to the facts. Teva operates on both sides of the pharmaceutical market. It manufactures branded medicines of

its own and develops generic versions of medicines made by others.

Among Teva's branded medicines are Austedo and Austedo XR, drugs used to treat involuntary muscle movements. Austedo XR is an extended-release formulation of Austedo. The FDA approved the two products under separate NDAs, but they share the same active moiety, and Teva holds both applications. Under CMS's grouping rule, those features cause the products to be treated as one qualifying single source drug. Teva has also developed generic versions of five innovator drugs selected for the 2027 initial price applicability year (IPAY 2027): Xtandi, Ofev, Linzess, Xifaxan, and Otezla.

In response to CMS's selection of Austedo, Teva sued in the United States District Court for the District of Columbia. It alleged that CMS had exceeded its statutory authority. In Teva's view, both the bona fide marketing requirement and CMS's definition of a qualifying single source drug constituted agency action in excess of statutory jurisdiction, authority, or limitations, or short of statutory right, in violation of 5 U.S.C. § 706(2)(C). Because the Guidance rested on those allegedly erroneous interpretations, Teva further contended that implementing it would be unlawful, arbitrary, capricious, an abuse of discretion, or contrary to law under 5 U.S.C. § 706(2)(A).

Teva also raised a constitutional claim, alleging that both the IRA and CMS's interpretation of it violated the Fifth Amendment's guarantee against deprivations of property without due process of law. For relief, Teva sought vacatur of the challenged Guidance under the APA, a declaration that CMS's interpretations were unlawful, and declaratory and injunctive relief on its due process claim.

The Government and Teva each moved for summary judgment. The district court granted summary judgment in favor of the Government, denying Teva's motion. It first held that the IRA's review bar did not foreclose Teva's challenges to the generally applicable Guidance. On the merits, however, the district court upheld CMS's definition of a qualifying single source drug as consistent with the IRA. It declined to consider Teva's challenge to the bona fide marketing standard, concluding that the claim was not yet ripe. And it rejected Teva's constitutional claim because Teva had identified no protected property interest. Teva timely appealed.

II.

Because the district court granted summary judgment, "[w]e have jurisdiction under 28 U.S.C. § 1291." *Capitol Hill Grp. v. Pillsbury, Winthrop, Shaw, Pittman, LLC*, 569 F.3d 485, 488 (D.C. Cir. 2009). Our review of the district court's grant of summary judgment is *de novo*. *Ward v. McDonald*, 762 F.3d 24, 31 (D.C. Cir. 2014). In conducting that review, we afford "no particular deference" to the district court's review of an agency action under the APA. *NACS v. Bd. of Governors of Fed. Rsrv. Sys.*, 746 F.3d 474, 482 (D.C. Cir. 2014) (citation modified).

We consider several issues on appeal: (1) whether Teva has standing to challenge CMS's interpretation of "qualifying single source drug"; (2) whether Congress barred judicial review of Teva's statutory challenges to the Negotiation Program; (3) whether the district court correctly rejected Teva's statutory challenges to the Negotiation Program; and (4) whether the district court correctly rejected Teva's due process challenge to the Negotiation Program. We address each argument in turn.

III.

A.

We first address the Government's argument that Teva lacks standing to bring its challenge against the Guidance "identify[ing] a potential qualifying single source drug using . . . all dosage forms and strengths of the drug with the same active moiety and the same holder of a New Drug Application (NDA), inclusive of products that are marketed pursuant to different NDAs." 2026 Guidance § 30.1, at 99; 2027 Guidance § 30.1, at 167.

To have standing, Teva "must have (1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016). As a general rule, a plaintiff may challenge an agency decision resting on an erroneous legal premise although the agency "might later, in the exercise of its lawful discretion, reach the same result for a different reason." *FEC v. Akins*, 524 U.S. 11, 25 (1998) (citation omitted). Indeed, "those adversely affected by a discretionary agency decision generally have standing to complain that the agency based its decision upon an improper legal ground." *Id.* More still, when a rule regulates the plaintiff, "there is ordinarily little question" that those requirements are met. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561–62 (1992). The parties' dispute concerns redressability alone. The Government accepts that the Guidance governs the selection of Austedo and regulates Teva. According to the Government, "[t]o the extent Teva seeks only prospective vacatur of CMS's guidance," that relief would not remedy any injury arising from the selection of Austedo. Appellee's Br. 32 n.5.

At first blush, that argument has a certain logic. Teva cannot ask us to overturn the selection of Austedo because Congress barred review of that determination. But if Teva urges us only to vacate the legal standard CMS used, the Government says, Austedo remains selected and Teva gains nothing. So from that premise, one form of relief is forbidden and the other is futile. The Government attempts to construct a jurisdictional vise: Seek relief that overturns the selection of Austedo, and the review bar forecloses suit; seek anything less, and Article III does.

We have heard a similar argument before. In *American Clinical Laboratory Ass'n v. Azar* (*ACLA*), Congress had barred review of "the establishment of payment amounts" under Medicare. 931 F.3d 1195, 1199 (D.C. Cir. 2019). The association challenged an antecedent data-collection rule that allegedly drove the unreviewable payment amounts downward. *See id.* at 1201–03. The Secretary responded that because Congress had insulated the payment amounts from review, those amounts could not supply a redressable injury. *See id.* at 1204.

We rejected that argument because it "conflate[d] two issues." *Id.* True, the association could not "challenge the rates themselves under the statute's jurisdiction-stripping provision." *Id.* But that did not mean the rates could not "be the source of ACLA's members' injury in a challenge to the data-collection rule." *Id.* The relevant question was whether the reviewable rule was "sufficiently linked" to the injury produced by the unreviewable payment amounts. *Id.* It was. Requiring the Secretary to collect the data the statute demanded and use that data to calculate a new weighted median "appear[ed] sufficiently likely to increase Medicare reimbursement rates to establish redressability." *Id.*

The same is true here. CMS continues to rely on the Guidance to treat Austedo and Austedo XR as one statutory drug, and Austedo's negotiated maximum fair price has yet to take effect. Prospective vacatur would remove the legal rule governing that ongoing treatment and require CMS to proceed under the proper statutory construction. That is enough to establish redressability. *See id.* at 1204. The possibility that CMS might reach the same result on remand does not change that analysis. *See Akins*, 524 U.S. at 25.

Moreover, the Government's authorities do not support a different result. In *Dobbin Plantersville Water Supply Corp. v. Lake*, the state commission had completed the challenged decertification, had nothing left to enforce, and need not authorize the competing utilities before they began service. 108 F.4th 320, 326 (5th Cir. 2024). An injunction against future enforcement therefore would have been "pointless." *Id.* And *Steel Co. v. Citizens for a Better Environment* involved no continuing or imminent violation that prospective relief could prevent. *See* 523 U.S. 83, 108 (1998). The Court explained that such relief could have redressed the plaintiff's injury had an ongoing or threatened violation been alleged. *See id.*

For those reasons, Teva has standing to bring its challenge against the Guidance "identify[ing] a potential qualifying single source drug using . . . all dosage forms and strengths of the drug with the same active moiety and the same holder of a New Drug Application (NDA), inclusive of products that are marketed pursuant to different NDAs," 2026 Guidance § 30.1, at 99; 2027 Guidance § 30.1, at 167.

B.

With standing resolved, we turn to the Government's contention that 42 U.S.C. § 1320f-7(2) bars Teva's statutory challenges. Neither the provision's text nor the IRA's structure

bears the weight the Government places on it. We therefore reject its reading of the review bar.

Congress, of course, controls the "subject-matter jurisdiction" of the lower federal courts. *Kontrick v. Ryan*, 540 U.S. 443, 452 (2004). But Congress controls it not CMS. An agency cannot expand a review bar simply by declaring its own conduct unreviewable.

That division of authority reflects a rule with longstanding pedigree. A court must "independently determine for itself whether the agency's interpretation of a statute is correct." *McLaughlin Chiropractic Assocs., Inc. v. McKesson Corp.*, 606 U.S. 146, 155 (2025). The rule does not vanish when Congress "delegates discretionary authority" to the Executive Branch. *Trump v. Cook*, No. 25A312, 2026 WL 1855613, at *7 (U.S. June 29, 2026) (quotation marks omitted). Put plainly, agencies administer statutes, but courts determine what those statutes mean. We are not bound by CMS's interpretation because "Congress expects courts to handle technical statutory questions." *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 402 (2024). Nor does the complexity of the Medicare program alter our duty. After all, a "mass of technical detail" is "the ordinary diet of the law." *Egelhoff v. Egelhoff*, 532 U.S. 141, 161 (2001) (Breyer, J., dissenting).

These principles yield a familiar starting point in the "strong presumption favoring judicial review of administrative action." *Salinas v. U.S. R.R. Ret. Bd.*, 141 S. Ct. 691, 698 (2021) (quotation marks omitted). That rule is "well-settled," so we presume Congress legislates with it "in mind." *Id.* (quotation marks omitted). To overcome that presumption, the Government must produce "clear and convincing evidence" that Congress intended to preclude review of the particular agency action challenged. *Amgen, Inc. v. Smith*, 357 F.3d 103,

111 (D.C. Cir. 2004) (quoting *Abbott Lab'ys v. Gardner*, 387 U.S. 136, 141 (1967)). Even when Congress "expressly prohibits judicial review," we construe that prohibition "narrowly." *El Paso Nat. Gas Co. v. United States*, 632 F.3d 1272, 1276 (D.C. Cir. 2011).

And the presumption is "particularly strong" when a party contends, as Teva does here, that an agency has acted "in excess of delegated authority." *Amgen*, 357 F.3d at 111. The reason is practical as well as doctrinal. If agencies could decide for themselves whether their actions fall within a review bar, they could enlarge their own authority merely by relabeling what they had done. *See id.* at 113. Congress rarely builds such a one-way ratchet into a statute. Put differently, "the jurisdiction-stripping provision does not apply" if the agency's action fails to qualify as the kind of action for which review is barred. *Sw. Airlines Co. v. TSA*, 554 F.3d 1065, 1071 (D.C. Cir. 2009).

Determining a review bar's reach requires attention to the whole statutory setting. "Whether and to what extent a particular statute precludes judicial review is determined not only from its express language, but also from the structure of the statutory scheme, its objectives, its legislative history, and the nature of the administrative action involved." *ACLA*, 931 F.3d at 1204 (quoting *Block v. Cmty. Nutrition Inst.*, 467 U.S. 340, 345 (1984)). Any genuine ambiguity cuts in favor of judicial review. "[W]hen a statutory provision is reasonably susceptible to divergent interpretation, we adopt the reading that accords with" the traditional and basic principle that "executive determinations generally are subject to judicial review." *Guerrero-Lasprilla v. Barr*, 589 U.S. 221, 229 (2020) (internal quotation marks omitted). With those rules in hand, we look to the text of 42 U.S.C. § 1320f-7(2) and the structure

of the IRA to determine whether it precludes Teva's statutory challenges to CMS's statutory interpretation.

C.

In determining the meaning of a statutory provision, we start with "the text of the statute." *Van Buren v. United States*, 593 U.S. 374, 381 (2021). In doing so, we give the words "their ordinary meaning." *Artis v. District of Columbia*, 583 U.S. 71, 83 (2018) (quotation marks omitted). And we "give effect, if possible, to every clause and word of a statute." *Parker Drilling Mgmt. Servs., Ltd. v. Newton*, 587 U.S. 601, 611 (2019) (quotation marks omitted). We read those words "in their context and with a view to their place in the overall statutory scheme." *Roberts v. Sea-Land Servs., Inc.*, 566 U.S. 93, 101 (2012) (quoting *Davis v. Mich. Dep't of Treasury*, 489 U.S. 803, 809 (1989)). Accordingly, we construe 42 U.S.C. § 1320f-7(2) as precluding review of CMS's drug-specific determinations while leaving its interpretation of the relevant IRA provisions reviewable.

For starters, § 1320f-7(2) provides that "[t]here shall be no administrative or judicial review of . . . the determination of qualifying single source drugs under section 1320f-1(e) of this title," or "the determination of negotiation-eligible drugs." 42 U.S.C. § 1320f-7(2). Based on this text, the object of the review bar, in each instance, is "the determination." That term describes a single, discrete act rather than "a group of decisions or a practice or procedure employed in making decisions." *See McNary v. Haitian Refugee Ctr., Inc.*, 498 U.S. 479, 492 (1991) (similarly construing "a determination" to describe a single act covered by the review bar while leaving challenges to the agency's generally applicable practices and policies reviewable).

Basic grammar supports that understanding. A definite article paired with a singular noun, as here, ordinarily identifies a discrete thing—not "an ongoing endeavor." *Niz-Chavez v. Garland*, 593 U.S. 155, 166 (2021); *see also Gates & Fox Co. v. OSHRC*, 790 F.2d 154, 156 (D.C. Cir. 1986) (explaining that "the definite article" suggests that some specific thing is referred to, rather than merely that thing in general); The Chicago Manual of Style § 5.75 (18th ed. 2024) ("A definite article points to a definite object.").

And the text of subsection (e) provides context. That subsection provides that "[f]or purposes of this part, the term 'qualifying single source drug' means" a drug satisfying specified criteria. 42 U.S.C. § 1320f-1(e)(1). One of the criteria requires that the "qualifying single source drug" be a "covered part D drug (as defined in [42 U.S.C. §] 1395w-102(e))." *Id.* Congress hence supplied the definition of "qualifying single source drug" and tasked CMS with deciding whether a particular drug satisfies its definition. Making the required drug-specific "determination" and interpreting the IRA are distinct tasks.

CMS cannot collapse those tasks by embedding its interpretation of the relevant term into each drug evaluation and then calling the whole package a "determination." Were that enough, CMS could shield even an interpretation exceeding its delegated authority simply by using it to make an unreviewable decision. Suppose subsection (e) requires that a qualifying single source drug be approved for at least seven years, but CMS decides that five will do. Once CMS applies that interpretation to a five-year-old drug, the Government's theory would place its interpretation beyond review because it now forms part of an unreviewable determination. A neat trick, but not one Congress authorized. CMS could rewrite the statute and then shield its rewrite merely by applying it. The

review bar would no longer constrain the agency's discretion; the agency would control the review bar. Its scope would then turn on the agency's label for its own conduct.

To be sure, the Supreme Court in *Mullin v. Doe*, 146 S. Ct. 2121 (2026) recently explained that "determination" "may be used as a synonym for 'decision'" or "may also be used to describe the chain of events leading up to a decision." *Id.* at 2133 (collecting sources). Although it is "common to use the term 'determination' in this broad sense," context decides which sense the term bears. *See id.*; *see also Pulsifer v. United States*, 601 U.S. 124, 133 (2024) (explaining that courts must read "text in context").

Unlike the one in this case, the review bar in *Mullin* swept broadly. The statute barred review of "any determination" made "with respect to" the designation, extension, or termination of temporary protected status. 146 S. Ct. at 2136. The phrase "with respect to" "generally has a broadening effect, ensuring that the scope of a provision covers not only its subject but also matters relating to that subject." *Patel v. Garland*, 596 U.S. 328, 339 (2022) (internal quotation marks omitted) (treating "regarding" and "with respect to" as synonymous). And in *Mullin*, the word "determination" was modified by "any." *Mullin*, 146 S. Ct. at 2133. The Supreme Court has "repeatedly explained" that word "has an expansive meaning." *Patel*, 596 U.S. at 338. Together, those textual signals brought the entire decisional process within the ambit of the review bar.

In enacting the IRA, however, Congress barred review not of "*any* determination" made "with respect to" the negotiation program, but of "*the* determination" specified in each subsection. *See* 42 U.S.C. § 1320f-7(2) (emphasis added). That difference is consequential under *Mullin* itself. The Court

there distinguished *McNary* because the narrower language in that case referred to "a single act" and emphasized that the result "turned on the specific wording of the provision at issue." *Mullin*, 146 S. Ct. at 2134. So too here. The definite article identifies a particular determination, and the words that follow identify its object: whether specified drugs qualify under subsection (e). Here, Congress also did not bar review of every decision "with respect to" those determinations.

What's more, Teva's APA claims also differ from those in *Mullin*. There, the respondents challenged how adequately the Secretary had "consulted the State Department about conditions in Syria." *Mullin*, 146 S. Ct. at 2134. As the Court understood the claims, they attacked a series of procedural choices: the Secretary communicated with the State Department "by email," sent a "terse and unspecific email," and terminated Syria's temporary protected status designation after receiving a "laconic answer." *Id.* Those objections went to the Secretary's exercise of discretion. They concerned "the quality of the [agency's] reasoning rather than the scope of its authority." *Ardelyx, Inc. v. Kennedy*, 179 F.4th 947, 963 (D.C. Cir. 2026) (holding that the court lacked jurisdiction to review an arbitrary-and-capricious claim when a review bar applied). Teva, by contrast, challenges CMS's generally applicable interpretation of the IRA announced in its Guidance rather than any particular drug-specific determination. Its claim therefore concerns the scope of CMS's statutory authority, not the quality of the reasoning underlying any such determination.

For those reasons, we reject the Government's reading of § 1320f-7(2).

D.

The Government raises several arguments resisting our review of CMS's statutory interpretation, but none are sound.

1.

The Government sees things differently. As it explains, CMS "determines the list of qualifying single source drugs by applying the statutory definition" of that term. Appellee's Br. 28. And because "CMS has no discretion over which drugs it determines are qualifying," "[d]etermining the drugs" simply means "generating the list of drugs that meet the definition." *Id.* From that premise, the Government concludes that Teva's challenge to CMS's interpretation is "inextricably intertwined" with the resulting drug determinations and therefore unreviewable. But that reasoning moves too quickly. Of course CMS must interpret the statutory definition before applying it. It does not follow that the interpretation and the resulting determination are the same act. As mentioned above, an agency cannot make its statutory interpretation unreviewable simply by using it in an unreviewable determination.

And the Government's cases do not carry that argument. Each involved an agency action within a task Congress has entrusted to the agency. The claims in those cases accordingly concerned "the quality of the [agency's] reasoning rather than the scope of its authority." *Ardelyx*, 179 F.4th at 963.

Start with *Texas Alliance for Home Care Services v. Sebelius*, 681 F.3d 402 (D.C. Cir. 2012). Congress directed the Secretary to formulate financial standards for bidders and barred review of both contract awards and "the bidding structure." *See id.* at 405, 409–11. The standards appeared in every request for bids, dictated what bidders had to submit, and determined which bidders were eligible for a contract. *See id.* at 410–11. We therefore held that they were "integral to" and "inextricably intertwined with the bidding structure." *Id.* at 411. Here, by contrast, Congress itself defined "qualifying

single source drug." 42 U.S.C. § 1320f-1(e)(1). Teva asks whether CMS's rule grouping those drugs fits within the definition that Congress supplied.

Florida Health Sciences Center, Inc. v. Secretary of Health & Human Services, 830 F.3d 515 (D.C. Cir. 2016), and *DCH Regional Medical Center v. Azar* (*DCH*), 925 F.3d 503 (D.C. Cir. 2019), fit the same mold. *Florida Health* concerned the Secretary's choice between March and April data in calculating an estimate that all agreed was unreviewable. *See* 830 F.3d at 517–18, 521. The claim thus invited "case-by-case review of the reasonableness or procedural propriety" of that choice and disclosed no "patent violation" of statutory authority. *Id.* at 522 (quoting *Amgen*, 357 F.3d at 113). *DCH*, in turn, challenged the methodology used to produce payment estimates Congress had expressly shielded from review. *See* 925 F.3d at 505–07. Because the hospital sought a new calculation under a different methodology, it was "trying to undo" an unreviewable estimate. *Id.* at 508. And the statute there barred review of "any estimate," language broad enough to preclude estimates adopted "across-the board and by rule." *Id.* at 506 (citation modified).

The text of § 1320f-7(2), however, speaks more precisely. It bars review of "the determination" identified in each listed subsection. "Any" sweeps across a category; whereas "the" identifies a particular determination. *See supra* Section III.C. These cases therefore leave untouched the question Teva raises—whether CMS's governing rules fall within the authority Congress granted.

ACLA also informs the "inextricably intertwined" question. *See* 931 F.3d at 1206–07. There, the challenged data-collection process supplied the information later used to establish unreviewable payment amounts. *See id.* at 1205. We

nevertheless held that the data collection and rate setting were not "inextricably intertwined" because the statute governed data collection through a separate, cross-referenced provision outside the review bar. *See id.* at 1205–08. We therefore rejected the Government's argument that Congress could not have intended to bar review of the "basic math" while "permitting review of every discretionary step that preceded that math." *See id.* at 1207 (citation omitted).

The same reasoning applies here. Section 1320f-1(e)(1) defines a qualifying single source drug through cross-references to the Medicare statute's definition of a "covered part D drug," 42 U.S.C. § 1395w-102(e), and the Medicaid statute's definition of a "covered outpatient drug," *id.* § 1396r-8(k)(2). Section 1320f-7(2) bars review of the resulting "determination of qualifying single source drugs." Teva challenges CMS's construction of the incorporated definitions. We may resolve that legal question while leaving CMS to apply those definitions to particular drugs. The two agency actions therefore remain distinct, and the usual rule permitting review of the "practices and policies" governing individual determinations applies. *McNary*, 498 U.S. at 492.

All told, CMS's interpretation and its drug determinations are connected. Of course they are. One supplies the governing legal rule, and the other applies that rule to a particular drug. But connected does not mean "inextricably intertwined." True, applying Teva's reading to the statute may cause CMS to reconsider its treatment of Austedo and Austedo XR as one selected drug. Such a result, nevertheless, "is a mere by-product of th[e] court's primary function of reviewing [the agency]'s interpretation of federal law" and "[t]he District Court's jurisdiction to award complete relief . . . is not barred by the possibility." *Bowen v. Massachusetts*, 487 U.S. 879, 910 (1988).

Given all of those reasons, we reject the Government's argument that CMS's interpretation of qualifying single source drug is "inextricably intertwined" with its individual determination under that interpretation.

2.

Moving past our precedent, the Government turns to the Third Circuit's. It warns that ruling for Teva would create a split with *Novo Nordisk Inc. v. Secretary United States Department of Health & Human Services*, 154 F.4th 105 (3d Cir. 2025). But our approach in construing review bars has long differed from our sister circuit's.

The Third Circuit follows *Bakran*, which holds that "when a statute prohibits review of a particular 'determination,' the bar extends to the ultimate decision and 'the process by which [the agency] reaches this decision.'" *Novo Nordisk*, 154 F.4th at 111–12 (alteration in original) (quoting *Bakran v. Sec'y, U.S. Dep't of Homeland Sec.*, 894 F.3d 557, 563 (3d Cir. 2018)). Our precedent takes the other path. *Castaneira v. Noem* rejected the Government's reliance on *Bakran* as "grammatical gymnastics" and held that Congress may shield an agency's ultimate determination without also shielding the standards that govern it. 138 F.4th 540, 549–50 (D.C. Cir. 2025). *Grace v. Barr* reflects the same divide; the majority applied *McNary* to permit review of the governing policies, while the dissent acknowledged that *Bakran*, among other out-of-circuit cases, took a different approach. *Contrast Grace v. Barr*, 965 F.3d 883, 892–93 (D.C. Cir. 2020), *with id.* at 914–15 (Henderson, J., dissenting).

The cases differ in another respect. Novo Nordisk challenged CMS's treatment of six identified insulin products as one negotiation-eligible drug. *See Novo Nordisk*, 154 F.4th at 109–12. Its claim thus ran straight at a completed, drug-

specific determination. Teva's claims do not. Teva seeks prospective vacatur of the challenged legal standards announced in CMS's Guidance, not an order reversing any particular drug determination. So our ruling need not conflict with *Novo Nordisk*'s result. And to the extent its reasoning points elsewhere, *Castaneira* controls ours.

For all those reasons, we hold that the review bar covers CMS's drug-specific determinations, but not the generally applicable legal standards that govern them.

IV.

Having settled the scope of the review bar, we turn to the merits. Teva contends that CMS misconstrued "qualifying single source drug" and grafted a "bona fide" marketing requirement onto the statute. It also contends that the Negotiation Program violates the Due Process Clause. We address each of Teva's arguments in turn.

A.

Teva's first challenge concerns the statutory unit that counts as a "qualifying single source drug." Its argument begins with the IRA's definition, which requires such a drug to be a "covered part D drug" under the Medicare statute. 42 U.S.C. § 1320f-1(e)(1). The Medicare statute then directs the reader to the Medicaid Drug Rebate Program, defining a "covered part D drug" as "a drug that may be dispensed only upon a prescription" and qualifies as a "covered outpatient drug" under that program. *Id.* § 1395w-102(e)(1). Medicaid continues the chain by defining a "covered outpatient drug" as "a drug which may be dispensed only upon a prescription" and "which is approved for safety and effectiveness as a prescription drug under [21 U.S.C. § 355] of the Federal Food, Drug, and Cosmetic Act." *Id.* § 1396r-8(k)(2). Section 355, in

turn, governs FDA approval of NDAs for prescription drugs. 21 U.S.C. § 355.

Teva draws a one-to-one relationship between a drug and its NDA from this chain of cross-references. In its view, "two drugs, approved under two NDAs, cannot be one qualifying single source drug." Appellant's Br. 20. CMS takes a broader view. Its Guidance instructs the agency to "identify a potential qualifying single source drug using . . . all dosage forms and strengths of the drug with the same active moiety and the same holder of a New Drug Application (NDA), inclusive of products that are marketed pursuant to different NDAs." 2026 Guidance § 30.1, at 99; 2027 Guidance § 30.1, at 167. Teva contends that this approach conflicts with the statutory definition and asks us to vacate it.

Several IRA provisions undercut Teva's NDA-specific theory. In negotiating a maximum fair price, CMS must consider the "applications and approvals under section 355(c) of title 21 or section 262(a) of this title for the drug." 42 U.S.C. § 1320f-3(e)(1)(D). The terms "applications" and "approvals" are plural; and the term "the drug" is singular. The negotiation provision then recognizes that a single "drug" can have multiple corresponding "approvals" and "applications." *Id.* Teva responds that the plural terms refer to an original NDA and later supplements. But Congress referred generally to applications and approvals under § 355(c), not to "an application and its supplements." Separate NDAs are applications under § 355(c) too.

The surrounding provisions make the point clearer. When calculating a drug's Medicare expenditures, CMS must aggregate data "across dosage forms and strengths of the drug, including new formulations of the drug, such as an extended release formulation," without relying on "the specific

formulation or package size or package type." 42 U.S.C. § 1320f-1(d)(3)(B). Congress likewise directed CMS to apply the negotiated price across a selected drug's "different strengths and dosage forms." *Id.* § 1320f-5(a)(2).

Teva notes that the aggregation provision operates after CMS identifies a qualifying single source drug. Even so, we do not read § 1320f-1(e) in isolation. *Cf. United States v. Morton*, 467 U.S. 822, 828 (1984) ("We do not . . . construe statutory phrases in isolation; we read statutes as a whole."). Subsection (e) supplies the conditions for qualification, while § 1320f-1(d)(3)(B) tells CMS what formulations belong to the drug whose expenditures it must calculate. Nothing in either provision draws a line at the edge of an NDA, especially after reading that "text in context," *Pulsifer*, 601 U.S. at 133.

Teva's interpretation also sits uneasily with the statute's treatment of new formulations. If CMS could consider only one NDA, Congress's instruction to account for Austedo's extended-release version—or any other "new formulations of the drug"—would add little to the expenditure calculation. 42 U.S.C. § 1320f-1(d)(3)(B) (requiring CMS to include expenditures for new formulations). A supplement to a § 355(b)(2) application, after all, cannot seek approval of a different drug from the one covered by the original NDA. *See* 21 U.S.C. § 355(b)(4)(A) (limiting supplemental applications to changes involving the same drug). So on Teva's view, any formulation approved through a supplement would already fall within the NDA-defined drug. CMS could simply identify that drug by its NDA and total the expenditures associated with it. *See* 42 U.S.C. § 1320f-1(d)(1) (directing CMS to rank drugs by total expenditures); *id.* § 1320f-1(e)(1) (defining a qualifying single source drug). But Congress went further. It told CMS to aggregate expenditures across dosage forms, strengths, and "new formulations of the drug," rather than calculate them by

"specific formulation." *Id.* § 1320f-1(d)(3)(B). That instruction makes more sense if a single statutory drug may include formulations approved under different NDAs. Applying Teva's one-NDA, one-drug rule would therefore create substantial tension with the IRA's treatment of new formulations.

Teva's reliance on the IRA's seven-year requirement rests on the same disputed premise. A qualifying single source drug must have been approved for at least seven years. *See id.* § 1320f-1(e)(1)(A)(ii). Some of the NDAs that CMS groups together, including the NDA for Austedo XR, are less than seven years old. Teva reasons that CMS therefore cannot group those products with an older qualifying single source drug. But that conclusion depends on treating each NDA as a separate statutory "drug," which is the very premise under dispute. The seven-year requirement measures the age of the drug once it has been identified. Whether that drug may encompass formulations approved under several NDAs comes first. Teva's argument therefore assumes its answer.

CMS's active-moiety and same NDA-holder requirements also align with our reading of the statute. Certainly, the IRA does not use the phrase "active moiety," and CMS may not "rewrite a statute just to serve a perceived statutory 'spirit.'" *Landstar Express Am., Inc. v. FMC*, 569 F.3d 493, 500 (D.C. Cir. 2009). But CMS uses "active moiety" as a marker for the pharmacologically active substance that remains constant across changes in strength, dosage form, or release mechanism. That term also comports with the ordinary meaning of "drug." *See* Drug, Black's Law Dictionary (12th ed. 2024) ("A substance intended for use in diagnosis, cure, treatment, or prevention of disease."); Drug, Merriam-Webster's Collegiate Dictionary (12th ed. 2025) ("[A] substance used as a medication or in the preparation of medication"). Patients take

drugs, not NDAs, after all. We have also recognized that active moiety "has long played a key role" in determining when a drug is new and when it instead uses "an approved moiety in a new way." *Otsuka Pharm. Co. v. Price*, 869 F.3d 987, 989–90 (D.C. Cir. 2017). And limiting the group to one NDA holder accords with the IRA's repeated direction that CMS negotiate with "the manufacturer" of the selected drug. *See* 42 U.S.C. §§ 1320f(c)(1), 1320f-2(a)(1), (4)(A).

Teva next enlists the canon against surplusage to challenge the Government's definition of "qualifying single source drug." But where Teva sees surplusage, the IRA offers continuity. Teva takes the position that if a "qualifying single source drug" already includes all "dosage forms and strengths," Congress had no reason to direct CMS to aggregate those same dosage forms and strengths when identifying negotiation-eligible drugs, 42 U.S.C. § 1320f-1(d)(3)(B), or to apply the negotiated price "across different strengths and dosage forms of a selected drug," *id.* § 1320f-5(a)(2). Appellant's Br. 33 (quotation marks omitted). Those provisions, however, govern different decisions made at different points in the Negotiation Program. Section 1320f-1(d)(3)(B) governs selection. Section 1320f-3(e)(1)(D) governs the negotiation offer. And § 1320f-5(a)(2) governs how the final negotiated price applies. Congress thus carried the same aggregation principle through each stage of the process. Teva offers no persuasive account of how its one-NDA, one-drug rule fits those repeated statutory directives.

Lastly, Teva leans on *United States v. Generix Drug Corp.*, 460 U.S. 453 (1983) for support, but that case does not help its cause. There, interpreting a statute concerned with safety and effectiveness, the Court held that a "drug" could encompass the finished product, including its active and inactive ingredients.

See id. at 459–61. But the Court expressly left open whether products containing the same active ingredients could "under some circumstances be the same drug." *See id.* at 461 (internal quotation marks omitted). *Generix* therefore does not make the NDA's application number dispositive under the IRA.

We therefore reject Teva's first statutory challenge and decline to vacate CMS's definition of a qualifying single source drug.

B.

Teva next challenges CMS's requirement that a generic drug be marketed on a "bona fide" basis. Those words, Teva says, are CMS's, not Congress's. Not reaching the merits of this issue, the district court held the claim prudentially unripe because Teva had not shown that the FDA had approved the relevant generics—a prerequisite, in the district court's view, to any CMS determination that a generic is "marketed" and the corresponding brand-name drug should be removed from the Negotiation Program. *See Teva Pharms. USA, Inc. v. Kennedy*, No. 25-113, 2025 WL 3240267, at *13–14 (D.D.C. Nov. 20, 2025). We disagree.

1.

Teva begins with forfeiture. The Government does not defend the district court's *sua sponte* ripeness ruling. And Teva says the Government forfeited the issue through its silence. It points to *Stolt-Nielsen S.A. v. AnimalFeeds International Corp.*, where the Supreme Court treated a prudential-ripeness argument as "waived." 559 U.S. 662, 670 n.2 (2010) (citation omitted).

Even assuming that the Government forfeited the argument, that answers only what the Government may press,

not what we may consider. The Supreme Court has expressly instructed that, even when ripeness presents "only prudential concerns," a court may consider the issue on its "own motion." *Nat'l Park Hosp. Ass'n v. Dep't of Interior*, 538 U.S. 803, 808 (2003). A party's forfeiture and a court's jurisdiction pose different questions. Whatever argument the Government may have abandoned, we remain free to ask whether Teva's claim is ripe. So we do.

2.

Prudential ripeness turns on "the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." *Crowley Gov't Servs., Inc. v. GSA*, 143 F.4th 518, 531 n.6 (D.C. Cir. 2025) (internal quotation marks omitted). Teva satisfies both factors.

A claim is fit for review when it presents a purely legal question, requires no further factual development, and challenges sufficiently final agency action. *See Energy Future Coal. v. EPA*, 793 F.3d 141, 146 (D.C. Cir. 2015) (Kavanaugh, J.). Teva's claim checks each box.

First, Teva's claim presents a pure question of law. Teva contends that CMS exceeded its statutory authority by adding a "bona fide" marketing requirement that the IRA does not contain. Whether CMS exceeded its statutory authority by imposing that requirement presents a "question of law, and only a question of law." *Marshall Cnty. Health Care Auth. v. Shalala*, 988 F.2d 1221, 1226 (D.C. Cir. 1993).

Second, no further factual development would aid that inquiry. The parties represented as much in the district court. We do not consider whether some particular generic will eventually satisfy CMS's standard but whether CMS may lawfully impose that standard at all. The district court itself

recognized that Teva brings "a facial challenge to set aside CMS's guidance." J.A. 180. We have "often observed" that a purely legal claim challenging an agency rule in this manner is presumptively fit for review. *Nat'l Ass'n of Home Builders v. U.S. Army Corps of Eng'rs*, 417 F.3d 1272, 1282 (D.C. Cir. 2005) (internal quotation marks omitted).

Third, the Guidance is final agency action. When an agency announces that a policy "governs and will continue to govern its decisions," the policy is final enough for ripeness purposes. *Better Gov't Ass'n v. Dep't of State*, 780 F.2d 86, 93 (D.C. Cir. 1986) (emphasis omitted). CMS has published the standard it intends to apply when deciding whether a generic is marketed and whether the corresponding brand-name drug should remain in the Negotiation Program. And when a suit presents the purely legal question whether final agency action violates a statute, "it is unnecessary to wait for [the agency's] legal conclusion to be applied in order to determine its legality." *Energy Future Coal.*, 793 F.3d at 146 (citation and internal quotation marks omitted). That settles fitness.

However, because the district court rested its contrary conclusion on several factual premises, we address those too. The district court believed that FDA had not approved Teva's relevant generics. Yet in the district court, Teva's declarant stated under oath that "FDA has approved" Teva's generic Xtandi capsules. J.A. 155. On appeal, Teva also identifies its other generics that have received final or tentative approval.

The district court also believed the 2027 Guidance would not apply to Teva's generics. But those generics correspond to innovator drugs selected for the 2027 initial price applicability year. The 2027 Guidance therefore governs whether those drugs will later be deselected. *See* 2027 Guidance at 131, 279. Nor did the record leave launch dates to speculation. Teva's

declarant explained that its generic Xtandi capsule is expected to launch shortly before August 13, 2027. And for Ofev, the record identifies no meaningful barrier to entry arising from the single, limited extension of exclusivity.

That leaves hardship. Precedent requires us to consider it, even when the dispute is purely legal. *See Sidak v. U.S. Int'l Trade Comm'n*, 174 F.4th 151, 157 & n.5 (D.C. Cir. 2026). But once fitness is established, a litigant need not demonstrate individualized hardship unless some "institutional interests" favor postponing review. *Id.* at 157 (quoting *Sabre, Inc. v. Dep't of Transp.*, 429 F.3d 1113, 1120 (D.C. Cir. 2005)).

No such interest appears here. CMS is not reconsidering its interpretation and no unfinished agency proceeding promises to sharpen the interpretative question. Meanwhile, Teva must plan its generic launches under a standard that CMS says already governs whether the corresponding innovator drugs will remain in the Negotiation Program.

Teva's challenge to CMS's "bona fide" marketing requirement is therefore ripe. We do not, however, decide its merits. The district court never addressed whether CMS's standard comports with the IRA, and we leave that question for it to consider in the first instance. We are, after all, "a court of review, not of first view." *Capitol Servs. Mgmt., Inc. v. Vesta Corp.*, 933 F.3d 784, 789 (D.C. Cir. 2019) (internal quotation marks omitted). We therefore reverse the district court's judgment as to this claim and remand for further proceedings.

C.

Turning next to whether the Negotiation Program violates the Fifth Amendment's Due Process Clause, we conclude that it does not.

1.

Before delving into the merits of this issue, we address one more jurisdictional question: Does 42 U.S.C. § 1320f-7(2) preclude Teva's constitutional claim? The Government is silent on the issue. Still, we have an independent obligation to decide it. *See Stabil LLC v. Russian Fed'n*, 167 F.4th 506, 525 (D.C. Cir. 2026) (explaining that arguments against subject matter jurisdiction cannot be forfeited or waived). We therefore address that issue briefly.

We begin with a settled rule. "[W]here Congress intends to preclude judicial review of constitutional claims its intent to do so must be clear." *Webster v. Doe*, 486 U.S. 592, 603 (1988). The reason for demanding clarity is not hard to see. Reading a statute to deny every judicial forum for a colorable constitutional claim would itself raise a "serious constitutional question." *Id.* (internal quotation marks omitted). So we require a "heightened showing," *id.*, and find constitutional claims precluded "only if the evidence of congressional intent to preclude is 'clear and convincing,'" *McBryde v. Comm. to Rev. Cir. Council Conduct & Disability Orders of the Jud. Conf. of the U.S.*, 264 F.3d 52, 59 (D.C. Cir. 2001) (collecting cases).

Consider our recent decision in *Doe v. Blanche*, 172 F.4th 901 (D.C. Cir. 2026). The statute there provided that, "[n]otwithstanding any other provision of law, a designation of a place of imprisonment under this subsection is not reviewable by any court." *Id.* at 912 (quoting 18 U.S.C. § 3621(b)). We held that categorical language alone could not foreclose constitutional review. Even "broad and seemingly comprehensive statutory language" did not by itself "supply[] the necessary clarity to bar as applied constitutional claims." *Id.* (alteration in original) (quoting *McBryde*, 264 F.3d at 59).

We required some further indication that Congress meant to reach constitutional claims. Finding none, we proceeded to the Eighth Amendment claim. *Id.* at 912–13.

Now compare the IRA. Section 1320f-7(2) does not mention anything about constitutional claims. Nor does the Government identify anything else in the statute showing that Congress meant to foreclose them. So if the broader language in *Doe* could not alone satisfy *McBryde*, the language before us cannot do so without some further evidence of preclusive intent. None appears.

Garland v. Aleman Gonzalez, 596 U.S. 543 (2022) colors that understanding. The Supreme Court there rejected a reading of 8 U.S.C. § 1252(f)(1) that would have left the provision operating mainly against constitutional claims. *See id.* at 553–54. That result struck the Court as "most unusual." *Id.* at 554. If Congress had wished to "target just constitutional claims," the Court reasoned, it "could have surely made the point more directly." *Id.* Congress made no such point in § 1320f-7(2).

We therefore hold that we have jurisdiction to consider Teva's due process claim.

2.

Teva argues that the IRA's "price-control program impairs Teva's protected interests in both its generics licenses and innovator products without providing the constitutional protections" it is due. Appellant's Br. 49. We reject that claim because Teva identifies no protected property interest.

The Due Process Clause protects against the deprivation "of life, liberty, or property, without due process of law." U.S. Const. amend. V. To state a claim for government deprivation

of property without due process of law, a plaintiff must possess a protected interest that triggers the Fifth Amendment's due process protections. *See Am. Mfrs. Mut. Ins. Co. v. Sullivan*, 526 U.S. 40, 59 (1999). It is well established that a property interest arises from an independent source, such as state or federal law. *See Bd. of Regents v. Roth*, 408 U.S. 564, 577 (1972). One "clearly must have more than an abstract need or desire for it" and "more than a unilateral expectation of it." *Id.*

"When a person has voluntarily relinquished [a] claim to property," the concerns served by procedural due process "disappear." *United States v. 8 Gilcrease Lane, Quincy, Fla. 32351*, 638 F.3d 297, 300 (D.C. Cir. 2011). Without a protected property or liberty interest, "one has no entitlement to procedural due process." *Sargeant v. Dixon*, 130 F.3d 1067, 1070 (D.C. Cir. 1997); *see also Muwekma Ohlone Tribe v. Salazar,* 708 F.3d 209, 219 (D.C. Cir. 2013) (characterizing *8 Gilcrease Lane* as holding that an individual "no longer possesses [a] due process right to challenge seizure of property that is voluntarily forfeited" (internal quotation marks omitted)).

In light of those principles, Teva invokes three sources of law for its protected property interest: (a) course of dealing; (b) common law; and (c) patents. Yet none supplied Teva with the protected property interest it needed to prevail on this claim.

a.

Teva first invokes its course of dealing with Medicare. It argues that the Negotiation Program interferes with its existing contracts to sell generic drugs and thus impairs a protected property interest. But those contracts do not obligate the Government to keep reimbursing drug purchases on the same terms.

"Congress has broad power under the Spending Clause of the Constitution to set the terms on which it disburses federal funds." *Cummings v. Premier Rehab Keller, PLLC*, 596 U.S. 212, 216 (2022). The Government may therefore "determine those with whom it will deal" and "fix the terms and conditions" of its purchases. *Perkins v. Lukens Steel Co.*, 310 U.S. 113, 127 (1940). Put simply, no one "has a 'right' to sell to the government that which the government does not wish to buy." *Coyne-Delany Co. v. Cap. Dev. Bd. of State of Ill.*, 616 F.2d 341, 342 (7th Cir. 1980) (per curiam).

The Second and Third Circuits have applied that rule to the Negotiation Program. The Third Circuit held that a manufacturer has "no protected property interest" in selling drugs at a price above what Medicare will pay when reimbursing the purchase. *AstraZeneca Pharms. LP v. Sec'y U.S. Dep't of Health & Hum. Servs.*, 137 F.4th 116, 125–26 (3d Cir. 2025). The Second Circuit likewise held that a manufacturer's voluntary participation in the Program creates no protected property interest in its preferred reimbursement terms. *See Boehringer Ingelheim Pharms., Inc. v. U.S. Dep't of Health & Hum. Servs.*, 150 F.4th 76, 94 (2d Cir. 2025).

Teva's prior dealings with Medicare do not change the analysis. A protected property interest requires a legitimate "claim of entitlement" to continued benefits, not merely an expectation built on past practice. *See Roth*, 408 U.S. at 577. Medicare's past reimbursement of Teva's customers, including Part D sponsors, did not promise reimbursement forever or freeze the governing terms in place. Past business is not an entitlement to future business. Teva's course of dealing therefore creates no protected property interest.

b.

Teva turns next to the common law. The Negotiation Program, it says, "impairs" its "'treasured' common-law right to sell its products at market prices free from arbitrary and undisclosed governmental constraints." Appellant's Br. 50 (citing *Cedar Point Nursery v. Hassid*, 594 U.S. 139, 149 (2021); *Old Dearborn Distrib. Co. v. Seagram-Distillers Corp.*, 299 U.S. 183, 192 (1936)). That argument fares no better than the last.

Start with *Cedar Point Nursery*. That case involved a state regulation requiring agricultural employers to admit union organizers onto their property for up to three hours a day, 120 days a year. 594 U.S. at 149. The Court treated the regulation as a physical taking because it invaded "the right to exclude," a right of "central importance to property ownership." *Id.* at 149–50. This case involves no invasion, occupation, or right to exclude. And *Cedar Point Nursery* says nothing about a manufacturer's asserted right to name its price while accepting federal reimbursement.

The difference runs deeper still. *Cedar Point Nursery* involved regulation imposed by law. Spending Clause programs rest on a bargain. "Unlike ordinary legislation, which imposes congressional policy on regulated parties involuntarily, Spending Clause legislation operates based on consent: in return for federal funds, the recipients agree to comply with federally imposed conditions." *Cummings*, 596 U.S. at 219 (citation modified). The Negotiation Program does not seize Teva's drugs or force Teva to sell them because it only offers federal reimbursement on negotiated terms. Teva may accept federal funds and their conditions, or it may decline both.

Old Dearborn comes closer in vocabulary but not in governing law. There, the Court described "the right of the owner of property to fix the price at which he will sell" in the broader marketplace. *Old Dearborn*, 299 U.S. at 192. That principle is not implicated here because "the Negotiation Program only sets prices for drugs that [the Government] pays for when it reimburses sponsors." *AstraZeneca*, 137 F.4th at 126 (emphasis omitted).

Teva's argument also overlooks the voluntary character of Medicare participation. Because "participation in the Medicare [and Medicaid spending] program[s] is wholly voluntary," "any obligations" imposed by the Negotiation Program "are as freely accepted as the benefits." *Baptist Hosp. E. v. Sec'y of Health & Hum. Servs.*, 802 F.2d 860, 869–70 (6th Cir. 1986). To be sure, the Government's size may make the choice an economically weighty one, but size is not compulsion. "Economic factors may have a strong influence on a company's choice to do business with the government, but a company that chooses to do so still acts voluntarily." *Bristol Myers Squibb Co. v. Sec'y U.S. Dep't of Health & Hum. Servs.*, 155 F.4th 245, 257 (3d Cir. 2025). And because that choice remains voluntary, "participation in the federal Medicare reimbursement program is not a property interest" protected by the Due Process Clause. *Shah v. Azar*, 920 F.3d 987, 998 (5th Cir. 2019).

Teva responds that the "Program controls the price at which [it] may sell to Medicare-eligible individuals, providers, and dispensers in completely private transactions." Appellant's Br. 55. It offers a more vivid version of the same point: "[W]hen your grandmother buys AUSTEDO XR, she is the purchaser; she does not act as an 'agent' or 'private intermediar[y] of the federal government.'" *Id.*

One's grandmother may stand at the pharmacy counter. But when Medicare Part B or D helps pay the bill, the federal government is no stranger to the sale. The Negotiation Program also does not regulate every sale of Teva's drugs because it governs only those transactions funded through Medicare. And "[t]hese are not private market transactions, regardless of the private hands through which CMS's funds pass." *AstraZeneca*, 137 F.4th at 126.

Teva's argument concerning retroactive conditions falls flat. The Negotiation Program is prospective because it does not reopen completed transactions, recoup prior reimbursements, or attach new consequences to past sales. It sets the terms governing future Medicare-funded purchases. Teva remains free to withdraw from the program rather than accept those terms.

Neither *National Federation of Independent Business v. Sebelius*, 567 U.S. 519 (2012), nor *Bowles v. Willingham*, 321 U.S. 503 (1944), rescues Teva's argument. *NFIB* concerned Congress's effort to condition a state's existing Medicaid funding on its acceptance of a substantial program expansion. *See* 567 U.S. at 575–85. The Court's analysis rested on federalism. Limiting Congress's spending power was "critical to ensuring that Spending Clause legislation does not undermine the status of the States as independent sovereigns." *Id.* at 577. And the threatened loss of more than ten percent of a state's budget amounted to "economic dragooning that le[ft] the States with no real option but to acquiesce." *Id.* at 582. Those concerns do not carry over to private businesses. That is because the "Tenth Amendment concerns are simply not present . . . where the federal government contracts with private parties, rather than dealing with separate sovereigns." *Bristol Myers Squibb*, 155 F.4th at 259–60. Teva is a corporation, not a sovereign. The Negotiation Program

therefore requires Teva to make a business choice, not to govern.

Bowles is farther afield still. There, the Court upheld wartime rent controls, observing that "there would be no constitutional objection if Congress as a war emergency measure had itself fixed the maximum rents." 321 U.S. at 517. Congress was responding to "conditions created by activities resulting from a great war effort" and regulating prices throughout the private housing market. *Id.* at 519. The Negotiation Program instead sets the terms on which Medicare funds drug purchases. For "the purpose of keeping its own house in order," the Government may "lay down guide posts by which its agents are to proceed in the procurement of supplies." *Perkins*, 310 U.S. at 127. A statute doing "no more than instruct its agents who were selected and granted final authority to fix the terms and conditions under which the Government will permit goods to be sold to it" is not "an exercise by Congress of regulatory power over private business." *Id.* at 128–29.

So too here. The Negotiation Program sets the terms on which Medicare funds may purchase selected drugs. Teva may reject those terms and forgo the funds. What it may not do is accept federal reimbursement while insisting on a price of its own choosing. And unlike in *Bowles*, the Government here "act[s] as [a] proprietor," not a regulator, which invokes "a crucial difference, with respect to constitutional analysis." *Engquist v. Or. Dep't of Agric.*, 553 U.S. 591, 598 (2008). Given the distinct constitutional underpinnings present in *NFIB* and *Bowles*, neither case supports Teva's argument. In short, Teva "suffers no deprivation of its property interests by voluntarily submitting to a price-regulated government program." *Boehringer*, 150 F.4th at 94.

c.

Teva's patent argument runs into a more basic problem. A patent grants its holder "the right to exclude others from making, using, offering for sale, or selling" the patented invention. 35 U.S.C. § 154(a)(1). But, as the Federal Circuit has explained, "federal patent laws do not create any affirmative right to make, use, or sell anything." *Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1372 (Fed. Cir. 2007) (quotation marks omitted).

The Negotiation Program leaves Teva's right to exclude untouched. It neither cancels Teva's patents nor licenses others to use them. Instead, it sets the price available when Medicare pays for Teva's drugs. And "where federal patent laws do not confer a right to sell at all, they do not confer a right to sell at a particular price." *AstraZeneca*, 137 F.4th at 125. Because Teva identifies no patent right that the Negotiation Program impairs, its patents cannot support a due process claim. *See id.* Therefore, we hold that the Negotiation Program does not violate the Fifth Amendment's Due Process Clause.

* * * * *

For the foregoing reasons, we affirm in part and reverse in part the district court's grant of summary judgment and remand Teva's challenge to CMS's "bona fide" marketing requirement for the district court to consider in the first instance.

So ordered.