ORAL ARGUMENT SCHEDULED FOR MAY 5, 2026

No. 25-5425

IN THE

United States Court of Appeals for the District of Columbia Circuit

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TEVA PHARMACEUTICALS USA, INC., *et al.*,
Plaintiffs-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,
Defendants-Appellees.

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

REPLY BRIEF FOR PLAINTIFFS-APPELLANTS

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GLOSSARY

APA:	Administrative Procedure Act
CMS:	Centers for Medicare & Medicaid Services
FDA:	Food and Drug Administration
IPAY:	Initial Price Applicability Year
IRA:	Inflation Reduction Act
NDA:	New Drug Application
Program:	Inflation Reduction Act's Medicare Drug Price Negotiation Program

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INTRODUCTION AND SUMMARY OF ARGUMENT

The Government's brief does everything except seriously grapple with the IRA's plain text. The Government argues that the Court cannot review Teva's APA claims *at all*—a position even the District Court rejected. The Government overlooks that the IRA closes the courthouse doors only to specific complaints about discrete actions, not challenges like Teva's that object to CMS's statutory interpretations. And if there is any doubt, the strong presumption of judicial review favors considering Teva's statutory claims.

On the merits, the Government largely skips over the textual violence that CMS's "active moiety" and "bona fide marketing" interpretations do to the IRA. The Government's argument for adding "active moiety" to the definition of "qualifying single source drug" rests on provisions that kick in only *after* CMS has already determined that a drug is a qualifying single source drug. And on "bona fide" marketing, the Government says "marketed" cannot mean "to expose for sale in a market," but cites dictionaries saying precisely that.

So the Government resorts to policy. But *Chevron* is no longer the law; it is not enough for the Government's interpretation to be reasonable given its policy aims. Even on the policy, the Government is wrong. The IRA struck a balance: It capped prices for certain innovator drugs, but preserved innovators' exclusivity periods and generics' ability to compete on price—both of which are essential for innovation, competition, and supply-chain diversity. Moreover, the government has ways outside the IRA to address bad-faith conduct, including through the FDA-approval process and antitrust enforcement. "If the government thinks" the IRA should include an active-moiety or bona-fide requirement, "the proper place to register that complaint is with those who drafted it." *Rico v. United States*, 607 U.S. __, slip op. at 11 (March 25, 2026); *see* U.S. Const. art. III, § 2, cl. 2. The "Court is not free to rewrite the directions Congress has provided." *Rico*, slip op. at 11.

Finally, the Government cannot defend the Program's obvious due-process violations. The Government's contentions—that CMS's coercive Program is voluntary, that contractual and patent rights are not property interests, and that private parties could engage in the same blatant tying as CMS—are contrary to the facts and the law. The Government also ignores Teva's unique status as both an innovator and generics manufacturer. Even if Teva has a nominal choice to participate in the Program as an innovator manufacturer, that option is unavailable to it as a generics manufacturer. That further underscores that it is unconstitutional to deny Teva *any* process in connection with the Program.

The Court should reverse.

ARGUMENT

I. TEVA'S APA CLAIMS ARE REVIEWABLE.

Attempting to further expand its already vast power under the Program, the Government contends that the IRA's judicial-review bar—which forbids review of CMS's particular selection and determination decisions—also precludes Teva's challenges to CMS's Guidance. Gov't Br. 24-34. But even where courts may not "second guess" a particular "determination," "they retain the responsibility to decide whether the agency acted within the scope of its statutory authority." *Steele v. United States*, 144 F.4th 316, 323 (D.C. Cir. 2025). So it is here.

A. Teva's Statutory Interpretation Challenges Are Reviewable.

The Supreme Court has "long applied a strong presumption favoring judicial review of administrative action." *Mach Mining, LLC v. EEOC*, 575 U.S. 480, 489 (2015). "That well-settled and strong presumption" "dictates" that jurisdiction-stripping provisions "must be read narrowly." *Make the Rd. N.Y. v. Wolf*, 962 F.3d 612, 624 (D.C. Cir. 2020) (citation and quotation marks omitted). To overcome the presumption, the government must produce "clear and convincing evidence of congressional intent to preclude judicial review." *Id.* (citation and quotation marks omitted). If the statute "is reasonably susceptible to" a reading permitting review, review is permitted. *Id.* (citation omitted). The reason: Congress knows "that legal lapses and violations occur" and "rarely intends to prevent courts from enforcing its directives to federal agencies." *Mach Mining*, 575 U.S. at 486, 489.

The Government cannot clear that high bar, as the District Court held. JA179-186. The IRA provides that "[t]here shall be no . . . judicial review of" eight defined actions under the Program, including "[t]he selection of drugs" for negotiation and "the determination" of "negotiation-eligible drugs," "qualifying single source drugs," and "a maximum fair price." 42 U.S.C. § 1320f-7. Each category involves CMS's decisions about which drugs are subject to the Program or what price to pay. JA180.

This lawsuit implicates neither. Teva does not argue that CMS erred as to the selection or determination of any specific product. In fact, Teva filed before AUSTEDO and AUSTEDO XR were selected. *Compare* JA13-73 (Complaint), *with* JA105-106 (Amended Complaint). And even though two different corporate entities hold the NDAs for AUSTEDO and AUSTEDO XR—violating CMS's own criteria for a qualifying single source drug—the judicial-review bar means Teva cannot challenge their selection in this suit. Opening Br. 13; *see* CMS, *Medicare Drug Price Negotiation Program: Final Guidance for IPAY 2027*, at 167 (Oct. 2, 2024), https://perma.cc/AJ33-F9U4 (2027 Guidance). Nor does Teva challenge CMS's selections or determinations with respect to the innovator drugs that Teva's generics will compete with. Teva instead brings a " 'general collateral challenge[ ]' to the agency's practices and policies," *Castaneira v. Noem*, 138 F.4th 540, 550 (D.C. Cir. 2025), arguing that CMS legally erred in redefining "qualifying single source drug" and adding a "bona fide marketing" requirement, JA115-128; *see* JA136-137 (seeking an order declaring that "CMS's definition of a Qualifying Single Source Drug" and " 'bona fide marketing' standard" are "unlawful" and "vacating and setting aside" those portions of CMS's Guidance).

The Supreme Court and this Court have long understood the "well-established" distinction between a general challenge to a *definition* and a challenge to how that definition is put to practice in a specific *determination*. JA180. Take

McNary v. Haitian Refugee Center, Inc., which involved a statute barring "district court jurisdiction" over "a determination respecting an application for adjustment of status"; those challenges must be brought in the court of appeals on review of "an order of exclusion or deportation." 498 U.S. 479, 486 & n.6, 491 (1991) (citations omitted). Unsuccessful applicants challenged in district court the government's "practices and policies" for administering the program. *Id.* at 487. The Supreme Court explained that the statute's "reference to 'a determination' describes a single act rather than a group of decisions or a practice or procedure employed in making decisions." *Id.* at 492. The applicants sought review of only "the procedures used" and winning that challenge would not "establish[ ] their entitlement to" adjusted status on the merits, so the district court had jurisdiction. *Id.* at 486 & n.6, 494-495.

This Court's cases are in accord. In *Grace v. Barr*, 965 F.3d 883 (D.C. Cir. 2020), the Court confronted a statute withdrawing district-court jurisdiction over "any individual determination . . . arising from or relating to the implementation or operation of an order of removal." 8 U.S.C. § 1252(a)(2)(A)(i). The Court held that the statute forbade district-court "review of individual aliens' negative credible-fear determinations," not "facial challenges to the written policies that govern those determinations." *Grace*, 965 F.3d at 893.

Likewise, in *ParkView Medical Associates, L.P. v. Shalala*, a hospital sought reclassification into a different wage-index region, which affected its Medicare reimbursement rate. 158 F.3d 146, 147 (D.C. Cir. 1998). The Secretary denied reclassification, citing a rule governing the time period of data considered in that evaluation. *Id.* at 148. This Court held it could not review the "denial itself" under a statute barring judicial review of "[t]he [reclassification] decision." *Id.* (citation omitted). Yet the Court had no problem reviewing the "general rules leading to [that] denial." *Id.*

One more for good measure: In *Castaneira*, this Court held that a bar on reviewing "no-risk determination[s]" did not preclude challenges to whether the agency applied the correct standard in rendering its determination. 138 F.4th at 548-549. "Under *McNary*, the presumption of judicial reviewability . . . applies with full force in cases involving facial challenges to standards [the agency] applies in making its no-risk determination." *Id.* at 550.

Those cases resolve this one. The judicial-review bar applies to eight specific "selection[s]" and "determination[s]," but *not* to CMS's Guidance or statutory interpretation writ large. *See* 42 U.S.C. § 1320f-7. That distinction reflects Congress's understanding of CMS's and courts' relative areas of expertise. Congress did not want manufacturers challenging things like CMS's total-expenditure calculation for each eligible drug and its associated ranking or CMS's

maximum-fair-price determination; Congress recognized that CMS may bring its expertise to bear in rendering those mathematical, quantitative, or discretionary determinations. But CMS has no discretion when interpreting statutes. *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 401 (2024). And there is no indication—let alone a clear and convincing one—that Congress intended to allow CMS to misconstrue and misapply the IRA with impunity. On the Government's reading, there is no recourse *at all* for even the most outlandish interpretations—not if CMS adopts a definition of "qualifying single source drug" treating 500 drugs with different active moieties as one, and not if CMS requires one sale per second to prove "bona fide" marketing. *See* Gov't Br. 33-34.

"[H]ad Congress intended" to bar judicial review more broadly, "it could easily have." *McNary*, 498 U.S. at 494. Congress knows how to craft judicial-review bars that block challenges to policies, regulations, or guidance. *See, e.g.*, 42 U.S.C. § 1395ff(e)(1) (precluding review of a "regulation or instruction that relates to a method for determining the amount of payment under" Medicare Part B). Congress also knows how to specify that decisions implicating a certain process are off-limits. *See, e.g.*, *id.* § 1395nn(i)(3)(A), (I) (instructing agency to "promulgate regulations to carry out" a particular "process" and prohibiting judicial review of "the process"). Congress even knows how to preclude judicial review of any decision, full stop. *See, e.g.*, 5 U.S.C. § 8128(b) (barring review of

"all questions of law and fact" arising from decision "allowing or denying a payment").

But Congress didn't here. This Court therefore "presume[s] Congress did not displace the courts' ordinary role in determining whether an agency has acted within the bounds of its legal authority." *Steele*, 144 F.4th at 322.

B. The Government Cannot Overcome The Strong Presumption Favoring Judicial Review.

1. The Government first contends that Teva is not challenging CMS's *definition* of "qualifying single source drug," but rather CMS's "*determination* of what constitutes a 'qualifying single source drug.' " Gov't Br. 24-25 (emphasis added). As the District Court recognized, JA186 n.6, the Government tried that gambit in *Castaneira*—and failed: Even when "determinations are unreviewable, 'general collateral challenges' to the agency's practices and policies still fall within judicial purview." 138 F.4th at 550 (quoting *McNary*, 498 U.S. at 492).

Castaneira also dooms the Government's reliance (at 25-27) on *Novo Nordisk Inc. v. HHS*, 154 F.4th 105 (3d Cir. 2025), *cert. petition docketed*, No. 25-761 (U.S. Dec. 29, 2025). The manufacturer there asked the court to declare that its selected products "are not properly subject to price controls under the statute." ECF No. 1 at 59, *Novo Nordisk Inc. v. Becerra*, No. 3:23-cv-020814 (D.N.J. Sept. 29, 2023). As the Third Circuit recognized, that is a challenge to CMS's "determin[ation]" that it would "treat[ ] six of Novo Nordisk's products as one

negotiation-eligible single-source drug." 154 F.4th at 111. Teva, by contrast, asks the Court to vacate the Guidance's definitions of "qualifying single source drug" and "marketing" generally.

Regardless, *Novo Nordisk* is inconsistent with this Court's precedent. *Novo Nordisk* expressly relied on *Bakran v. Secretary*, 894 F.3d 557 (3d Cir. 2018), which held 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.' " 154 F.4th at 111-112 (brackets omitted) (quoting *Bakran*, 894 F.3d at 563). But this Court has rejected *Bakran* as inconsistent with "*McNary* and circuit precedent." *Castaneira*, 138 F.4th at 550; *see Grace*, 965 F.3d at 892-893 (applying *McNary*), 914-915 (Henderson, J., dissenting) (invoking *Bakran* as a reason to deny review).

2. Nor is this the rare case in which a process challenge is part-and-parcel of a challenge to the underlying determination. The Government invokes a narrow line of cases holding that courts may not review issues that are "inextricably intertwined" with unreviewable decisions. Gov't Br. 27-28 (citation omitted). Yet those cases also make clear that, "even if judicial review of a [specific] decision is barred," parties are still "free to challenge the general rules leading to that decision." *Florida Health Scis. Ctr., Inc. v. HHS*, 830 F.3d 515, 521 (D.C. Cir. 2016) (citation and quotation marks omitted). The question is whether the litigant

is truly challenging a "general rule[ ]" or is instead "attempt[ing] to undo a shielded determination." *Id.* at 522 (citation and quotation marks omitted).

The Government's cases fall into the latter category; they involve challenges to particular payment determinations dressed up in general-rule garb. For example, the hospital in *DCH Regional Medical Center v. Azar* challenged the "methodology" used to determine its disproportionate-share hospital payment, which is the product of "three statutory 'factors' estimated by the Secretary." 925 F.3d 503, 504 (D.C. Cir. 2019). But Congress barred review of "[a]ny estimate of the Secretary for purposes of determining" those payments. *Id.* at 505 (citation omitted). In that "statutory scheme, a challenge to the methodology for" determining hospital-specific payments "is unavoidably a challenge to the estimates themselves." *Id.* at 506. The hospital's complaint confirmed it "attack[ed] the very estimates" that Congress insulated from review by seeking to vacate its payment calculation. *Id.* at 508; *see Florida Health*, 830 F.3d at 518-521 (explaining that reviewing challenge to agency's "refusal to use" certain data in producing estimate would eviscerate bar on reviewing "any estimate" based on that data).

Similarly, *Texas Alliance for Home Care Services v. Sebelius* found that a challenge to a CMS rule articulating "financial standards" for contract bidders was precluded under a provision barring review of "the awarding of contracts" and

related "bidding structure." 681 F.3d 402, 409, 411 (D.C. Cir. 2012). The statute required the Secretary to specify "financial standards" and stated that contracts could not be awarded unless the bidder met those standards; "[t]he financial standards, as eligibility criteria," were also "integral to the bidding structure." *Id.* at 405, 409-411. By "ty[ing] the development and application of appropriate financial standards to the" unreviewable actions, Congress made clear that judicial review of those standards was likewise off-limits. *Id.* at 409 (citation omitted).

"[T]hese cases are inapposite," and provide no "reason to deviate from the usual rule that challenges to 'practices and policies' are not barred." JA182, 185 (quoting *McNary*, 498 U.S. at 492). The IRA's bar applies only to *the selection* or *determination*, not anything and everything leading up to it. 42 U.S.C. § 1320f-7; JA185-186; *see, e.g.*, *General Elec. Co. v. EPA*, 360 F.3d 188, 191 (D.C. Cir. 2004) (per curiam) (statute restricting review of "any challenges to" certain actions barred review of only those challenges, not " 'any challenge,' without qualification") (citation omitted). And, as explained (*supra* pp. 9-10), this Court has already rejected the idea that a "determination" necessarily includes all "internal processes . . . used to reach [it]." *Novo Nordisk*, 154 F.4th at 112.

3. The Government finally protests that *McNary*'s distinction between determinations and general policies is inapplicable, supposedly because (1) the judicial-review bar in *McNary* applied to only "a single act" as opposed to a group

of decisions or practice or procedure employed in making decisions, and (2) Teva's challenge is not "collateral to the merits." Gov't Br. 29-31 (citation omitted). The Government is wrong.

First, the IRA's judicial-review bar applies to singular actions. The IRA commands CMS to make, and the judicial-review bar only reaches, "the determination" of what drugs are qualifying single source drugs. 42 U.S.C. § 1320f-7(2); *see* JA185; *National Min. Ass'n v. Department of Lab.*, 292 F.3d 849, 856 (D.C. Cir. 2002) (per curiam) (statute barring district-court review of "a final order" did not preclude review of "regulations") (citation omitted). Practice bears this out; CMS determines which drugs are qualifying single source drugs once a year, not a rolling basis. *See* Kristi Martin, *Medicare Drug Price Negotiations: All You Need to Know*, Commonwealth Fund (May 15, 2025), https://perma.cc/8GH2-BJU5. That "determination" is also wholly separate from CMS's process for issuing guidance. *See* CMS, Fact Sheet: Medicare Drug Price Negotiation Program Final Guidance for 2027 (Oct. 2024), https://perma.cc/8C22-BB9T (outlining dates). Thus, like *McNary*, the bar on challenging determinations does not reach challenges to the definition CMS uses in making the singular list of qualifying single source drugs.

Second, Teva's lawsuit is not a determination challenge in disguise.[1] Teva seeks an order declaring CMS's interpretations unlawful and vacating those aspects of the Guidance. JA136-137. To be sure, applying the IRA as written may cause CMS to deselect AUSTEDO XR. But that "outcome is a mere by-product of th[e] court's primary function of reviewing [CMS'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). And though the Government (at 31) points to Teva's request for injunctive relief as purported evidence that Teva seeks a broad remedy, Teva sought injunctive relief only as to its due-process claim, *see* JA73, which the Government does not contend is barred.

Accepting the Government's argument would mean that a manufacturer can never bring a pre-enforcement challenge to CMS's policies if its argument could collaterally affect whether the manufacturer's product counts as a qualifying single source drug. That is important because the Government has elsewhere argued that manufacturers cannot raise pre-enforcement challenges to CMS's Guidance when

[1] The Government cites several cases (at 29-30) asking whether "a statutory scheme of administrative and judicial review forecloses parallel district-court jurisdiction." *Miriyeva v. USCIS*, 9 F.4th 935, 939 (D.C. Cir. 2021) (citation omitted). The burden under that test is flipped: If such a "scheme exists," courts presume "Congress intended that procedure to be the exclusive means of obtaining judicial review." *Federal L. Enf't Officers Ass'n v. Ahuja*, 62 F.4th 551, 558 (D.C. Cir. 2023) (citation omitted). No one argues the IRA has an exclusive- review procedure.

the challenged aspects of the Guidance "had no bearing on [the drug's] selection for negotiation." Appellees Br. 30, *AstraZeneca Pharms. LP v. HHS*, No. 24-1819 (3d Cir. Sept. 12, 2024), 2024 WL 5219932. Taken together, this would mean *no party* would ever have standing to "challenge the policies at issue in this suit" in the usual course. *Grace*, 965 F.3d at 893; *accord McNary*, 498 U.S. at 496-497 (rejecting result "tantamount to a complete denial of judicial review"). The IRA's judicial-review bar is not a whipsaw that denies review to the only parties that would have standing. And the Court "need not doubt [CMS's] trustworthiness, or its fidelity to law, to shy away from that result." *Mach Mining*, 575 U.S. at 488-489.

II. CMS'S DEFINITION OF "QUALIFYING SINGLE SOURCE DRUG" IS UNLAWFUL.

The IRA's text demonstrates, multiple times over, that Congress adopted an NDA-specific definition of "a qualifying single source drug": the singular "a drug"; the cross-references incorporating FDA's NDA-specific definition; the seven-year approval requirement keyed to an individual NDA's approval date; and the fact that generic approvals are linked to individual NDAs. Opening Br. 20-24. Yet CMS maintains that "a qualifying single source drug" actually includes multiple drugs approved under multiple NDAs, so long as they share the same active moiety and the NDAs are held by the same entity—two caveats found

nowhere in the statute. *See* 2027 Guidance 167; Gov't Br. 34-45. The Court should reject CMS's atextual approach.

1. The Government hangs its hat almost entirely on the IRA's direction that, "[i]n determining whether a qualifying single source drug" is negotiation-eligible, "the Secretary shall use data that is aggregated across dosage forms and strengths of the drug, including new formulations of the drug, such as an extended release formulation, and not based on the specific formulation or package size or package type of the drug." 42 U.S.C. § 1320f-1(d)(3)(B). The Government maintains that this applies to every "stage of the process," including "the identification" of a qualifying single source drug. Gov't Br. 35.

That is wrong. Section 1320f-1(d)(3)(B) says nothing about how to define or identify a qualifying single source drug. "Qualifying single source drug" is defined in an entirely different subsection, § 1320f-1(e)(1). *See* Opening Br. 20-25. Aggregation under § 1320f-1(d)(3)(B) comes into play only *after* CMS has already identified a drug as a qualifying single source drug. *See* 42 U.S.C. § 1320f-1(d)(1).

That is why, as Teva explained, the far-better reading is that CMS must identify a particular NDA that meets the definition of a qualifying single source drug and *then* aggregate data from that NDA and any amendments, modifications, or supplements across dosage forms, strengths, and formulations. Opening Br. 30-

32. The Government worries that this approach would leave CMS with nothing to aggregate. Gov't Br. 42-43. But the Government does not dispute that manufacturers often submit—and FDA often approves—multiple submissions under one NDA, including for different dosage forms, strengths, and formulations. *See* Opening Br. 30-31. For example, FDA approved the original NDA for Eliquis®, an IPAY 2026 selected drug, for a tablet in two different doses.[2] The manufacturer has since submitted supplements adding an oral-suspension formulation and expanding the treatment indications. FDA also approved injectable, vaginal suppository, oral tablet, and delayed-release oral tablet versions of Stilbestrol® all under one NDA.[3] And FDA first approved an oral tablet for Dimetane® and then approved an extended-release version under a supplemental NDA.[4] The Government also does not dispute that FDA has the power to reclassify a manufacturer's separate NDA as a supplemental NDA to avoid mischief. *See* Opening Br. 30-31, 34-35; *see also* Bausch Amicus Br. 14-16 (explaining "product hopping" concerns are misplaced).

[2] NDA 202155, Drugs@FDA, https://tinyurl.com/524ashuc (last visited Mar. 31, 2026).

[3] NDA 004056, Drugs@FDA, https://tinyurl.com/45wftar3 (last visited Mar. 31, 2026).

[4] NDA 010799, Orange Book, https://tinyurl.com/yak56e89 (last visited Mar. 31, 2026).

That identify-then-aggregate approach makes good sense of the IRA's other aggregation instructions, too. *See Kasten v. Saint-Gobain Performance Plastics Corp.*, 563 U.S. 1, 7 (2011) (statutory interpretation "depends upon reading the whole statutory text") (citation omitted). After CMS determines that a drug meets the statutory definition of qualifying single source drug, it then (but only then) aggregates the applicable spending data across the NDA and any supplements to identify the top-50-spend drugs. 42 U.S.C. § 1320f-1(d)(1), (3)(B). CMS then rank-orders that list and selects the top drugs for negotiation. *Id.* § 1320f-1(b). CMS uses the same data aggregated across all "applications and approvals" under an NDA to "negotiat[e] the maximum fair price of a selected drug," *id.* § 1320f-3(e)(1)(D), and applies that price across all the "different strengths and dosage forms" under that single NDA, *id.* § 1320f-5(a)(2). In short, reading the aggregation instruction to encompass amendments, modifications, or supplements to an existing NDA is the best way to make sense of Congress's instruction to consider " 'applications and approvals,' in the plural, 'for the drug,' in the singular," in light of the overall statutory scheme. *See* Gov't Br. 36 (quoting 42 U.S.C. § 1320f-3(e)(1)(D)).

2. With the Government's error corrected, the rest follows. Congress defined "qualifying single source drug" using a series of cross-references that lead to FDA's NDA-specific approach. *See* Opening Br. 21-22. The Government

grumbles that these cross-references are too "attenuated." Gov't Br. 40. At most, Congress's resort to cross-references in lieu of a self-contained definition again shows that the Medicare statute is "among the most completely impenetrable texts within human experience." *Rehabilitation Ass'n of Va. v. Kozlowski*, 42 F.3d 1444, 1450 (4th Cir. 1994). Yet even the Government does not disagree that dutifully following the cross-references results in an NDA-specific definition.[5]

By contrast, the Government's active-moiety and same-manufacturer approach is so attenuated that it appears nowhere in the IRA, directly or by cross-reference. The Government says that "active moiety" has "a long history and prominent role in FDA's practice." Gov't Br. 43-44. Yes. But FDA has long understood that "active moiety" and "drug" are *distinct*—as the regulation the Government cites shows. *See* 21 C.F.R. § 314.3. Congress has, too. That's why it wrote "active moiety" into several other statutes, including § 355(c). Opening Br. 26-27. Yet Congress used only the word "drug" here. *See Motion Picture Ass'n of Am. v. FCC*, 309 F.3d 796, 801 (D.C. Cir. 2002) (statutory provisions on the same subject are "construed together").

[5] The Government objects (at 40) that 42 U.S.C. § 1396r-8(k)(2)(A)(i) does not specify whether FDA's approval "creates a distinct, new 'covered outpatient drug.'" But a "covered outpatient drug" is a drug "which is approved for safety and effectiveness as a prescription drug under" 21 U.S.C. § 355. 42 U.S.C. § 1396r-8(k)(2)(A)(i). The Government agrees that § 355's process is NDA-specific. *See* Gov't Br. 38.

The Government protests that Congress did not need to include "active moiety" in the IRA "for CMS to rely upon [it] in describing the necessary features of products that can be considered together under the statute." Gov't Br. 44. Actually, it did. "[A]s a rule," Congress's decision to declare what the "term [qualifying single source drug] means excludes any meaning that is not stated." *Burgess v. United States*, 553 U.S. 124, 130 (2008) (quotation marks and ellipses omitted); *see* 42 U.S.C. § 1320f-1(e)(1) ("For purposes of this part, the term 'qualifying single source drug' means . . . ."). Active moiety is not part of that stated definition.

3. The Government glosses over the other statutory edits that its active-moiety definition requires. The Government says that the "same holder" caveat flows from 42 U.S.C. § 1320f(c)(1) and § 1320f-2. Gov't Br. 44. Section 1320f(c)(1) defines "manufacturer" by cross-referencing § 1395w-3a(c)(6)(A), which cross-references § 1396r-8(k)(5), which defines a manufacturer as "any entity" engaged in the drug's production, preparation, packaging, labeling, or distribution. Section 1396r-8(k)(5)'s definition could lead to multiple entities being considered a manufacturer of a qualifying single source drug. But the Government argues that § 1320f-2's command to negotiate with "the manufacturer," based on the drug price set by "the manufacturer" shows that only one entity can be "the manufacturer." *Id.* § 1320f-2(a)(1), (4)(A). Putting this

together, the Government concludes, means there can only be one manufacturer, supporting its view that "different dosage forms and strengths of a drug with the same active moiety are the same qualifying single source drug only when the NDA is held by the same manufacturer." Gov't Br. 44.

That argument boomerangs. If, as the Government says, the IRA's repeated use of "the manufacturer" means there can be only one manufacturer, then Congress likewise meant there could only be one drug—that is, one NDA—when it said "a" or "the qualifying single source drug." *See Niz-Chavez v. Garland*, 593 U.S. 155, 165-166 (2021); Opening Br. 23. Moreover, an NDA-specific definition of qualifying single source drug makes it easy to identify "the manufacturer" of the qualifying single source drug—the NDA holder. And CMS's approach gets things backwards by making all drugs that share an active moiety a single qualifying single source drug *only if* they share the same manufacturer. Under the IRA's plain text, a qualifying single source drug has a manufacturer; a drug's manufacturer does not determine whether the drug is a qualifying single source drug.

CMS's reading also allows it to immediately price control newly approved products, circumventing the IRA's minimum-seven-year-approval requirement. *See* Opening Br. 25 & n.5. Enforcing that requirement as written is critical to protecting innovators' patent rights and continued drug development. *See* Bausch

Amicus Br. 11-13, 16-18. The Government responds that it is "reasonabl[e]" to say "the relevant date is the earliest approval date of a product in the set." Gov't Br. 40. But "reasonableness" died with *Chevron*. *See Loper Bright*, 603 U.S. at 383. And there is no need to look beyond the IRA's text to decide the "relevant" approval date unless the Court follows CMS down its active-moiety rabbit hole.

So too for the generic-deselection provision. A qualifying single source drug is ineligible for selection if it is "the listed drug" for "at least one" generic. 42 U.S.C. § 1320f-1(c)(1). Yet on CMS's reading, a drug could be released from price controls even if it has no approved generic so long as one of its active-moiety cousins does. The Government frets about how the Program can best price cap "the drugs responsible for the greatest Medicare expenditures." Gov't Br. 41-43. But CMS undermines that goal by allowing one generic to knock out 12-plus innovators, even when there is no lower-cost option for 11 of them. *See* Opening Br. 24, 28. Unable to explain the absurdity, the Government ignores it.

III. CMS'S SUBJECTIVE, ATEXTUAL "BONA FIDE MARKETING" STANDARD IS UNLAWFUL.

The Government mounts virtually no textual defense of its "bona fide" requirement; its counterargument is pure policy. *See* Gov't Br. 45-50. But no statute pursues its goals "at all costs, and [courts] are not free to rewrite [the IRA] as if it did." *Advocate Christ Med. Ctr. v. Kennedy*, 605 U.S. 1, 19 (2025) (citation omitted). Regardless, the Government's objections fail.

1. The Government asserts that reading "marketed" to "mean 'expose for sale in a market' or 'bring or send to a market' " is inconsistent with dictionary definitions. Gov't Br. 48-49. But the Government's own dictionaries (at 49 & n.7) define "market" as "to expose for sale in a market," *Market*, Merriam-Webster's Collegiate Dictionary 760 (11th ed. 2020); "to bring or send to a market," *Market*, Oxford English Dictionary (3d ed. 2023); and "[t]o offer for sale," *Market*, The American Heritage Dictionary of the English Language 1075 (5th ed. 2011). The Government says the "broader context" of these definitions shows that "to market" means "to actually sell the product." Gov't Br. 49. True enough: A generic manufacturer must actually sell a unit of its generic. Opening Br. 44-45. But that does not imply the sales must be "bona fide." That is why Congress specified nearly 500 times in the U.S. Code that various other requirements must be "bona fide"—including in the IRA itself. Opening Br. 46. The Government has no response.

The Government's other textual arguments revolve around Congress's directive that a selected drug is ineligible for price controls if the generic "is approved" and "is marketed pursuant to such approval." 42 U.S.C. § 1320f-1(c)(1); *id.* § 1320f-1(e)(1)(A)(iii). The Government contends the present tense "is marketed" permits CMS to constantly reevaluate whether the generic has an "ongoing" market presence. Gov't Br. 49. But as Teva explained, CMS and FDA

elsewhere treat the "marketed" determination as a point-in-time inquiry. *See* Opening Br. 44-45, 47-48. The IRA's present-tense usage does not change that. If Congress wanted CMS to continuously or periodically reconsider whether the generic's marketing was "meaningful," Gov't Br. 46, it could have said so, *see* Opening Br. 46. Or it could have required that the drug "continue[] to be marketed," as it did elsewhere in the IRA. 26 U.S.C. § 223(c)(2)(G)(ii)(II). And even under the Government's reading, a requirement that a generic be marketed continuously would not require any particular *level* of marketing.

The Government finally argues that giving "marketed" its plain meaning renders the approval requirement superfluous. Gov't Br. 48-49. But the IRA reflects Congress's and FDA's longstanding recognition that a drug's approval and its marketing are distinct events. Marketing *follows* approval. *See*, *e.g.*, 21 U.S.C. § 355(j)(5)(D)(i)(I) ("[f]ailure to market" generic by certain date following approval forfeits 180-day generic exclusivity period); 21 C.F.R. § 314.105(d) ("A new drug product may not be marketed until the date of approval."). "Even if" the Government "had the better of the policy arguments"—and it does not—"those arguments could not overcome the statute's plain language." *Sandoz Inc. v. Amgen Inc.*, 582 U.S. 1, 21 (2017).

2. The thrust of the Government's argument is that only its atextual bona-fide requirement can prevent manufacturers from "collud[ing]" to "escape the

[Program's] strictures." Gov't Br. 47, 50. But the Government has plenty of mechanisms to combat bad-faith behavior. Any "agreement" between innovator and generic manufacturers related to the drug's "manufacture, marketing, or sale" must be filed with the Federal Trade Commission and the Assistant Attorney General for Antitrust. 21 U.S.C. § 355 note. Those agreements are reviewed for "anticompetitive" terms, including "[q]uantity restrictions." FTC, *Reverse Payments: From Cash to Quantity Restrictions and Other Possibilities* (Jan. 15, 2025), https://perma.cc/9YBA-6HZU. And the government and private plaintiffs do not hesitate to sue over what they perceive to be anticompetitive conduct with respect to generic marketing. *E.g.*, *FTC v. Actavis, Inc.*, 570 U.S. 136, 145 (2013); *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 146 (3d Cir. 2017).

Generic manufacturers also have ample incentives to maximize generic sales. Generics are costly to develop, so generics must meaningfully compete with the innovator drug on price, particularly during the critical post-launch months. *See* Ass'n for Accessible Meds. Amicus Br. 8-10, 12. The first-to-file generic enjoys a statutory exclusivity window over other generics, during which it can price its product "at a significant discount—often 20% to 40%—below the brand price," which "typically accounts for 60% to 80% of a generic product's total lifetime profits." DrugPatentWatch, *The 'Use It or Lose It' Rule: Decoding 180-*

Day Generic Exclusivity Forfeiture (Feb. 6, 2026), https://perma.cc/FN7U-CPGK. Given these natural incentives, Congress had no reason to engraft a bona-fide qualifier onto "marketed."

3. The Government cannot escape the problems with its bona-fide-marketing requirement by flipping the burden onto Teva or deriding Teva's concerns as premature. The Government says Teva cannot prevail on a definitional challenge because it cannot show the IRA authorizes "bad faith" marketing. Gov't Br. 47-48. But Teva is not pressing that extreme position; all it argues is that the IRA says nothing about the quality or quantity of a generic's marketing. Policing sham marketing is the domain of *other* laws.

On prematurity, the Government does not defend the District Court's ripeness holding. *See* Opening Br. 36-44; *see also Stolt-Nielsen S.A. v. AnimalFeeds Int'l Corp.*, 559 U.S. 662, 670 n.2 (2010) (rejecting prudential ripeness argument as "waived").[6] The Government instead promises that "Teva has nothing to fear." Gov't Br. 50. But this isn't about Teva's fears; it's about Congress never giving CMS the power to judge marketing's bona fides. Besides, CMS has never defined *what* bona fide marketing means. And the data delays Teva highlighted will make it essentially impossible for generics approved close to

[6] FDA recently approved Teva's application to market generic Xifaxan® (Rifaximin) 550 mg tablets, which Teva anticipates will enter the market on January 1, 2028. *See* Opening Br. Add. 5.

a relevant cutoff date, including several of Teva's generics, to shed price controls. Opening Br. 47-48. This Court's review is needed now.

IV. THE PROGRAM VIOLATES DUE PROCESS.

1. The Government does not disagree that the Program denies Teva constitutionally adequate process. *See* Gov't Br. 51-57; Opening Br. 53-54. And the arguments the Government makes about whether Teva has a constitutionally protected property interest fundamentally mischaracterize the Program. Medicare is not like "the Departments of Defense and Veterans Affairs," which buy pharmaceutical products directly. Gov't Br. 8-9, 52-53. CMS does not buy a single pill under Medicare. *E.g.*, 42 U.S.C. § 1395w-112(b)(1). Nor does it directly reimburse insurers for the actual or "negotiated" price of a drug. *Id.* § 1395w-115(a), (b). Medicare instead funds completely private transactions. *Id.* § 1320f-2(a)(1), (a)(3); Opening Br. 55. And when the Government leverages manufacturers' participation in Medicare and Medicaid to dictate drug prices, it is not acting like a "private individual[]"or "business." Gov't Br. 52 (citation omitted). Although the Program's prices are extended to only Medicare beneficiaries, if a manufacturer does not accept the CMS-set price for a selected drug, the manufacturer must withdraw *all* its drugs from Medicare *and* Medicaid. 26 U.S.C. § 5000D(c); 42 U.S.C. § 1396r-8(a)(1). No private party has that much coercive power, nor would the Antitrust Division allow one to.

The Government's argument has no limiting principle; the government, after all, subsidizes many purchases. Under the Government's view, the Department of Housing and Urban Development can force landlords to accept whatever it deems "maximum fair rents" for Section 8 voucher recipients on pain of being shut out of the Section 8 program *and* being denied federally guaranteed mortgages. There is no precedent for such all-consuming economic controls absent constitutionally adequate process. *See National Fed'n of Indep. Bus. v. Sebelius* (*NFIB*), 567 U.S. 519, 550 (2012) (courts should "consider the implications of the Government's arguments when confronted with . . . new conceptions of federal power") (citation and quotation marks omitted); *Bowles v. Willingham*, 321 U.S. 503, 520-521 (1944) (government cannot mandate rent controls, even during wartime, without affording landlords due process).

2. The Government protests that Teva's interests in its generic licenses, right to sell its products at prices free from government constraints, and patents are "abstract," "unilateral expectation[s]." Gov't Br. 51-52 (citation omitted). Yet the Government has no substantive response to Teva's argument that, when the Government creates a program that operates "in the nature of a contract," it cannot surprise participants with "post-acceptance or 'retroactive' conditions." Opening Br. 51 (citation omitted). Drug manufacturers that chose to participate in Medicare "could hardly anticipate that Congress's reservation of the right to 'alter' or

'amend' the . . . program included the power to transform it so dramatically." *NFIB*, 567 U.S. at 584.

Teva has never claimed an unqualified right to dictate prices. *Cf.* Gov't Br. 54-55. But Teva has actual and substantial reliance interests in free-market prices based on *the government's choice* to create Medicare as a free-market-driven program. *See Perry v. Sindermann*, 408 U.S. 593, 601-603 (1972). The same goes for Teva's interests in its licenses and patents. *See* Opening Br. 50-52. Before the government can strip Teva of its interests, it must provide some process. And that differentiates the Program from those like the 340B program where manufacturers knew at the program's inception of the statutory price caps and the consequences of not agreeing to them. *See* Gov't Br. 52-53.

3. Finally, the Government's voluntariness arguments miss the forest for the trees. The Government brushes past the Program's gun-to-the-head nature, insisting Teva can "opt-out." Gov't Br. 56 n.8. Hardly. The choice between abandoning nearly 50% of the market and the patients Medicare and Medicaid serve—or paying penalties so crushing that Congress never expected any manufacturer to incur them—is no choice at all. *See* Joint Comm. on Tax'n, *Estimated Budget Effects of the Revenue Provisions of Title XIII*, at 8 (Nov. 19, 2021), https://perma.cc/U9TQ-TMYS; Bausch Amicus Br. 8-9. But even if innovator manufacturers have a nominal choice, Teva as a generic manufacturer

has no way to opt out of the Program's effects on generics. That makes this case fundamentally different from others challenging the Program. Opening Br. 54. Again, the Government has no response.

CONCLUSION

The Court should reverse and remand with instructions for the District Court to vacate CMS's definitions of "qualifying single source drug" and "marketed" and enjoin the Government from implementing the Program as to Teva.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(g)(1), the undersigned hereby certifies that this brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B)(i).

1. Exclusive of the exempted portions of the brief, as provided in Fed. R. App. P. 32(f), the brief contains 6,493 words.

2. The brief has been prepared in proportionally spaced typeface using Microsoft Word in 14-point Times New Roman font. As permitted by Fed. R. App. P. 32(g)(1), the undersigned has relied upon the word count feature of this word processing system in preparing this certificate.

/s/ Sean Marotta
Sean Marotta

March 31, 2026

CERTIFICATE OF SERVICE

I certify that on March 31, 2026, the foregoing was electronically filed through this Court's CM/ECF system, which will send a notice of filing to all registered users.

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