IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

TEVA PHARMACEUTICALS USA, INC., *et al.*,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., in his official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES, *et al*.,

Defendants.

No. 1:25-cv-00113-SLS

TEVA'S COMBINED MEMORANDUM IN OPPOSITION TO DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT AND REPLY IN SUPPORT OF TEVA'S MOTION FOR SUMMARY JUDGMENT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page

CASES:

* Authorities upon which we chiefly rely are marked with an asterisk.

TABLE OF AUTHORITIES—Continued

Page

TABLE OF AUTHORITIES—Continued

Page

TABLE OF AUTHORITIES—Continued

Page

TABLE OF AUTHORITIES—Continued

Page

TABLE OF AUTHORITIES—Continued

Page

STATUTES:

TABLE OF AUTHORITIES—Continued

Page

TABLE OF AUTHORITIES—Continued

Page

REGULATIONS:

EXECUTIVE MATERIALS:

TABLE OF AUTHORITIES—Continued

Page

OTHER AUTHORITIES:

INTRODUCTION

The Inflation Reduction Act's (IRA) Drug Price Negotiation Program (Program) gave extraordinary powers to federal regulators to control the prescription drug market. Yet the Centers for Medicare & Medicaid Services (CMS) was apparently not content with those already sweeping powers, grasping for even more in its Guidance by unlawfully blue penciling the statutory text to expand the definitions of a "qualifying single source drug" and adding an atextual "bona fide marketing" requirement. These modifications blow a hole in the few—but critical—limitations on the Program that Congress established, harming Plaintiffs Teva Pharmaceuticals USA, Inc.; Teva Branded Pharmaceutical Products R&D LLC; and Teva Neuroscience, Inc. (for simplicity, Teva).

Although the statute says that CMS will select a certain number of drugs for "negotiation" each year—10 for Initial Price Applicability Year (IPAY) 2026, 15 for IPAY 2027, and so on—CMS has redefined a "qualifying single source drug" as an aggregation of multiple *different* drugs approved by the Food & Drug Administration (FDA) under *different* New Drug Applications (NDAs) and, in so doing, has expanded the statutory cap to make more drugs eligible for price controls than Congress intended. That is contrary to the IRA's plain text, which reflects that a "qualifying single source drug" refers to a product approved under a single, unique NDA. Using its made-up definition, CMS selected for negotiation as a single "drug" multiple different pharmaceutical products with the same active moiety despite being approved under different NDAs. CMS also ensured that its over-selection of drugs will remain subject to price controls for even longer than the IRA requires by demanding that a generic of the targeted innovator product be "bona fide" marketed before those price controls fall away, even though that language is nowhere in the statute. And CMS does all of this against the threat of ruinous

penalties against manufacturers of innovator products that do not accede to CMS's demands—without allowing any opportunity for generics manufacturers like Teva to be heard.

The government paints Teva's case as a "me-too" challenge to the Program, no different from the arguments made by other manufacturers in other cases in other courts. But Teva's suit is fundamentally different, as Teva has explained. ECF No. 9, Amended Compl. ¶¶ 13-14. As a manufacturer of both innovator and generic drugs, Teva uniquely feels the IRA's impact on not just the incentives to innovate new drugs and biologics, but also the incentives to create lower-priced generic drugs and biosimilars that bring down costs for patients and payors. In actuality, it is the government's response that is a "me-too" version of prior briefs. The government barely acknowledges Teva's distinct interest, cut-and-pasting freely from its prior filings involving differently positioned pharmaceutical manufacturers. Unlike those prior cases, Teva brings targeted statutory claims regarding the IRA's "qualifying single source drug" and marketing definitions that no court has yet addressed on the merits. That the government never squares up with these distinctions is indicative of the strength (and difference) of Teva's arguments.

To dodge defending CMS's unlawful Guidance on the merits, the government contends that Teva is statutorily barred from seeking judicial review of its APA—but not its due-process—arguments. But accepting the government's view requires casting aside the longstanding presumption in favor of judicial review. And in any event, Congress was clear about the specific and narrow aspects of the IRA for which the courthouse doors are closed: complaints about *which specific drugs* are actually subject to the Program or *what specific price* to charge. Congress did not withdraw judicial review of facial definitional challenges to the legal standards CMS applies in implementing the Program. Otherwise, CMS would be able to redefine the statute *however* it wants—drugs could be made eligible for negotiation immediately

after being FDA-approved—and manufacturers would have no legal redress. CMS could even subject *generic* drugs to IRA price controls and insist that obviously unlawful decision would be free from review. Congress did not insulate such lawlessness from judicial scrutiny. Congress knows how to craft an unqualified judicial-review bar when it wants to, as other federal statutes reflect; Congress decided not to do in the IRA. And even if it had, CMS's Guidance would be reviewable as *ultra vires* because CMS had no statutory authority to rewrite what it means to be a "qualifying single source drug" or for a generic to be "marketed" for Program purposes.

With its procedural objections to the side, the government offers only a meager defense of the Guidance's merits. On CMS's redefinition of a "qualifying single source drug" to cover *all* drugs with the same active moiety, even those approved under different NDAs, the government ignores the statutory definition and instead cherry-picks from three other provisions that appear *elsewhere* in the IRA and that do not modify what it means to be a "qualifying single source drug." The government also ignores Teva's explanation as to why those other IRA provisions are perfectly consistent with the statute's NDA-specific approach to defining what is a "qualifying single source drug"—they refer only to supplements to a single, original NDA, not distinct NDAs. Teva thus offers the most straightforward reading of the statute: A "qualifying single source drug" is a drug that was approved under a distinct NDA at least seven years ago, for which there is no generic product. The government's hodgepodge of competing policy concerns cannot overcome the statutory text's plain meaning and are wrong in any event: FDA is fully capable of policing whether an application should be filed as a separate original NDA or as a supplement to an already-approved NDA, and, in fact, FDA does so routinely as part of its regulatory review and approval process.

On bona fide marketing, the government admits that the statute refers only to a drug that is "marketed" without any qualification, limitation, or restriction. The government nonetheless insists that Congress implicitly vested CMS with free-wheeling discretion through the word "determine," but that does not support the expansive authority CMS claims. The government conflates distinct statutory provisions that would at most empower CMS to determine if a generic went to market—not afford CMS the unreviewable discretion to decide whether the generic holds whatever market share CMS believes is sufficient to be meaningful enough to warrant excluding the innovator product from the IRA's price controls.

On due process, the government contests only whether a protected property interest is at stake. But the government does not dispute that it must lose if there is: All agree that the Program does not afford Teva adequate process. Indeed, the government does not even address that generics manufacturers like Teva are denied a seat at the negotiating table entirely, even though the price CMS sets for innovator drugs will determine the generic price. At bottom, the government's due-process theory comes down to the idea that it is just another buyer in the marketplace, and, like any other buyer, it has the right to "negotiate" with manufacturers of innovator drugs like Teva. That is doubly wrong. To begin, the government is not *buying* Teva's products. The government is an insurer. It does not purchase any drugs directly from Teva, whether at the actual price or a "negotiated" price. Nor does the government stand on the same footing as any other market participant. When the only other options the IRA provides are draconian penalties that "no manufacturer could afford to pay," or "walking away" and "losing the" entire Medicaid and "Medicare market for all of its drugs"—thereby jeopardizing patients' access to essential life-saving medications—"basic economic rationality" dictates that manufacturers are "all but certain" to acquiesce to CMS's demands. *National Infusion Ctr. Ass'n*

v. Becerra, 116 F.4th 488, 495, 500 (5th Cir. 2024). And in fact, every manufacturer to date has done so. No ordinary market participant could leverage that type of coercive power and credibly claim the Program is "voluntary." The Program's unprecedented expansion of federal regulatory authority—and CMS's implementation of it—violate the Constitution's due-process guarantee.

The Court should vacate CMS's two unlawful definitions and enjoin the Program as to Teva.

ARGUMENT

I. Teva's APA Claims Are Reviewable.

In a bid 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 selection and determination decisions with respect to particular drugs—also precludes judicial review of Teva's facial challenge to CMS's Guidance. That is wrong. And even if the bar did apply, CMS's Guidance would be reviewable as *ultra vires*.

A. The IRA Does Not Preclude Review Of Teva's APA Claims.

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). "This default rule is well-settled, and Congress is presumed to legislate with it in mind." *Salinas v. United States R.R. Ret. Bd.*, 592 U.S. 188, 197 (2021) (citation and quotation marks omitted). The presumption "dictates" that "statutory provisions specifically designed to limit judicial review . . . must be read narrowly," *Make the Rd. N.Y. v. Wolf*, 962 F.3d 612, 624 (D.C. Cir. 2020) (quotation marks omitted), and that any "ambiguity . . . must be resolved in" favor of permitting judicial review, *Salinas*, 592 U.S. at 197. To overcome the strong presumption of reviewability, the government must produce "clear and convincing evidence of congressional

intent" to exempt the specific executive action from judicial oversight. *Guerrero-Lasprilla v. Barr*, 589 U.S. 221, 229 (2020) (citation and quotation marks omitted).

The reason for this rule is simple: Congress knows "that legal lapses and violations occur" within the executive branch and "rarely intends to prevent courts from enforcing its directives to federal agencies." *Mach Mining*, 575 U.S. at 486, 489. As Chief Justice Marshall put it, "[i]t would excite some surprise if, in a government of laws and of principle, furnished with a department whose appropriate duty it is to decide questions of right," a government official can decide an issue for which the affected individual has "no remedy, no appeal to the laws of his country, if he should believe [the decision] unjust." *United States v. Nourse*, 34 U.S. 8, 28-29 (1835).

The government acknowledges this "strong presumption" only in passing. Gov't Br. 10. And it neglects to mention that *it* bears the "heavy burden" to overcome it, *Mach Mining*, 575 U.S. at 486 (quotation marks omitted); the high clear-and-convincing-evidence standard required to do so; or that any doubt should be resolved in favor of judicial review. That silence is understandable; the government cannot carry its substantial burden of showing it may misconstrue the IRA with impunity.

1. 42 U.S.C. § 1320f–7 provides that "[t]here shall be no . . . judicial review of" eight clearly defined actions under the Program: (1) "[t]he selection of drugs" for negotiation under section 1320f–1(b)"; (2) "the determination of negotiation-eligible drugs under section 1320f–1(d)"; (3) "the determination of qualifying single source drugs under section 1320f–1(e)"; (4) "the application of section 1320f–1(f)," which concerns delaying the selection and negotiation of biologics; (5) "[t]he determination of a maximum fair price under" section 1320f–3(b), (f); (6) "[t]he determination of renegotiation-eligible drugs under section 1320f–3(f)(2)";

(7) "the selection of renegotiation-eligible drugs under section 1320f–3(f)(3)"; and (8) "[t]he determination of" what constitutes "a unit" of a drug, which affects how CMS negotiates the maximum fair price of a selected drug "pursuant to section 1320f(c)(6)."

Each of those carefully and narrowly delineated categories involves CMS's decisions about *which drugs* are subject to the Program or *what price* to charge. Teva is not challenging either. Teva does not argue that CMS erred with respect to the selection or determination of any specific product under any particular IRA subsection. In fact, Teva filed this lawsuit *before* its innovator drugs, AUSTEDO and AUSTEDO XR, were even selected for negotiation.[1] Nor did Teva challenge CMS's selection or determination of the various branded innovator drugs marketed by other companies for which Teva plans to launch generics over the coming years, as the government seems to acknowledge. *See* Gov't Br. 16-17 & n.6; *see also* Teva Br. 34.

Put simply, Teva did not and does not challenge CMS's Guidance as applied to any particular product; Teva instead brought a facial challenge, arguing that CMS unlawfully *redefined* "qualifying single source drug" and added a "bona fide marketing" requirement contrary to the IRA's plain text. Teva's prayer for relief makes that clear: It asks this Court to declare that "CMS's definition of a Qualifying Single Source Drug" and " 'bona fide marketing' standard" are "unlawful" and to "vacat[e] and set[ ] aside" those portions of CMS's Guidance. ECF No. 9, Amended Compl. ¶¶ A-C.

2. Unable to dispute these facts, the government resorts to a sleight of hand. The government argues that by challenging CMS's *definition* of "qualifying single source drug," Teva actually "challenge[d] CMS's '*determination* of qualifying single source drugs,' " over

[1] *Compare* ECF No. 1 (original complaint filed January 15, 2025), *with* ECF No. 9 ¶ 93 (amended complaint filed February 10, 2015, explaining that HHS announced AUSTEDO and AUSTEDO XR's selection on January 17, 2025).

which the statute "expressly preclude[s] review." Gov't Br. 10-11 (emphasis added) (quoting 42 U.S.C. § 1320f–7(2)). But a definition and a determination are not the same thing. A "definition" is a "statement of the meaning of a word or word group." *Definition*, Merriam-Webster Dictionary 187 (2016); *see* Gov't Br. 12 (quoting similar definition). A "determination" is "the decision or conclusion reached." *Determination*, Merriam-Webster Dictionary 196.

As the Supreme Court explained in rejecting a similar jurisdiction-stripping argument, "the reference to 'a determination' describes a single act rather than a group of decisions or a practice or procedure employed in making decisions." *McNary v. Haitian Refugee Ctr., Inc.*, 498 U.S. 479, 492 (1991). The statute in *McNary* precluded judicial review of "a determination respecting an application for adjustment of status" for a special agricultural worker. 8 U.S.C. § 1160(e)(1). Several unsuccessful applicants challenged the government's "practices and policies" for administering the special agricultural worker program. *McNary*, 498 U.S. at 487. Because the applicants sought review of only "the procedures used" and not an "individual determination[ ]" on a particular status-adjustment application, their suit was allowed to proceed, notwithstanding the judicial-review prohibition. *Id.* at 486, 494.

Courts have not hesitated to enforce this line between facial (definitional) and as-applied (determination-based) challenges in interpreting judicial-review bars. For example, 8 U.S.C. § 1252(a)(2)(A)(i) withdraws jurisdiction over "any individual determination or . . . any other cause or claim arising from or relating to the implementation or operation of an order of removal." The D.C. Circuit has held that forbids only "review of individual aliens' credible-fear determinations"—that is, as-applied challenges—not "facial challenges to the written policies that govern those determinations." *Grace v. Barr*, 965 F.3d 883, 893 (D.C. Cir. 2020).

The IRA's statutory structure likewise supports distinguishing between determinations and definitions. Recall that the judicial-review bar applies to only eight specific "selection" and "determination" decisions by CMS with respect to certain drugs or biological products, rendered under various subsections of 42 U.S.C. §§ 1320f, 1320f–1, and 1320f–3. *See* 42 U.S.C. § 1320f–7. And recall that, in the IRA, Congress explicitly instructed CMS to "implement [the Program]" using "guidance." *Id.* § 1320f note. Yet the judicial-review bar does not preclude review of CMS's guidance or any decision rendered under *that* authority.

That distinction reflects Congress's understanding of CMS's and courts' relative areas of expertise. Congress did not want manufacturers coming to court to challenge things like CMS's calculation of the total expenditures for each eligible drug and its associated ranking or whether a given drug is "[l]ow spend," *see id.* § 1320f–1(b)(1), (d)(1), (e)(3)(B); CMS's decision that there is "a high likelihood" a particular biosimilar "will be licensed and marketed" within two years, *id.* § 1320f–1(f)(1)(A); or CMS's determination of what constitutes a "maximum fair price," *id.* § 1320f–3(b)(1). As Congress recognized, CMS can bring its experience and expertise to bear in rendering those kinds of mathematical, quantitative, or discretionary determinations. But although CMS has "subject matter expertise regarding the statutes [it] administer[s]," the same is not true when it comes to statutory interpretation. *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 401 (2024). It is "elemental" that "courts decide legal questions by applying their own judgment." *Id.* at 391-392.

Of course, Congress is "always free to" mandate otherwise, as it has in other statutes. *See id.* at 403. Congress knows how to craft a judicial-review bar that applies not only to specific determinations, but more broadly 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); 8 U.S.C. § 1252(a)(2)(A)(iv), (e)(3)(A)(ii) (barring review of informal "procedures and policies" while expressly authorizing review of regulations and other written policies and guidelines).

Congress also knows how to specify that decisions that may "implicate" or "relate to" a certain process are off limits. *Cf.* Gov't Br. 11 (arguing decisions that "implicate" a specified action are unreviewable); *see also* 8 U.S.C. § 1252(a)(2)(A)(i) (barring review of decisions "arising from or relating to the implementation or operation of an order of removal"). Take 42 U.S.C. § 1395nn(i)(3)(A), where Congress instructed that "the Secretary shall promulgate regulations to carry out" a particular "process" and prohibited judicial review of "the process." That "unqualified" judicial-review bar "preclud[es] review of 'the process' in its broadest sense," in stark contrast to narrower provisions that delineate a specific "list" of unreviewable agency actions. *Knapp Med. Ctr. v. Hargan*, 875 F.3d 1125, 1130-31 (D.C. Cir. 2017).

Congress even knows how to preclude judicial review of any decision made under a particular statutory provision, full stop. *See, e.g.*, 8 U.S.C. § 1252(a)(2)(B) (barring review of "any other decision or action . . . the authority for which is specified under this subchapter"). Congress could have tacked on similar limits to judicial review of actions taken under the IRA here. It did not. *See McNary*, 498 U.S. at 494 ("[H]ad Congress intended" a broader judicial-review bar, "it could easily have used broader statutory language.").

3. The government next argues that Teva's APA challenges to CMS's Guidance are unreviewable under a narrow doctrine holding that certain decisions that are "indispensable" to "unreviewable agency action" likewise cannot be reviewed. Gov't Br. 11 (quotation marks omitted). But "the mere fact that some acts are made reviewable should not suffice to support an implication of exclusion as to others"; "[t]he right to review is too important to be excluded on

such slender and indeterminate evidence of legislative intent." *Bowen v. Michigan Acad. of Fam. Physicians*, 476 U.S. 667, 674 (1986) (quotation marks omitted). Thus, "even if judicial review of a [specific] decision is barred," affected parties are still "free to challenge the general rules leading to" that decision. *Florida Health Scis. Ctr., Inc. v. Secretary of HHS*, 830 F.3d 515, 521 (D.C. Cir. 2016) (citation and quotation marks omitted). Conversely, "review is not permitted when a procedure is challenged *solely* in order to reverse an individual decision that" is otherwise unreviewable. *Id.* (quotation marks and alteration omitted and emphasis added). The question is thus whether the litigant is truly challenging a widespread and "general rule[ ]" or "is simply trying to undo" "a shielded [individual] determination" "by recasting its challenge" as one to "the general rules leading to" that determination." *Id.* at 522.

The government's cited cases (at 11-13) fall into the latter category; they were challenges to a shielded determination dressed up in general-rule garb. Three of the government's cases involved challenges under a provision precluding review of "[a]ny estimate of the Secretary for purposes of determining" "[a]djustments to" Medicare payments to disproportionate-share hospitals. 42 U.S.C. § 1395ww(r)(3). The adjustment is the product of an "estimate[ ] by the Secretary" of costs incurred by "each . . . hospital," "based on appropriate data." *Id.* § 1395ww(r)(2)(C). In each case, the hospital claimed that the Secretary got the math wrong—and that, with the right math, the hospital was entitled to more money. In each case, the court rightly held that was really a challenge to the calculation itself. A hospital therefore could not "challenge the Secretary's refusal to use" certain data the hospital had submitted, as that would eviscerate the bar against reviewing "any estimate of the Secretary" based on that data. *Florida Health Scis. Ctr.*, 830 F.3d at 518-521 (quotation marks omitted). Nor could a hospital challenge "the methodology" used to calculate the hospital-specific estimate because, in that "statutory

scheme, a challenge to the methodology for" determining the estimates "is unavoidably a challenge to the estimates themselves." *DCH Reg'l Med. Ctr. v. Azar*, 925 F.3d 503, 505-506 (D.C. Cir. 2019). And a hospital could not challenge the Secretary's failure to follow notice and comment in choosing which data to use because the data selected were "not just underlying data for the relevant estimate"—they were "the estimate" itself. *Yale New Haven Hosp. v. Becerra*, 56 F.4th 9, 15-26 (2d Cir. 2022) (quotation marks omitted).

The cases the government cites arising under other statutes are in the same vein. *See Mercy Hosp., Inc. v. Azar*, 891 F.3d 1062, 1067 (D.C. Cir. 2018) (hospital's challenge to specific reimbursement rate-adjustment barred where the statute precluded review of the ultimate rate, expressly "tie[d] together" the adjustment and rate determinations, and any ruling that the adjustment was flawed would necessarily "ask[ ] the court to remand the [final rate] to be recalculated" using the correct adjustment); *John Balko & Assocs. Inc. v. Secretary of HHS*, 555 F. App'x 188, 192-193 (3d Cir. 2014) (statute barring review of the "determination[ ]" that a particular Medicare provider had a "high level of payment error" precluded review of argument that auditor used the wrong procedure to determine the provider had "a high level of payment error," leading to a significant overcharge); *Texas All. for Home Care Servs. v. Sebelius*, 681 F.3d 402, 410 (D.C. Cir. 2012) (challenge to rule articulating financial standards for contract-bidders was precluded under provision barring review of "the awarding of contracts" where the statute "require[d] the formulation and application" of such standards and stated that contracts could not be awarded to entities that did not meet those standards).[2]

[2] The government describes *Knapp Medical Center* as "similar" to *DCH Regional Medical Center*. Gov't Br. 12. That is incorrect. *Knapp Medical Center* rested primarily on the fact that the judicial-review bar was "unqualified" and explicitly encompassed "review of the process in its broadest sense." *Knapp Med. Ctr.*, 875 F.3d at 1130-31 (quotation marks omitted).

The government cannot reconcile its position with cases that fall on the other side of the ledger, like *McNary* or *ParkView Medical Associates, L.P. v. Shalala*, 158 F.3d 146 (D.C. Cir. 1998). In *ParkView*, a hospital sought to be geographically reclassified into a different wage index region, which affected Medicare reimbursement rates. *Id.* at 147. The Secretary denied reclassification, based in part on a rule governing what time period of data the Secretary would consider in evaluating reclassification. *Id.* at 148. The D.C. Circuit held that it could not review the "denial itself" under a statute barring review of the Secretary's reclassification decisions. *Id.* But the court had no problem reviewing the Secretary's "general rules leading to denial." *Id.*; *see also, e.g.*, *Anna Jacques Hosp. v. Burwell*, 797 F.3d 1155, 1163 (D.C. Cir. 2015) (reviewing whether final rule increasing wage-index calculation for a particular region "violated the statut[e]," even though challengers were located in that region and so were necessarily affected by the challenged rule).

Just like in *McNary* and *ParkView*, section 1320f–7's judicial-review bar "target[s] only a particular kind of . . . decision"—the determination or the selection of a specific drug—"rather than any [consideration] used to make the decision." *Cf. DCH Reg'l*, 925 F.3d at 508. As in those cases, Teva has not asked the Court to direct CMS to "reverse an individual" decision governing any particular drug. *Cf. id.* (quotation marks omitted) (noting DCH sought "vacatur of the [challenged] calculation" and "an order requiring the Secretary to recalculate it").[3] And as in

[3] In every one of the payment-calculation cases, the plaintiff specifically requested that the court direct the Secretary to correct the erroneous calculation. ECF No. 1 at 16, *DCH Reg'l Med. Ctr. v. Burwell*, No. 1:16-cv-00212 (D.D.C. Feb 8, 2016); ECF No. 1 ¶ 53, *Mercy Hosp., Inc. v. Burwell*, No. 1:15-cv-01236 (D.D.C. July 31, 2015). Several also requested a court order "directing the Secretary to pay" the plaintiff "the additional amount due as a result of that correction." ECF No. 1 ¶ 46, *Florida Health Scis. Ctr., Inc. v. Secretary of HHS*, No. 1:14-cv-00791 (D.D.C. May 9, 2014); *see* ECF No. 1 at 24, *Yale New Haven Hosp. v. Azar*, No. 3:18-cv-01230 (D. Conn. July 24, 2018) (similar); ECF No. 1 at 21, *John Balko & Assocs., Inc. v. Sebelius*, No. 2:12-cv-00572 (W.D. Pa. April 30, 2012) (similar).

those cases, ruling for Teva on its APA challenges would not have "the practical effect of also deciding" non-existent challenges to individual decisions "on the merits." *Cf. id.* (quotation marks omitted). It is unclear what the final list of selected drugs might have looked like had CMS properly applied the statutory criteria. Holding that "qualifying single source drug" means a drug approved and marketed under its own NDA would not force CMS to act with respect to any particular drugs. CMS would still need to evaluate which drugs were approved on distinct NDAs, verify the amount of time that has lapsed since each such approval, ask whether a drug is the reference listed drug for a generic, determine whether any exclusions apply, assess the drugs' respective expenditures, and rank the drugs. *See generally* 42 U.S.C. § 1320f–1. Likewise, even if this Court were to hold that "marketed" means marketed, CMS would still need to assess when a particular generic "is approved and marketed" and determine what effect, if any, that has on the corresponding branded drug's eligibility. *See id.* § 1320f–1(e)(1)(A)(iii).

One last point bears emphasis: Accepting the government's interpretation would mean that "no one [is] able 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 that would be "tantamount to a complete denial of judicial review"); *see infra* pp. 15-17 (discussing *ultra vires* review). On the government's reading, a manufacturer cannot ever challenge CMS's policies if the logical conclusion of the manufacturer's argument could potentially affect whether one or more of the manufacturer's products count as a "qualifying single source drug." But even parties raising definitional challenges must show standing. And the government has elsewhere argued that manufacturers lack standing to raise a facial definitional claim when the challenged aspects of CMS's Guidance "had no bearing on [the drug's] selection for negotiation." Br. for Appellees at 30, *AstraZeneca Pharms. LP v. HHS*, No. 24-1819, 2024 WL 5219932 (3d Cir. Sept. 12,

2024); *see Union of Concerned Scientists v. Department of Energy*, 998 F.3d 926, 927-931 (D.C. Cir. 2021) (party bringing facial challenge to rule allegedly denying it access to certain data lacked standing where there was no indication the rule would actually affect the party's access). The government is thus trying to have its cake and eat it too, and the end result would leave interpretation of the IRA in CMS's "hands alone." *Mach Mining*, 575 U.S. at 488. The Court "need not doubt [CMS's] trustworthiness, or its fidelity to law, to shy away from that result" when Congress did not clearly command it. *Id.* at 488-489.

For these reasons, the Court should hold as a matter of first impression that section 1320f–7 does not bar Teva's APA claims.[4] In light of the strong presumption in favor of judicial review, so long as the statute "is reasonably susceptible to" Teva's "interpretation," the Court should allow Teva's claims to proceed. *American Clinical Lab'y Ass'n v. Azar*, 931 F.3d 1195, 1204 (D.C. Cir. 2019) (quotation marks omitted). Teva's APA claims hurdle that low bar with room to spare.

B. CMS's Guidance Is Reviewable As *Ultra Vires*.

CMS's Guidance is also reviewable for a second reason: It is *ultra vires*. "Review for *ultra vires* acts rests on the longstanding principle that if an agency action is 'unauthorized by the

[4] No Court has applied the D.C. Circuit's "inextricably intertwined" principle to 42 U.S.C. § 1320f–7. The government cites one case holding the IRA's judicial-review bar precluded an APA suit challenging various decisions related to the "selection" and "aggregation of" the plaintiffs' products. *Novo Nordisk Inc. v. Becerra*, No. 3:23-cv-20814, 2024 WL 3594413, at *2 (D.N.J. July 31, 2024), *appeal pending*, No. 24-2510 (3d Cir.). The court's analysis was a mere two sentences. After quoting the judicial-review bar, the court summarily concluded that, "[b]y this provision, Congress has divested this Court of jurisdiction to consider challenges under the APA to CMS's determinations under 1320f–1(b),(d),(e), and (f)." That cursory, nonprecedential decision does not warrant any weight. Moreover, the manufacturer also asked for a judicial declaration that CMS erred in "subject[ing]" its products "to price controls under the statute" and "[e]njoin[ing] CMS from applying price controls to any of Novo's products"—requests that directly implicate the judicial-review bar and which Teva has not made. ECF No. 1 at 59, *Novo Nordisk v. Becerra*, No. 3:23-cv-20814 (D.N.J. Sept. 29, 2023).

statute under which the agency assumes to act,' " the agency has 'violated the law' and 'the courts generally have jurisdiction to grant relief.' " *National Ass'n of Postal Supervisors v. United States Postal Serv.*, 26 F.4th 960, 970 (D.C. Cir. 2022) (quoting *American Sch. of Magnetic Healing v. McAnnulty*, 187 U.S. 94, 108 (1902)) (brackets omitted). Agency action is reviewable as *ultra vires* when "(i) the statutory preclusion of review is implied rather than express; (ii) there is no alternative procedure for review of the statutory claim; and (iii) the agency plainly acts in excess of its delegated powers," contrary to "clear and mandatory" statutory language. *DCH Reg'l*, 925 F.3d at 509 (quotation marks omitted); *see National Ass'n of Postal Supervisors*, 26 F.4th at 971 (citations omitted) (clarifying that the third prong of this test embraces "review of claims involving 'positive statutory commands,' questions of statutory interpretation, and questions regarding whether an agency decision was supported by a contemporaneous justification").

All three requirements are satisfied here. *First*, as explained, the judicial-review bar does not expressly prohibit review of challenges to CMS's Guidance; it bars review only of specific "selection" or "determination" or "calculation" decisions, none of which Teva challenges. *Second*, the government does not even bother suggesting there is an alternative review procedure available—because there is not. *See* Gov't Br. 13-14. *Third*, CMS's Guidance was plainly "[u]nauthorized" in that it exceeded "the scope of power allowed or granted by . . . law" by fundamentally reinterpreting, reimagining, and rewriting the IRA's plain text. *Ultra Vires*, Black's Law Dictionary (12th ed. 2024); *see National Ass'n of Postal Supervisors*, 26 F.4th at 971 (agency action is *ultra vires* where it violates "a statutory provision [that] plainly delineates the outer limits of agency authority"). The IRA expressly defines "qualifying single source drug" and does not include a "bona fide marketing" requirement; by changing the text to mean

something different, CMS "plainly and openly crossed a congressionally drawn line in the sand." *Federal Express Corp. v. Department of Com.*, 39 F.4th 756, 765 (D.C. Cir. 2022); *see* Teva Br. 21-37; *infra* pp. 17-37. CMS's Guidance is accordingly reviewable as *ultra vires*.

II. CMS's Definition Of Qualifying Single Source Drug Is Unlawful.

The IRA takes an NDA-specific approach to the definition of a "qualifying single source drug" that is eligible for selection. The IRA says that a "qualifying single source drug" is "a covered part D drug" that (i) "is approved" under an NDA "and is marketed pursuant to such approval"; (ii) for which "at least 7 years . . . have elapsed since the date of such approval"; and (iii) "is not the listed drug" for a generic. 42 U.S.C. § 1320f–1(e)(1)(A); *see* Teva Br. 21-22. By saying what "the term 'qualifying single source drug' means," 42 U.S.C. § 1320f–1(e)(1), the IRA itself makes clear that two drugs, approved under two separate NDAs, cannot be considered one "qualifying single source drug," *see* Teva Br. 21-22.

CMS nevertheless decided to adopt its own definition—one that bears no relationship to the statute. According to CMS, a "qualifying single source" drug includes "all dosage forms and strengths of the drug with the same active moiety and the same holder of an NDA, inclusive of products that are marketed pursuant to different NDAs."[5] The government does not dispute that the terms "active moiety" or "active ingredient" are found nowhere in the IRA. Nor does the government explain where its "same holder" limitation can be found in the IRA.

[5] CMS, *Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191-1198 of the Social Security Act for IPAY 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027*, at 167 (Oct. 2, 2024), https://perma.cc/AJ33-F9U4 (2027 Guidance). For biological products, CMS similarly defined a "qualifying single source drug" as "all dosage forms and strengths of the biological product with the same active ingredient and the same holder of a Biologics License Application (BLA), inclusive of products that are marketed pursuant to different BLAs." *Id.* at 168.

1. In search of a textual hook, the government cobbles together three subsections of the IRA—none of which appear in the part defining "the term 'qualifying single source drug' "—and insists that the "combined direction" of these provisions compels CMS's approach. Gov't Br. 22 (citing 42 U.S.C. §§ 1320f–1(d)(3)(B), 1320f–3(e)(1)(D), and 1320f–5(a)(2)). The government then accuses Teva of "fail[ing] to explain how [its] approach can be reconciled with" those provisions. *Id.* But Teva does not have to reconcile its approach with anything: "As a rule, a statutory definition which declares what a term 'means' excludes any meaning that is not stated." *Burgess v. United States*, 553 U.S. 124, 130 (2008) (citation, quotation marks, and alterations omitted). The government must make the rest of the statute conform to 42 U.S.C. § 1320f–1(e)(1)'s specific definition, not the other way around.

In any case, Teva *did* address each of the three provisions the government cites. As Teva explained, the provisions do not permit CMS to aggregate drugs across multiple NDAs held by the same entity: The "far easier reading" is that they tell CMS what to do when "different dosage forms and strengths" have been approved through "supplemental applications to a single NDA." Teva Br. 27-28. That the government ignores Teva's explanation shows that the government has no response.

Teva's reading makes sense of the IRA. As Teva explained, manufacturers "commonly" update their NDAs or BLAs with amendments and supplements for everything from a labeling change to adding new formulations, indications, strengths, or dosage forms. *Id.* The government agrees that variations of a drug "are often approved within a single original NDA, and through sNDAs." Gov't Br. 18 n.7. The IRA accounted for this reality by providing that CMS should consider those variations at certain stages of the Program. Start with the government's first cited provision, section 1320f–1(d)(3)(B). When CMS is determining the amount of Medicare

spending on a drug, it should "use data that is aggregated across dosage forms and strengths of the drug" under that drug's unique NDA or BLA. 42 U.S.C. § 1320f–1(d)(3)(B). ENBREL, which was selected for negotiation for IPAY 2026, is a good example. ENBREL was originally approved in 1998 to treat rheumatoid arthritis in 25 mg vials; in 2004, after additional clinical testing, FDA approved a supplement to the original BLA for a prefilled 50 mg syringe.[6] The IRA thus directs CMS to aggregate the government's spending on *both* the 25 mg (original) and the 50 mg (supplement) strengths and forms in determining ENBREL's share of Medicare spending, rather than looking at spending on each version in isolation. Congress was free to make that choice.

The government's second cited provision works in much the same way. The IRA directs CMS, when determining the "maximum fair price" it will offer for a selected drug, to consider the "applications and approvals under section 355(c) of title 21 or section 262(a) of [title 42] for the drug." 42 U.S.C. § 1320f–3(e)(1)(D). The government makes much of the fact that the IRA refers to " 'applications and approvals,' in the plural, 'for the drug,' in the singular." Gov't Br. 15. But there is no reason to read "applications and approvals" as referring to multiple different NDAs or BLAs, as opposed to amendments and modifications that FDA approves for a single NDA or BLA. In fact, the cross-references to FDA's approval process also encompass supplements to an original NDA or BLA. *See* 21 U.S.C. § 355(c)(5) (regarding "the approval of a supplemental application"); 42 U.S.C. § 262(a); 21 C.F.R. § 601.12 (addressing "[c]hanges to an approved application"). It was entirely logical for Congress to direct CMS to consider

[6] *See* Amgen, Press Release, *FDA Approves New and Easy Way to Take ENBREL; Benefits of ENBREL Delivered in Convenient Once-Weekly 50 mg/mL Prefilled Syringe* (Sept. 28, 2004), https://tinyurl.com/593m62bn; CDER, Letter Approving Supplement to BLA (Sept. 27, 2004), https://perma.cc/5N3X-5FTN.

supplements to a drug's original approval when developing an offer price. For example, when CMS develops its offer price for XIFAXAN, selected for IPAY 2027, it will consider the drug's original NDA approval in 2004 for 200 mg, as well as the supplemental approval in 2015 for a new indication available in 550 mg.[7]

The government's final cited provision is also no help. Section 1320f–5(a)(2) provides that among CMS's "administrative duties" is the "establishment of procedures to compute and apply the maximum fair price across different strengths and dosage forms of a selected drug." Far from endorsing aggregation across different NDAs, this provision directs CMS to develop a methodology to apply the maximum fair price on a per-unit basis. For example, once CMS has determined the maximum fair price for a drug like XIFAXAN, CMS must apply that price to the "different strengths" listed under XIFAXAN's single NDA—200 mg and 550 mg—in order to compute the drug's per-unit cost. Section 1320f–5(a)(2) directs CMS to develop a methodology for accomplishing that; it does not permit CMS to aggregate drugs across different NDAs or BLAs.

2. The government's approach is divorced from the IRA's text. Assume the government were correct that the three statutory provisions discussed above direct CMS to aggregate drugs approved under different NDAs if they share the same active moiety. Aggregation should not depend on *who* happens to hold those different NDAs; after all, sections 1320f–1(d)(3)(B), 1320f–3(e)(1)(D), and 1320f–5(a)(2) say nothing about active moieties, distinct NDAs, or which entity holds them. So, the government's position, taken to its natural conclusion, would mean that drugs approved under *different* NDAs held by *different* companies must be aggregated as a

[7] *See* FDA, *Drugs@FDA, XIFAXAN, Products on NDA 021361*, https://tinyurl.com/zrc3h7yu (last visited May 19, 2025).

single "qualifying single source drug" so long as the drugs share the same active moiety. But CMS refused to accept that outcome: CMS is explicit that it aggregates products across "different NDAs" *only* if those NDAs are "held by the same entity." 2027 Guidance at 167; *see also id.* at 16 (CMS "will not . . . aggregate across NDA or BLA holder names that do not represent the same entity"). Yet neither the Guidance nor the government point to any statutory authority for this "same entity" distinction. Nor can the government point to anything in the text that would support CMS's claimed authority to "investigate" whether NDAs and BLAs "are held by the same entity." *Id.* at 15-16, 167-168.

3. The government's argument also ignores the IRA's definition of a "qualifying single source drug," which is where the legal analysis should begin. If Congress meant to aggregate multiple drugs approved under different NDAs held by the same entity, Congress presumably would have said so when it defined what "the term 'qualifying single source drug' means." 42 U.S.C. § 1320f–1(e)(1). Congress instead explained that a "qualifying single source drug" is "a covered part D drug" that (i) was "approved under [21 U.S.C. § 355(c)] and is marketed pursuant to such approval," (ii) "at least 7 years [ ] have elapsed since the date of such approval," and (iii) is "not the listed drug" for a generic "that is approved and marketed." 42 U.S.C. § 1320f–1(e)(1). Congress could have—*but did not*—say that a "qualifying single source drug" includes all products sharing the same active moiety, even if approved under different NDAs, so long as the same entity holds the NDAs. Indeed, section 1320f–1(e) does not say anything about active moieties or same-manufacturer ownership at all.

As Teva explained, the distinct-NDA or -BLA interpretation is the only logical way to read section 1320f–1(e). Teva Br. 22-23. That is because section 1320f–1(e) expressly incorporates FDA's approval framework in the Food, Drug, and Cosmetic Act (FDCA), which is

based on specific and unique NDAs. *Id.* at 23-24. The government derides Teva's discussion of FDA's approval framework, insisting that "the IRA and the FDCA are different statutes with fundamentally different objectives and functions." Gov't Br. 17-18. But the government does not and cannot contest that the IRA *itself* incorporates the FDCA. The IRA defines a "qualifying single source drug" as a "drug . . . that is approved under section 355(c) of title 21," 42 U.S.C. § 1320f–1(e)(1)(A)(i)—that is, a drug that FDA has "approved" through a "[new drug] application" under the FDCA, 21 U.S.C. § 355(c). Under the IRA, a "qualifying single source drug" must be "marketed pursuant to such approval"—that is, marketed pursuant to the specific approved NDA. 42 U.S.C. § 1320f–1(e)(1)(A)(i). The IRA further requires that "at least 7 years" must have "elapsed since the date of such approval" of the NDA to make an innovator drug eligible for the Program. *Id.* § 1320f–1(e)(1)(A)(ii). And the IRA incorporates the FDCA's definition of a generic drug in explaining what a "qualifying single source drug" is not: It "is not the listed drug for any drug that is approved and marketed under section 355(j)" of the FDCA, *id.* § 1320f–1(e)(1)(A)(iii); *see* 21 U.S.C. § 355(j) (requirements for "abbreviated new drug applications"); *see also* Manufacturers' Amicus Br. 13. If Congress had intended the definition of "qualifying single source drug" to be divorced from the FDCA's distinct-NDA approach, Congress would not have defined "the term 'qualifying single source drug' " by reference to the FDCA. 42 U.S.C. § 1320f–1(e)(1).

Teva also outlined yet another way in which the IRA points to a single NDA as determining what counts as a "qualifying single source drug"—by following the statutory cross-references to "a covered part D drug." Teva Br. 22-23. The government agrees that this chain "ends with a reference to FDA approval," but complains that the series of links are too "attenuated." Gov't Br. 19. The government's real objection appears directed at the statute that

Congress wrote. That Congress resorted to cross-references rather than setting out every definition directly in the IRA does not make those references "attenuated." And there is nothing unusual about "two programs shar[ing] similarities, each function[ing] in partial independence of the other, albeit with many cross-references." *Cooper Hosp. / Univ. Med. Ctr. v. Burwell*, 179 F. Supp. 3d 31, 36 (D.D.C. 2016).

Here, the reader need only follow the directions that Congress explicitly set. Start with the IRA, which says that a "qualifying single source drug" is "a covered part D drug (as defined in section 1395w–102(e)" of the Medicare statute. 42 U.S.C. § 1320f–1(e)(1). The IRA thus directs the reader to look to section 1395w–102(e) of the Medicare statute, which in turn says that "a covered part D drug" is a drug—not multiple drugs—"that is described in subparagraph (A)(i), . . . of section 1396r–8(k)(2)." *Id.* § 1395w–102(e)(1). So the reader must flip to section 1396r–8(k)(2)(A)(i), which in turn describes "a covered outpatient drug . . . which is approved for safety and effectiveness as a prescription drug under section 505 [21 U.S.C. 355] . . . of the Federal Food, Drug, and Cosmetic Act," 42 U.S.C. § 1396r–8(k)(2)(A)(i) (brackets in original), meaning that the drug was approved through an NDA, 21 U.S.C. § 355. The IRA thus defines a "qualifying single source drug" as a drug "approved for safety and effectiveness" through an NDA under the FDCA.

The government resists this plain reading, contending that "a new NDA alone does not suffice to establish" a new drug. Gov't Br. 19 (citing *Ipsen Biopharmaceuticals, Inc. v. Azar*, No. 1:16-cv-02372, 2020 WL 3402344, at *10 (D.D.C. June 19, 2020)). But *Ipsen* actually reinforces the NDA-specific approach. In *Ipsen*, the manufacturer argued there was no basis to treat an original NDA differently from a supplemental NDA for purposes of calculating Medicaid rebates. The court disagreed: Different treatment was warranted based on the

statutory and regulatory "contrast between NDAs and sNDAs." *Ipsen*, 2020 WL 3402344, at *9. "Just as the name suggests, sNDAs are *supplements* to preexisting drug applications that FDA *has already approved*"; "a sNDA does not establish a unique '*drug* . . . approved for safety and effectiveness . . . under section 505,' because it merely adds to a preexisting drug." *Id.* (quoting 42 U.S.C. § 1396r–8(k)(2)). Therefore, "a new drug for Medicaid rebate purposes is defined by the FDA's approval of a new drug application under section 505 of the FDCA," not a supplemental NDA. *Id.*

The government latches on (at 19) to a few sentences in *Ipsen* where the court speculated that "[m]inor changes approved via NDA" might not "establish" a new drug "under certain circumstances." 2020 WL 3402344, at *10 (citing CMS Sur-Reply at 3 n.1, *Ipsen Biopharmaceuticals, Inc. v. Azar*, No. 1:16-cv-02372 (D.D.C. Apr. 6, 2020), ECF No. 32). But that does not help the government. For one thing, the court expressed doubt as to whether "FDA regulations even permit such approvals." *Id.* And the court did not elaborate as to what these "circumstances" might be, beyond citing the government's brief, which in turn only cited *Mallinckrodt ARD LLC v. Verma*, 444 F. Supp. 3d 150 (D.D.C. 2020).

Mallinckrodt, too, reinforces the distinct-NDA approach. In *Mallinckrodt*, the manufacturer argued that a supplemental application for an additional indication that used a different NDA number from the original NDA should be treated as a distinct NDA. The court disagreed because FDA made clear that it was approving a supplement only: the second NDA number "will no longer be used"; "all submissions" should be directed "to the original NDA 008372"; and "FDA approved the drug for marketing pursuant to [the original] NDA number 008372, not [the second] defunct NDA number." *Id.* at 161, 179; *see also Mallinckrodt ARD LLC v. Verma*, No. 1:19-cv-01471, 2020 WL 7265325, at *2 (D.D.C. May 29, 2020) ("[N]o

distinct 'drug' was 'approved by' the FDA under defunct provisional NDA number 022432; rather, NDA number 022432 served solely as a ministerial (and temporary) mechanism for the FDA to facilitate another division reviewing what Mallinckrodt does not dispute was, in fact, 'a supplement to the existing NDA'—i.e., NDA number 008372."). *Mallinckrodt* thus underscores FDA's ability to properly classify an application as a supplement rather than a distinct NDA when circumstances so warrant. And therefore neither *Ipsen* nor *Mallinckrodt* undermine the NDA-specific approach the IRA adopted. To the contrary: The IRA's NDA-specific approach is entirely consistent with CMS's usual practice. *See Ipsen*, 2020 WL 3402344, at *10 n.4 (noting "CMS's practice of treating NDA approval as determinative"); 42 C.F.R. § 447.502 (CMS regulation providing that the term "[s]ingle source drug means a covered outpatient drug, . . . which is produced or distributed under a new drug application approved by the FDA").

The government also relies on a Congressional Budget Office (CBO) letter sent nine months *after* CMS first announced that it would (re)define a "qualifying single source drug" to be "all dosage forms and strengths of the drug with the same active moiety and the same holder of a [NDA], inclusive of products that are marketed pursuant to different NDAs."[8] But the CBO letter only "incorporate[d] the expectation that CMS will negotiate drug prices on the basis of a drug's active ingredient" because, "in practice, that is how CMS has approached negotiations thus far." CBO, Letter to Congress, at 3 (Dec. 21, 2023), https://perma.cc/9A9B-6SM6. It did not say anything about "Congress's intent," *contra* Gov't Br. 22 n.8, nor could it. *Cf. Brusewitz v. Wyeth LLC*, 562 U.S. 223, 242 (2011) ("Post-enactment legislative history (a contradiction in terms) is not a legitimate tool of statutory interpretation.").

[8] CMS, *Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191–1198 of the Social Security Act for IPAY 2026*, at 8 (Mar. 15, 2023), https://perma.cc/9CSY-LWGZ.

4. The government's various policy arguments fare no better. The government says that Teva's straightforward NDA-specific interpretation is "striking" because it means "CMS must treat each drug product" approved under a distinct NDA or BLA "as a separate drug." Gov't Br. 20. But that is the statute that Congress wrote. And, in any event, CMS's "same entity" qualification would require the same result if different companies held the NDAs. So, although the government scoffs that the IRA would possibly treat the capsule form of Xtandi "as distinct from the tablet form of Xtandi," even though they were approved under different NDAs, *id.*, CMS's Guidance would *also* have treated the Xtandi capsule and Xtandi tablet as separate drugs if the NDA holders were different. Astellas—the holder of the NDAs for both the Xtandi capsule and Xtandi tablet—could have therefore theoretically escaped CMS's forced aggregation and selection if Astellas had transferred ownership of one NDA to a subsidiary or another entity. Indeed, the government took the position in a different company's challenge to the Program that, "[u]nder settled principles of the corporate form," a parent company is not the same "entity" for IRA purposes as a "subsidiary" that "holds th[e] drug's NDA." Gov't Mot. Summ. J. at 1, *Merck & Co., Inc. v. Becerra*, No. 1:23-cv-01615 (D.D.C. Sept. 11, 2023), ECF No. 24-1.

The government next complains that accepting the IRA's NDA-specific approach would facilitate gamesmanship by prompting manufacturers to file new NDAs making only "slight[ ]" changes in an effort to avoid selection. Gov't Br. 19. That ignores the significant costs associated with developing "[n]ew indications and new easier-to-administer products" and the "countless real-life examples" in which such new NDAs have had tangible, life-saving benefits for patients. Manufacturers' Amicus Br. 15-20.

Besides, the government has the authority to prevent such hypothetical manipulation: FDA can always refuse to accept or could reclassify an NDA that it believes should have been

filed as a supplement. *See supra* pp. 24-25.[9] Indeed, FDA commonly directs that certain changes, although technically filed under a new NDA number, should be considered as made to the original NDA. For example, FDA originally approved AUSTEDO as indicated for Huntington's disease chorea. Faulkingham Decl. ¶ 10. Several months later, FDA approved an indication for tardive dyskinesia under a different NDA number, while also specifying that FDA had "administratively closed this NDA" and that all subsequent "submissions should be addressed to the original NDA."[10] As a result, both indications for AUSTEDO are "marketed pursuant to [the original] approval," 42 U.S.C. § 1320f–1(e)(1)(A)—and AUSTEDO is therefore a single "qualifying single source drug." That stands in contrast to AUSTEDO XR, which was approved and marketed pursuant to a *distinct* NDA, Faulkingham Decl. ¶ 10, and is therefore a *distinct* qualifying single source drug. The government's policy reasons for distorting the statutory standard are thus wrong on their own terms—and cannot overcome the text anyway.

III. CMS's Subjective, Atextual "Bona Fide Marketing" Standard Is Unlawful.

Congress created a straightforward test in the IRA to assess whether a drug subject to generic competition is ineligible for selection: Has a competitive generic drug been "approved and marketed"? If yes, the reference listed drug—the innovator product upon which generic competitors' FDA approvals are based—is ineligible for selection. 42 U.S.C. § 1320f–1(e)(1)(A)(iii). If the generic launches after the reference listed drug has been selected for

[9] *Cf.* FDA, *Guidance for Industry, Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees*, at 2 (Dec. 2004), https://www.fda.gov/media/72397/download (discussing factors FDA considers when "determining whether separate applications should be submitted").

[10] CDER, Letter from Mitchell V. Mathis (Aug. 30, 2017), https://perma.cc/43NC-L6C2; *see* Faulkingham Decl. ¶ 10.

negotiation, once the generic is "approved and marketed," that either cuts off the negotiation process or cuts short the time period to which the price control applies. *Id.* § 1320f–1(c)(1)(B).

CMS has attempted to override the IRA's mandate through its Guidance. Under the agency's rewritten version of the statute, the generic manufacturer must now prove that its marketing is somehow "bona fide," as determined in CMS's sole discretion, even though the IRA does not use that qualifier. The end result is that innovator drugs may be subject to the double-whammy of generic competition *and* price controls, and generic drugs will be unable to compete with price-controlled branded drugs during their prime launch periods—largely based on CMS's unknowable whims. That is not the statutory scheme Congress enacted.

1. The government opens by noting that "marketed" "suggests the actual availability of a product for sale." Gov't Br. 23-24. True. As Teva already explained, to "market" means to expose for sale. Teva Br. 29 (explaining at least one unit must be sold to qualify).

But the government veers off course when it argues that "available for sale" necessarily entails a "bona fide," "totality of the circumstances" test. Gov't Br. 22; *see* 2027 Guidance at 278. Indeed, the government implicitly concedes as much when it says the plain meaning of marketed "does not *foreclose* CMS from" attaching a bona fide requirement. Gov't Br. 24 (emphasis added). But the question is not whether CMS's reading is *foreclosed*—language that sounds in the now-defunct *Chevron* two-step. *See, e.g.*, *Sorenson Commc'ns, LLC v. FCC*, 897 F.3d 214, 223-224 (D.C. Cir. 2018) (under *Chevron*, courts asked whether Congress "unambiguously foreclosed the agency's statutory interpretation") (quotation marks omitted). The question is whether Congress spoke clearly when it used the term "marketing" without any qualifier: It did. But even if the statute were ambiguous, following *Loper Bright*, the court asks

whether, "after applying all relevant interpretive tools," CMS's interpretation is the "single, best meaning." 603 U.S. at 400. It is not.

2. The government tries to evade the Supreme Court's command that "courts, not agencies," interpret statutes, *id.* at 392, by arguing that Congress vested CMS with freewheeling discretion through the word "determine," Gov't Br. 24. As the government sees it, because CMS must "determine" whether a generic competitor "is marketed," CMS "must exercise at least some judgment in applying this standard," *id.*, including, apparently, the right to continually perform a "holistic inquiry" based on assorted data from various sources, 2027 Guidance at 278.

That argument conflates two separate provisions. In section 1320f–1(e), Congress defined "qualifying single source drug" as a drug that "is not the listed drug for any" generic or biosimilar "that is approved and marketed." 42 U.S.C. § 1320f–1(e)(1)(A)(iii), (B)(iii). But that provision does not authorize the Secretary to "determine" anything. The language the government invokes is in section 1320f–1(c), which commands that a selected drug "shall" remain selected until "the first year that begins at least 9 months after the date on which the Secretary determines at least one" generic "is approved or licensed" and "is marketed pursuant to such approval or license." 42 U.S.C. § 1320f–1(c)(1). If "determine" is dispositive, as the government suggests, CMS should have treated these provisions differently. Yet CMS redefined *both* uses of "marketed" through its Guidance. *See* 2027 Guidance at 170, 278-279.

In any case, "determine" is too slender a reed to bear the weight the government requires. As explained, *supra* pp. 8-9, the word ordinarily means to ascertain or establish something. The question under the IRA is "*determine what*?" *See Whitman v. American Trucking Ass'n*, 531 U.S. 457, 475 (2001) ("the degree of agency discretion that is acceptable varies according to the scope of the power congressionally conferred"). Where the statute requires the Secretary to

"determine" whether a generic "is marketed," the Secretary's determination power is limited to investigating whether the generic is in fact on the market—period.

Contrast that with *Transitional Hospitals Corp. of Louisiana v. Shalala*, 222 F.3d 1019 (D.C. Cir. 2000), which the government cites for the proposition that "determine" is an "express delegation of authority." Gov't Br. 24. The statute there excluded from the definition of a specific type of hospital any "hospital which has an average inpatient length of stay (as determined by the Secretary) of greater than 25 days." 42 U.S.C. § 1395ww(d)(1)(B)(iv). That phrase was inherently ambiguous: "[A]n average is a criterion that can only be assessed over a period of time," and "average 'of' 25 days" "necessarily indicate[s] that the period of measurement must be more than 25 days in order reasonably to determine whether the 'average' during that period was at least 25 days." *Transitional Hosps. Corp.*, 222 F.3d at 1026. Congress therefore specifically delegated the Secretary the power to resolve over what period the averaging should take place. *Id.* at 1025-26; *see, e.g.*, *San Bernardino Mountains Cmty. Hosp. Dist. v. Secretary of HHS*, 63 F.3d 882, 885-887 (9th Cir. 1995) (finding Congress delegated authority to the Secretary under a statute defining a sole community hospital as "[a] hospital that, by reason of factors such as isolated location, weather conditions, travel conditions, or absence of other hospitals (as determined by the Secretary), is the sole source of [certain] patient hospital services") (quotation marks omitted). The same cannot be said of the IRA here; "marketed" is a binary yes-or-no fact of the marketplace. *See* Teva Br. 29, 32 (explaining the plain meaning of "marketed").

Tellingly, Congress vested the Secretary with far more discretion with respect to certain biosimilars. 42 U.S.C. § 1320f–1(f)(1)(A). The IRA contains a special carve-out that allows CMS to delay the selection of specific biologics upon a biosimilar manufacturer's request, "[i]f

the Secretary determines that there is a high likelihood" the biosimilar "will be licensed and marketed" before a set date. *Id.* A "high likelihood" exists "if the Secretary finds . . . clear and convincing evidence that" the biosimilar will "be marketed" within the time period. *Id.* § 1320f–1(f)(3)(B). The statute puts the onus on the biosimilar manufacturer to provide "information and documents" to support the request, though the Secretary may also request and review any "additional information and documents" to assist in making that determination. *Id.* § 1320f–1(f)(1)(B)(ii)(I)(aa), (II). According to CMS's Guidance, the biosimilar's submissions must demonstrate "that patents related to the Reference Drug are unlikely to prevent the Biosimilar from being marketed" within the next year and "that the Biosimilar Manufacturer will be operationally ready to market the Biosimilar" in that timeframe. 2027 Guidance at 185. That language necessarily calls on CMS to use its judgment in deciding what evidence to consider, how to weigh it, and what evidence is sufficient to support a conclusion that a biosimilar is highly likely to come onto the market in a certain window.

But Congress did *not* confer on the Secretary similar discretion over the distinct inquiry into whether a generic is marketed. It did not authorize the Secretary to request and review whatever data he sees fit. It did not entrust the Secretary to assess the likelihood that the generic's marketing is "meaningful" or "genuine." Gov't Br. 23, 24. It did not attach a clear-and-convincing standard to the inquiry. Those different words show that Congress intended different meanings. *See, e.g.*, *Southwest Airlines Co. v. Saxon*, 596 U.S. 450, 457 (2022).

The government also highlights Congress's choices in the Inflation Rebate Program, but that argument backfires. *See* Gov't Br. 24-25. The provision in question states that a generic drug is eligible for certain rebates if no equivalent drug—innovator or generic—is "being marketed, as identified in the [FDA]'s National Drug Code Directory." 42 U.S.C. § 1395w–

114b(g)(1)(C)(ii). According to the government, this proves that Congress knew how to use a "yes-or-no inquiry" to determine whether a generic "is marketed" under the Program. Gov't Br. 25. But manufacturers self-update that directory only twice per year; FDA merely does its best to verify the information on the backend.[11] As a result, the marketing "start date" for drugs may well be incorrect. In fact, FDA expressly permits manufacturers to "list a drug before it is marketed, while providing a future start marketing date." 81 Fed. Reg. 60,170, 60,193 (Aug. 31, 2016). But estimates are just that. If the supply chain is disrupted, or if the generic manufacturer provides an anticipated start-marketing date for its product but then finds itself enjoined from marketing that product, meeting the anticipated start-marketing date could prove impossible. Even FDA has acknowledged that its database is plagued with inaccuracies. *See, e.g.*, 84 Fed. Reg. 40,417, 40,417 (Aug. 19, 2019). So although the Directory might be sufficient to prove the *absence* of marketing when manufacturers self-report as much, it is not surprising that Congress deemed the Directory unsuitable to determine whether a generic "is marketed."

3. With respect to the timing question, the government argues that the present tense "is marketed" permits CMS to constantly reevaluate whether the generic has "a continuing presence on the market." Gov't Br. 25. That, too, ignores the text. The full phrase is "is approved and marketed." A generic that has received FDA approval "is approved"; similarly, a generic that enters the market "is marketed." The present-tense language does not change the point-at-time inquiry. If Congress wanted CMS to continuously monitor or even periodically reconsider whether the generic's marketing was "meaningful," *see id.* at 27, it could have said so. Or it could have required that the drug "continue[ ] to be marketed," as it did elsewhere in the IRA. 26

[11] FDA, *National Drug Code Database Background Information* (updated Mar. 20, 2017), https://tinyurl.com/kknpbafc.

U.S.C. § 223(c)(2)(G)(ii)(II). Again, Congress did not, and CMS is required to follow the words Congress chose.

Subsection (c)—the deselection provision—confirms as much. A previously selected drug "shall" remain selected until "the first year that begins at least 9 months after the date on which the Secretary determines at least one" generic "is marketed." 42 U.S.C. § 1320f–1(c)(1). In other words, once CMS determines a generic "is approved and marketed," the selected drug must be deselected for the coming initial price applicability year that is at least nine months away. *See* Teva Br. 32, 34 (explaining timing). The statute does not instruct CMS to assess this issue at multiple points, assess it over a period of time, or to revisit the determination once it has been made, which would constantly bring a drug in and out of the shadow of the IRA's price controls.

Even under the government's reading, a requirement that a generic be marketed at all times still would not require any particular *level* of marketing. And nothing in the IRA permits CMS to reconsider its prior determination that a generic is marketed *after* the innovator drug has been deselected in order to *reselect* that drug and "reimpose price mandates if it decides that generic competition slips below some ill-defined threshold." Ass'n for Accessible Medicines Amicus Br. 13. Teva made this very point in its opening brief, *see* Teva Br. 35, but the government simply ignores it.

Finally, the government suggests in a pair of parentheticals that Congress legislates against the background presumption of *de minimis non curat lex*, Gov't Br. 26, meaning "the law cares not for trifles," *Wisconsin Dep't of Revenue v. William Wrigley, Jr., Co.*, 505 U.S. 214, 231 (1992). But like its cousin, the absurdity canon, this principle does not authorize courts "to depart from the statute." *Alabama Power Co. v. Costle*, 636 F.2d 323, 360 (D.C. Cir. 1979); *see*

Bostock v. Clayton Cnty., 590 U.S. 644, 789 n.4 (2020) ("The absurdity canon . . . is an implementation of (rather than an exception to) the ordinary meaning rule.") (quotation marks and ellipses omitted). "Marketed" means "marketed," even if the standard is not as robust as CMS might like.

4. The government maintains that its bona fide standard is not amorphous or vague, Gov't Br. 28, but its defense is self-defeating. Even in objecting that "bona fide" is *not* standardless, CMS still cannot articulate a coherent standard because the term is inherently subjective. The government doubles down on its promise to consider "the totality of the circumstances," without specifying the full universe of data inputs, to determine "whether there is a regular and consistent volume of sales" that shows "meaningful competition," without defining those terms. Gov't Br. 28; *see* 2027 Guidance at 20. Imagine a generic manufacturer has a banner first month, but then sales drop to a trickle because of insurmountable supply-chain issues. The data might suggest this is all a "sham," even though the manufacturer is working diligently to market its product to the best of its ability. Or imagine that one month after the generic launches, a new, competing innovator comes to market and immediately captures a significant market share. Does that sudden drop-off mean the manufacturer's marketing is no longer bona fide? Or what if the manufacturer's sales are cyclical—say, a prescription allergy medication, where sales spike during pollen season and plummet during winter. Is the lack of a "regular and consistent volume of sales" fatal to the "bona fide marketing" analysis?

Under the IRA, the answer to each hypothetical would be easy: The generic "is marketed." The government may well protest that of course the answer would be the same under its "bona fide marketing" test. But nothing in the statute or CMS's Guidance tells manufacturers how CMS will approach these or myriad other situations. And if the generic manufacturer

objects to CMS's conclusion on its particular product, CMS will surely take the position that section 1320f–7 bars any "administrative or judicial review" of the agency's "bona fide marketing" assessment.

The government's response to potential data delays likewise misses the point. The government concedes that PDE data are time-lagged, but argues that delay is "relatively short" and largely irrelevant because AMP data are reported "on a monthly basis." Gov't Br. 29 n.12. Yet the government freely admits that it will have *no data*—either AMP or PDE—for generics launched in March, making it impossible for those generics to be "bona fide marketed" under CMS's standard by the March 31 cutoff date. As Teva explained, one of its generics is set to launch just two weeks before the deselection cut-off date, and another is set to launch on the cutoff date itself—dates set by patent dispute settlements years prior to the enactment or administration of the IRA. Teva Br. 34; *see* Groff Decl. ¶¶ 24(d), 25(d). Teva thus cannot rely on AMP or PDE data to prove "bona fide marketing" for those products. *See also* Ass'n for Accessible Medicines Amicus Br. 15-16 (detailing other issues with PDE and AMP data).

The government retorts that Teva is free to rely on its own data and suggests that any inability to show "bona fide marketing" will be because Teva cannot collect supporting data. *See* Gov't Br. 29. That just proves Teva's point: CMS's 2027 Guidance does not tell Teva how to show more than a "token or *de minimis*" amount of marketing. *Id.* at 30 (quoting 2027 Guidance at 20). CMS has made clear that one "sham" sale is not enough. *Id.* at 24. What about two sales? Or three? And does the answer change if the product has only been on the market for two weeks, as will be the case for Teva's generic form of XARELTO, or for less than a full day, as will be true for Teva's generic form of LINZESS? *See* Groff Decl. ¶¶ 24(d), 25(d). Where the statute provides clear specifics, the government again offers only murky generalities.

5. Unable to prevail on the statutory text, the government resorts to invented policy. The government accuses Teva of asking the Court to bless "sham transaction[s]" and "bad faith marketing." Gov't Br. 24, 27. Nothing could be further from the truth. Teva is one of the world's largest generics manufacturers. Teva has invested significant amounts in developing thousands of generics to date—1 in 14 prescriptions in the U.S. is a Teva generic.[12] Teva has poured additional resources into developing generic competitors for several other innovator drugs, which it intends to launch in the coming years as patents expire, are invalidated, or are withdrawn. *See* Groff Decl. ¶¶ 4-5, 21-32. And Teva intends to market those generics to the maximum extent possible, as permitted by law. But Teva's ability to recoup its investments in pursuing and launching generic products depends on its ability to "compete with branded drugs on price" in a meaningful way, particularly during the critical post-launch months. *Id.* ¶¶ 7-9. CMS's Guidance makes clear that its amorphous "bona fide" standard will operate to Teva's detriment, forcing Teva's generic drugs to compete with price-controlled innovator drugs for months or years longer than the IRA requires.

The government accuses Teva of crying wolf because "requiring more than mere token or *de minimis* marketing" would not "seriously" alter generics manufacturers' incentives. Gov't Br. 30. But—again—the problem is that CMS has arrogated to itself the supposedly unreviewable power to judge the legitimacy and quality of a generic's marketing on a case-by-case basis, using an unknowable, made-up, subjective standard based on data that by definition cannot capture marketing of generic drugs launched close to the March 31 cutoff date. And the government's repeated protests that "[t]oken or *de minimis* marketing is not merely a theoretical worry," *e.g.*,

[12] *See* Teva, Product Search, https://tinyurl.com/mvtw5b66 (last visited May 19, 2025); Steven Scheer, *Teva Pharm CEO Calls on Trump for Faster US Drug Approvals*, Reuters (Feb. 17, 2025), https://tinyurl.com/3usp7kvx.

id., just prove Teva's main point: If "[t]oken or *de minimis* marketing" was as widespread as the government proclaims such that Congress clearly intended or "contemplated that a generic or biosimilar would have a continuing presence on the market," *id.* at 26, 30, Congress could have said so in the IRA. It did not, and the Court is duty-bound to respect those limits.

IV. The Program Violates The Due Process Clause.

The Program empowers a self-interested agency to unilaterally impose price controls on Teva's products with no meaningful opportunity to be heard in advance and no way to seek review of its product-specific decisions after the fact. The government understandably does not argue that the Program contains "appropriate procedural safeguards." *Cleveland Bd. of Educ. v. Loudermill*, 470 U.S. 532, 541 (1985). It instead denies that the Due Process Clause is implicated at all, contending that Teva chooses to participate in the Program and that its property interests are not impaired when CMS slashes Teva's prices and diminishes the value of Teva's patents, licenses, and patent dispute settlement agreements. The government is mistaken at every turn and fails even to address the impact these price controls have on Teva's generic products.

A. The Program Deprives Teva Of Protected Property Interests.

The government takes a head-in-the-sand approach, denying that the Program diminishes any of Teva's property interests. That position is unsupportable.

1. Because of its unique industry position as a manufacturer of both innovator and generic products, Teva feels a broader swath of harms as a result of CMS's actions than many other manufacturers. Yet the government ignores Teva's unique property interests as a generics manufacturer in its licenses and settlement agreements with innovators, and instead recycles arguments from briefing in cases involving only innovator manufacturers.

When Teva applies to market a generic drug, it must certify that its marketing will not infringe a valid patent covering the referenced innovator drug. 21 U.S.C. § 355(j)(2)(A)(vii)-

(viii). Those certifications often trigger patent litigation. *See* 35 U.S.C. § 271(e)(2)(A). And litigating those patent-infringement cases "can run over $10 million" per case. Groff Decl. ¶ 5. To avoid those costs and the inherent business uncertainty caused by litigation, innovators and generics often reach patent-dispute settlements, including licenses, that allow the generic to launch its product before expiration of the patents ostensibly protecting the innovator drug. For a generics manufacturer like Teva, those licenses' value depends on the price and market share its products can achieve upon launch. *See id.* ¶¶ 8-11. Teva thus invests significant resources into forecasting generic market conditions before accepting a license that allows it to launch on a particular date. *Id.* ¶ 12. And if the price or market share Teva can reasonably expect its generic to achieve declines, the value of its license drops as well. *Id.* ¶ 30.

That is exactly the harm the Program inflicts on Teva. Prior to the IRA's enactment, Teva negotiated license agreements to sell generic versions of at least five products on which CMS has now imposed or will impose an IRA price cap. *Id.* ¶¶ 22(d)-(e), 24(d)-(e), 25(d)-(e), 26(d)-(e), 27(d)-(e). Those price caps will force Teva to charge significantly less for its planned generic versions in order to have any hope of attaining material market share. *Id.* ¶ 18. As a result, Teva's property interests in its license agreements will be degraded as soon as CMS's price caps go into effect. *Id.* ¶ 30. These contractual rights "fully vested upon the completion of the transaction[s]" with the innovator manufacturers, and so "the Federal Government cannot evade the due process protections" that Teva must receive. *Ralls Corp. v. Committee on Foreign Inv. in U.S.*, 758 F.3d 296, 316 (D.C. Cir. 2014). The government has no answer for this unconstitutional property deprivation.

2. The Program will likewise devalue Teva's patents on AUSTEDO and AUSTEDO XR. Teva Br. 40. The government denies that this effect counts as a deprivation because patents do

not entitle a patentee to receive any particular price. Gov't Br. 33; *see AstraZeneca Pharms. LP v. Secretary of HHS*, No. 24-1819, __ F.4th __, 2025 WL 1338088, at *6-7 (3d Cir. May 8, 2025) (rejecting manufacturer's due process argument on same ground). That misses the point: Teva is not arguing that patents provide a *categorical* right to charge a particular price. A patent's value comes from the exclusivity period during which the patent holder has unique price-setting leverage. If the government restrains those prices during that protected period, the patent is worth less—a deprivation that must be supported by due process. *AstraZeneca* does not compel a different result.

Courts have repeatedly confirmed this understanding. States are not permitted to fix the price of patented products precisely because doing so interferes with the exclusivity patents confer. *E.g.*, *Pharmaceutical Rsch. & Mfrs. of Am. v. District of Columbia*, 406 F. Supp. 2d 56, 66-67 (D.D.C. 2005), *aff'd sub nom. Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1371-74 (Fed. Cir. 2007); *Delano Farms Co. v. California Table Grape Comm'n*, No. 1:07-cv-01610, 2010 WL 2952358, at *26 (E.D. Cal. July 26, 2010). When a patentholder is forced to "lower its prices," the system's "tradeoffs between exclusivity and access" are re-wired to the patentholder's detriment. *Southeastern Pa. Transp. Auth. v. Gilead Scis., Inc.*, 102 F. Supp. 3d 688, 703 (E.D. Pa. 2015). Price regulation, in other words, "diminish[es] the reward to patentees" that patents otherwise provide. *Biotechnology Indus. Org.*, 496 F.3d at 1374.

Unlike the States, the federal government is not outright forbidden from interfering with patent protections. *See Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 152 (1989). But that does not make it any less of a deprivation when the government does so. Patents are " 'property' of which no person may be deprived . . . without due process of law." *Florida Prepaid Postsecondary Educ. Expense Bd. v. College Sav. Bank*, 527 U.S. 627, 642

(1999). Reductions in the market value or utility of property are therefore "sufficient to merit due process protection"—there is no requirement that a deprivation be "complete, physical, or permanent." *Connecticut v. Doehr*, 501 U.S. 1, 12 (1991). Teva's patents for AUSTEDO and AUSTEDO XR will be worth less the moment CMS imposes a price cap on those products, and the severity of that injury increases with the size of the discount CMS ultimately imposes. For that reason, Teva is entitled to procedural protections against "substantively unfair and simply mistaken" price caps. *Fuentes v. Shevin*, 407 U.S. 67, 81 (1972).

The government asks the Court to ignore all of this on the theory that, "[i]n negotiating the price that Medicare will pay for drugs, the government is acting" just like any other "market participant" that buys drugs. Gov't Br. 33-34. But the government has intentionally constructed the Medicare market so that it is *not* an ordinary "buyer" of drugs. *Cf. id.* at 33. The government is a buyer of insurance—and a buyer-once-removed at that. Insurers bid to sponsor Medicare Part D plans, 42 U.S.C. § 1395w–111(b); CMS selects eligible plans based on the strengths of their bids, *id.* § 1395w–111(d)-(e); and drug manufacturers must offer discounts to selected plans, *e.g.*, *id.* § 1395w–114c. The government subsidizes Part D plans based on the average bid, with a "reinsurance" payment on the back end to protect against significant cost overruns, but the private plans "bear insurance risk" and are the primary payors. Medicare Payment Advisory Comm'n, *Report to the Congress: Medicare and the Health Care Delivery System* 119-120 (June 2020), https://tinyurl.com/3u2ry825. CMS does not buy anything from drug manufacturers, it never takes title of drugs, and it never pays drug manufacturers a dime—insurance plans do. And CMS might not even reimburse the insurance plans for the full price they paid for those drugs.

The government's analogy to its dealings with defense contractors is accordingly inapposite. Gov't Br. 34. In defense contracting, the government *is* a direct purchaser, which is why it sets rules within the Defense Federal Acquisition Regulation Supplement, rather than by using generally applicable legislative and regulatory power. *See generally* 48 C.F.R. § 201.101 *et seq*. With respect to Medicare and the Program, the government is instead acting as a *regulator* with respect to drug manufacturers by limiting what they can charge Part D plans.

3. Finally, the Program implicates Teva's protected expectation in receiving the market rates that have long prevailed in Medicare Part D transactions. The parties' "course of dealing" "conduct," and "practice" over a long period can create a property interest protected by the Due Process Clause. *Ezekwo v. New York City Health & Hosps. Corp.*, 940 F.2d 775, 782 (2d Cir. 1991) (citing *Perry v. Sindermann*, 408 U.S. 593, 601-602 (1972)). That is true of manufacturers' right to receive market prices for drugs purchased by Medicare Part D plans, but Teva need not rely solely on that practice here. The right to be free from government interference with Medicare Part D prices is codified in federal law. 42 U.S.C. § 1395w–111(i). And where government "establishe[s]" a rate "under the law"—in this case, the market rate—it creates "a legitimate claim of entitlement to reimbursement at [that] rate." *Rock River Health Care, LLC v. Eagleson*, 14 F.4th 768, 774 (7th Cir. 2021).

The government's attempt to distinguish *Rock River* falls flat. It points out that the case involved a "statutory formula," while the Program supposedly establishes only "procedures for determining the amount the government will pay." Gov't Br. 32. But it is wrong to suggest that the IRA lacks any price-setting content. For one thing, the maximum fair price is capped by a statutory ceiling. 42 U.S.C. § 1320f–3(c)(1). And CMS's "procedures" have a substantive objective: to "achieve the lowest maximum fair price for each selected drug." *Id.* § 1320f–

3(b)(1). What matters is that CMS's decisions about how to implement the Program can ultimately affect whether Teva gets the market rates generally established for covered Part D drugs or a much lower rate of CMS's choosing. "[C]ontrolling Medicare law generally entitles" Teva to the former, and that is enough to require sound procedures before Teva is subjected to the latter. *Furlong v. Shalala*, 156 F.3d 384, 395-396 (2d Cir. 1998) (emphasis omitted).

The government overlooks the significance of CMS's vast discretion when it points out that the IRA amended Medicare Part D's noninterference provision. Gov't Br. 31-32. No doubt, Congress could have done away with that protection, but that is not what it did. The IRA created an exception to the general rule that CMS "may not institute a price structure," which applies only to "qualifying single source drugs." 42 U.S.C. § 1395w–111(i)(3); *see also id.* § 1320f–1(d)(1), (e). And who decides whether a product is a qualifying single source drug and therefore subject to this exception? CMS does, using an ersatz definition it created—not the one Congress wrote—and an opaque and unreviewable decisional process for applying it. Put differently, Teva's right to charge a market price is a contingent right, but that is exactly the point: "An interest that gives rise to an entitlement is always a conditional interest, because if the plaintiff possessed an absolute right there would be no need for a hearing as there would be no issue to resolve." *Rock River*, 14 F.4th at 774 (quotation marks omitted).

The government similarly attacks a straw man with its criticism of *Old Dearborn Distributing Co. v. Seagram-Distillers Corp.*, 299 U.S. 183 (1936). Gov't Br. 32 n.13. Teva is not challenging "a legislature's ability to fix the price of goods." *Id.* Teva is challenging the *process*—or the lack thereof—by which a federal agency determines that a legislative price-fixing scheme applies to particular products and the prices their owners can charge. *Old Dearborn*'s significance is its recognition of the stakes of that agency action: The seller loses

"an inherent attribute of the property itself." 299 U.S. at 192. That principle has not been overruled; the Supreme Court still recognizes that the right to decide the terms on which one will dispose of property is "one of the most treasured rights of property ownership." *Cedar Point Nursery v. Hassid,* 594 U.S. 139, 149 (2021) (quotation marks omitted). But the upshot of the government's position is that this "treasured" right is subject to confiscation by administrative fiat while the Due Process Clause stands idly by. That is not and should not be the law.

B. "Voluntariness" Is Irrelevant And Inapplicable.

The government insists that the Program does not deprive Teva of any property interest because the Program—and Medicare and Medicaid writ large—are "voluntary." Gov't Br. 35-37. That is legally irrelevant, and incorrect to boot.

1. The government never explains why "voluntariness" matters for the Due Process Clause, and it does not. The government seems to be responding to a Takings Clause argument Teva never made. In fact, the government cites several out-of-circuit voluntariness cases that it admits involved the Takings Clause, then blithely asserts that this distinction is immaterial. *See* Gov't Br. 35 & n.14. But "a legitimate claim of entitlement to a benefit that is sufficient to trigger due process protection does not transform the benefit itself into a vested property right protected by the Takings Clause." *Roth v. King*, 449 F.3d 1272, 1286 (D.C. Cir. 2006). The former can be created in diverse and flexible ways. *See Perry*, 408 U.S. at 601, 603 (for example, "policies," "practices," "rules," or "understandings"). The latter must be "vested"; property rights the government "retains the power to alter" do not count. *Democratic Cent. Comm. of D.C. v. WMATA*, 38 F.3d 603, 606 (D.C. Cir. 1994) (quotation marks omitted).

That distinction makes perfect sense. If the plaintiff voluntarily subjected her property to the government's power "in exchange for . . . economic advantages," it "can hardly be called a taking." *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1007 (1984). That analysis no longer

applies in the due-process context. Mere "assurances" over the course of a business relationship are enough to create a protected property interest; there is no requirement that that plaintiff's relationship with the government be coercive from the jump. *Esparraguera v. Department of the Army*, 101 F.4th 28, 33 (D.C. Cir. 2024) (quotation marks omitted).

Bowles v. Willingham, 321 U.S. 503 (1944), illustrates the distinction. Congress passed a wartime price-control act that gave a federal agency the power to cap rents. *Id.* at 505-506. The affected landlords chose to lease their property, so the Takings Clause did not apply. *Id.* at 517. But the Due Process Clause *did* apply; the Court proceeded to ask whether the statute's judicial-review "satisfie[d] the requirements of due process." *Id.* at 519-520. The Court even considered it "[o]bvious" that "Congress would have been under necessity to give notice and provide a hearing before it acted, had it decided to fix rents on a national basis." *Id.* at 519; *see Livingston Care Ctr., Inc. v. United States*, 934 F.2d 719 (6th Cir. 1991) (resting due-process holding on availability of judicial review). Takings principles and due-process principles are not fungible.

The government's contrary rule would flip due-process precedent on its head. No doubt, George Eldridge chose to apply for disability benefits. Yet when the Social Security Administration took away Eldridge's benefits once obtained, it still had to "provide all the process that is constitutionally due." *Mathews v. Eldridge*, 424 U.S. 319, 332-333 (1976). So too for the plaintiffs in *Goldberg v. Kelly*, 397 U.S. 254, 256 (1970), who applied for "financial aid" under publicly funded programs. The "[r]elevant constitutional restraints" still applied, even though the plaintiffs came to the state, and not the other way around. *See id.* at 262. Or take James Loudermill, who elected to work for a municipal school board instead of a private employer. *See Loudermill*, 470 U.S. at 535. Even so, he had a "property right in continued employment" that could not be eliminated "without due process." *Id.* at 538.

The government's argument would change the result in all of these cases. Nothing strictly "require[d]" these plaintiffs to interact with public institutions in these ways. *Contra* Gov't Br. 35. For that matter, due-process claims would *never* be viable in the employment context if the government had its way. Yet the D.C. Circuit has held the opposite many times. *E.g.*, *Esparraguera*, 101 F.4th at 281; *Thompson v. District of Columbia*, 530 F.3d 914, 920 (D.C. Cir. 2008); *Ashton v. Civiletti*, 613 F.2d 923, 930 (D.C. Cir. 1979).

That just leaves the government with two out-of-circuit IRA decisions. *AstraZeneca Pharms. LP v. Becerra*, 719 F. Supp. 3d 377, 395-397 (D. Del. 2024), *aff'd on other grounds*, No. 24-1819, __ F.4th __, 2025 WL 1338088 (3d. Cir. May 8, 2025); *Dayton Area Chamber of Com. v. Becerra*, 696 F. Supp. 3d 440, 457 (S.D. Ohio 2023), *on appeal*, No. 24-3868 (6th Cir.); *see also Bristol Myers Squibb Co. v. Becerra*, No. 3:23-cv-03335, 2024 WL 1855054, at *6-9 (D.N.J. Apr. 29, 2024) (addressing only a takings claim). But those out-of-circuit courts also failed to distinguish between takings and the procedural-due-process claims. For the reasons explained, those decisions cannot be squared with binding D.C. Circuit caselaw—or the weight of authority nationwide. *See, e.g.*, *Hignell-Stark v. City of New Orleans*, 46 F.4th 317, 323 (5th Cir. 2022) ("[T]here's a big difference between saying that something is property for purposes of procedural due process and saying that it is property for purposes of the Takings Clause.").

2. Even if voluntariness matters under the Due Process Clause, the Program—and participation in Medicare and Medicaid writ large—is anything but. The government doubles down on the fiction that the IRA's price-control regime involves an arms-length "negotiation" with CMS. That fails to grapple with the reality of what the IRA requires. CMS must use "a consistent methodology" that will always "achieve the *lowest* maximum fair price." 42 U.S.C. § 1320f–3(b)(1) (emphasis added). Once CMS makes its first demand, the manufacturer of the

selected drug gets one chance to respond, and it must support its requested price "based on" government-approved "factors." *Id.* § 1320f–3(b)(2)(C), (e). After that, CMS's only procedural requirement is to "respond in writing." *Id.* § 1320f–3(b)(2)(D). There is no reason CMS cannot simply repeat its initial demand, and once it responds, the process "shall end." *See id.* § 1320f–3(b)(2)(E). No commercial transaction would be so stilted.

The IRA's shock-and-awe penalty scheme further discredits the government's narrative. An innovator that refuses to accede to CMS's price demands is subject to a fast-escalating penalty that caps at *1900 percent* of total revenue. *See* 26 U.S.C. § 5000D(b). A sanction that severe has no place in a "voluntary" transaction; it amounts to a "gun to the head." *National Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 581 (2012) (opinion of Roberts, C.J.). If the choice between accepting this penalty and accepting CMS's price caps were truly voluntary, one might expect manufacturers to split over which path to take. But that is not what Congress expected when it projected the penalty to raise exactly $0—ever. Teva Br. 11. And that is not what has happened in practice, as the government acknowledges. *See* Gov't Br. 8.

In any event, the government again ignores Teva's unique place as both an innovator and a manufacturer of generic drugs. In its capacity as a generics manufacturer, Teva lacks even the illusory choice afforded to innovators: Teva has no role in deciding what happens to the innovator products against which its generics must compete, but price caps imposed on those products force down the prices that Teva can charge, too. Groff Decl. ¶¶ 28-29. To compete with an innovator drug, a generics manufacturer must be able to price its products substantially lower, but the generic cannot do that when the innovator drug is already artificially priced so low that the generic will be unable to recoup its investment. *Id.* ¶¶ 8-11. The Program thus harms

Teva even outside of its direct dealings with CMS, regardless of whether those dealings are inaccurately characterized as negotiations.

The government tries to dodge the IRA's obviously coercive elements by blithely suggesting that manufacturers can avoid the price-control-or-penalty choice by entirely withdrawing from Medicare and Medicaid. Gov't Br. 35-37. This, too, ignores the fact that Teva's generic-pricing behavior will be constrained by innovator competitors regardless of whether Teva itself participates in federal programs. More broadly, participation in Medicare and Medicaid is not genuinely voluntary because manufacturers cannot rationally abandon these programs or their patients. Teva Br. 9-11, 43-44.

3. For its final salvo, the government again contends that Teva is "free to negotiate pricing with any buyers in the marketplace, including the government." Gov't Br. 37. That argument collapses for the reasons already explained. *Supra* pp. 40-41.

But even if the government were simply setting the terms of its business transactions, it still would not follow that participation in Medicare and Medicaid is truly voluntary. The government is not just "any buyer" of drugs. *Contra* Gov't Br. 37. The outer bounds of a government's ability to act as a market participant have been fleshed out in cases addressing the restrictions imposed on States by the dormant Commerce Clause. In that context, courts recognize that a government is treated like a private party for constitutional purposes only if it acts as a private party would. *See, e.g.*, *South-Central Timber Dev., Inc. v. Wunnicke*, 467 U.S. 82, 97 & n.10 (1984) (plurality op.) (rejecting the argument that States are free to set any conditions they have "the economic power to impose"); *Asante v. Azar*, 656 F. Supp. 3d 185, 197 (D.D.C. 2023) (rejecting the argument that a state was acting like a "private insurer" because it was controlling federal funds) (quotation omitted), *aff'd sub nom. Asante v. Kennedy*, 133 F.4th

97 (D.C. Cir. 2025). So, for instance, a government is not acting as market participant if it "forces others to buy its services under the threat of criminal penalties." *Pharmaceutical Rsch. & Mfrs. of Am. v. Thompson*, 259 F. Supp. 2d 39, 80 (D.D.C. 2003), *aff'd* 362 F.3d 817 (D.C. Cir. 2004). And just as a mere market participant cannot criminally charge its counterparties, neither can it fine them into oblivion if they fail to bend the knee, as the government has tried to do here. 26 U.S.C. § 5000D(d).

Another way the government has exceeded a private buyer's role is by occupying so much space in the market that sellers cannot afford to do business with it. That is by design. "The federal government dominates the healthcare market" and "uses that market power to get drug makers to subsidize healthcare." *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 699 (3d Cir. 2023). As a result, withdrawing Teva's products from all federal programs "would cause Teva to lose an unsustainable amount of revenue and jeopardize Teva's future." Faulkingham Decl. ¶ 20. No private buyer has—or should have—that much power.

Nor is Teva just "any" seller. If it were to "choose not to sell [its] drugs to Medicare" as the government posits, Gov't Br. 35-36, Teva would have to terminate its participation in Medicaid, too. 26 U.S.C. § 5000D(c)(1); *see also* 42 U.S.C. § 1396r–8(a)(1). Medicare and Medicaid provide critical healthcare to some of the country's most vulnerable patients: the elderly and poor. Many of those patients would completely lose access to Teva's critical innovator products, such as AUSTEDO and AUSTEDO XR, an outcome Teva cannot accept. Faulkingham Decl. ¶ 20. Federal law recognizes the seriousness of that possibility by requiring Medicare Part D plans to cover at least two drugs per "therapeutic category and class." 42 U.S.C. § 1395w–104(b)(3)(C)(i). But without AUSTEDO and AUSTEDO XR, only one drug indicated for the treatment of tardive dyskinesia, INGREZZA, would remain covered. The

government, of course, does not actually want this public-health harm to occur. The supposed voluntariness of Medicare and Medicaid is just a momentarily convenient litigating position.

The D.C. Circuit recently rejected a similar gunboat-diplomacy theory of voluntariness, even in the takings context. When a book publisher contested a statutory requirement that it forfeit some of its products to the Copyright Office, the government argued the mandate was "part of a voluntary exchange" for "copyright protection" and could therefore be avoided by forgoing that protection. *Valancourt Books, LLC v. Garland*, 82 F.4th 1222, 1235 (D.C. Cir. 2023). The court disagreed, pointing out the lack of any "known and costless option" for making the trade. *Id.* "For an abandonment option to render" participation in a government program "a voluntary choice, the option would have to at least be cognizable to [property] owners." *Id.* Here, the supposed choice of exiting Medicare and Medicaid is not cognizable to pharmaceutical manufacturers—and certainly not "costless"—because it would destroy their businesses and impair public health. The Program is not just an onerous set of terms in a business proposal—it is a deprivation of Teva's property interests that it cannot avoid absent judicial relief.

* * *

The government does not even bother to argue that the IRA offers Teva constitutionally sufficient protections. Gov't Br. 30-31; *see, e.g.*, *Al-Tamimi v. Adelson*, 916 F.3d 1, 6 (D.C. Cir. 2019) ("A party forfeits an argument by failing to raise it in his opening brief."). For good reason: It does not. Teva Br. 42-45. For its generic products, Teva gets nothing; CMS deals only with innovators. The result is a competitive environment so unfavorable that Teva may not be able to launch its generic products at all. Groff Decl. ¶ 20. The situation is scarcely better for Teva's innovator drugs. CMS's selection methodology is almost completely opaque. During the "negotiation" process, Teva has no impartial adjudicator. There is no pre- or post-deprivation

hearing. And to top it off, the IRA's judicial-review bar stops Teva from seeking administrative or judicial review of CMS's key decisions as to specific products—something the government tries to exploit here to bar even Teva's challenge to CMS's Guidance.

The scope of CMS's attempted power grab is breathtaking. And the stakes for Teva and for the American healthcare system are too high to let the government stifle innovation and quash generic competition without recourse.

CONCLUSION

For the foregoing reasons and those in Teva's opening memorandum, Teva's motion for summary judgment should be granted and the government's cross-motion should be denied. CMS's reimagined definition of "qualifying single source drug" and creation of a "bona fide marketing" standard should be set aside, and the government should be enjoined from implementing the Program as to Teva.

Respectfully submitted,

/s/ Sean Marotta
Sean Marotta (D.C. Bar 1006494)
Danielle Desaulniers Stempel (D.C. Bar 1658137)
Dana A. Raphael (D.C. Bar 1741559)
Jacob T. Young (D.C. Bar 90014334)
HOGAN LOVELLS US LLP
555 Thirteenth Street N.W.
Washington, D.C. 20004
(202) 637-4881
sean.marotta@hoganlovells.com

Attorneys for Plaintiffs Teva Pharmaceuticals USA, Inc.; Teva Branded Pharmaceutical Products R&D LLC; and Teva Neuroscience, Inc.

May 19, 2025

CERTIFICATE OF SERVICE

I hereby certify that on May 19, 2025, I caused a true and correct copy of the foregoing to be filed with the Court electronically and served by the Court's CM/ECF System upon the listed counsel of record.

/s/ Sean Marotta
Sean Marotta