

[ORAL ARGUMENT HELD MAY 5, 2026]

No. 25-5425

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

TEVA PHARMACEUTICALS USA, INC., *et al.*,
Plaintiffs-Appellants,

v.

ROBERT F. KENNEDY, JR., *in his official capacity as Secretary of Health
and Human Services, et al.*,
Defendants-Appellees.

On Appeal from the United States District Court
for the District of Columbia

APPELLEES' PETITION FOR REHEARING EN BANC

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to D.C. Circuit Rule 28(a)(1), the undersigned counsel certifies as follows:

A. Parties and Amici

Plaintiffs-appellants are Teva Pharmaceuticals USA, Inc.; Teva Branded Pharmaceutical Products R&D, LLC; and Teva Neuroscience, Inc.

Defendants-appellees are Robert F. Kennedy, Jr., in his official capacity as Secretary of Health and Human Services; and Mehmet Oz, in his official capacity as Administrator of the Centers for Medicare & Medicaid Services.

The following amici appeared in the district court in support of plaintiffs: Association for Accessible Medicines; Bausch Health Companies Inc.; Eli Lilly and Company; Johnson & Johnson; Pfizer Inc.; Sanofi-Aventis U.S. LLC; and Biotechnology Innovation Organization.

The following amici appeared in the district court in support of defendants: Richard G. Frank; Fiona M. Scott Morton; Aaron S. Kesselheim; Gerard F. Anderson; Rena M. Conti; David M. Cutler; Jack Hoadley; Public Citizen; Doctors for America; Protect Our Care; and Families USA.

The following amici appeared in this Court in support of plaintiffs: Association for Accessible Medicines; Bausch Health Companies, Inc.;

Bristol Myers Squibb Company; Eli Lilly and Company; Johnson & Johnson; Sanofi-Aventis U.S. LLC; and Biotechnology Innovation Organization.

The following amici appeared in this Court in support of defendants:

Public Citizen; Doctors for America; Protect Our Care; Families USA; AARP; AARP Foundation; Center for Medicare Advocacy; Medicare Rights Center Inc.; Justice in Aging; and Patients for Affordable Drugs.

B. Rulings Under Review

Plaintiffs appealed from the memorandum opinion (Dkt. 46) and order (Dkt. 47) issued by the district court (Sooknanan, J.) on November 20, 2025. The memorandum opinion is not published but is available at 2025 WL 3240267. It is reproduced in the Joint Appendix (JA) at JA168-203.

Defendants seek en banc reconsideration of the decision of the panel (Henderson, Childs, Pan, JJ.) issued on August 18, 2026. The panel opinion is not yet published but is available at 2026 WL 2409591. It is reproduced in the Addendum (Add.) to this petition at Add.1-43.

C. Related Cases

This case has not previously been before this Court or any court other than the district court. Counsel for defendants-appellees are unaware of any related cases within the meaning of D.C. Circuit Rule 28(a)(1)(C).

/s/ Maxwell A. Baldi

Maxwell A. Baldi

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GLOSSARY

Add.	Addendum
CMS	Centers for Medicare & Medicaid Services
FDA	Food and Drug Administration
JA	Joint Appendix
QSSD	qualifying single source drug
TPS	temporary protected status

INTRODUCTION AND RULE 40(B)(2) STATEMENT

To address unsustainable price increases, Congress gave the Centers for Medicare & Medicaid Services (CMS) authority to negotiate the prices Medicare pays for certain prescription drugs. Each year CMS applies statutory criteria to select drugs for negotiation by determining the universe of potentially eligible “qualifying single source drugs” (QSSDs), ranking those drugs in order of Medicare spending, and then selecting the top drugs from that ranked list. Congress expressly precluded judicial review of CMS’s “determination of [QSSDs].” 42 U.S.C. § 1320f-7(2).¹

The panel nevertheless permitted plaintiffs to bring two contrary-to-law claims challenging CMS’s definition of QSSDs. In so holding, the panel created a direct split with the Third Circuit, which interpreted the same provision to bar an identical claim. *See Novo Nordisk Inc. v. HHS*, 154 F.4th 105, 111-13 (3d Cir. 2025), *cert. denied*, 146 S. Ct. 2656 (2026). On its own, that conflict between the two most important circuits for pharmaceutical litigation justifies en banc review.

The panel’s decision also conflicts with the Supreme Court’s recent decision in *Mullin v. Doe*, which rejected the notion that in barring judicial

¹ Unless otherwise specified, statutory citations are to Title 42.

review of an agency “determination,” Congress intends to leave open challenges to related practices and policies. 609 U.S. 324, 340-41 (2026). The panel adopted an unduly narrow reading of *Mullin* and held that plaintiffs may challenge CMS’s definition of QSSD—just not its ministerial selection of individual drugs. The panel also reasoned that plaintiffs’ challenges may proceed because they raise questions of statutory interpretation. That holding conflicts with decisions of the Supreme Court, this Court, and other circuits recognizing that Congress may preclude review of contrary-to-law claims.

These weighty questions are important on their own. In the context of this multibillion-dollar drug-discount scheme, they take on critical significance. The panel opened a path for manufacturers to challenge CMS’s statutory authority and, potentially, to halt the Negotiation Program in its tracks. A successful effort in the future to vacate any load-bearing Negotiation Program regulation could lead to immediate price hikes for seniors at pharmacy counters; some prices could leap by more than 550%. Congress expressly barred judicial review to prevent such chaos. Rehearing en banc is warranted to consider key issues related to this program.

STATEMENT OF THE ISSUES

1. Whether § 1320f-7(2) bars challenges to CMS's determination of what constitutes a QSSD and the resulting determination of which drugs are eligible and may be selected for negotiation.

2. Whether a provision barring judicial review of an agency's action precludes contrary-to-law claims.

STATEMENT OF THE CASE

1. Congress empowered CMS to negotiate the prices Medicare pays for certain prescription drugs. Add.2. Each year, CMS selects a fixed number of drugs for negotiation. Add.6-7. CMS first determines the universe of potentially eligible drugs—the QSSDs—by identifying all the Food and Drug Administration (FDA) approved prescription drugs covered by Medicare that are at least seven years old and for which there are no generic competitors and by excluding a few specific categories of drugs from that list. § 1320f-1(e)(1)(A), (3). Next, CMS goes through the ministerial process of ranking drugs by Medicare spending to determine which drugs are negotiation-eligible and which drugs are selected. § 1320f-1(a)(2), (d)(1); *see* Add.6-7. For negotiated prices taking effect in 2027, CMS selected 15 drugs. § 1320f-1(a)(2). Once a drug is selected, CMS and the manufacturer

negotiate; if they agree on a price, it must be made available for Medicare sales. Add.7-8. Negotiated prices generally remain in effect until after CMS determines that a generic competitor “is approved” and “marketed.” § 1320f-1(c)(1).

Starting in 2029, CMS will implement the program through notice-and-comment rulemaking. CMS anticipates finalizing its first rule for the Negotiation Program this autumn. *See* 91 Fed. Reg. 36236 (June 16, 2026) (proposed rule). But for the first three negotiation cycles, Congress instructed CMS to implement the program through guidance. Add.8-9. Two aspects of the guidance are relevant here. *First*, CMS explained that a QSSD includes “all dosage forms and strengths of the drug with the same active moiety [(ingredient)]” made by the same primary manufacturer. Add.9 (cleaned up). Accordingly, CMS aggregates some forms of drugs for purposes of the Negotiation Program even if they have separate FDA regulatory approvals. Add.9. *Second*, CMS explained that a drug is subject to generic competition when “‘the totality of the circumstances’ shows that the [generic] manufacturer ‘is engaging in bona fide marketing of that drug.’” Add.10. After a drug faces generic competition, it no longer meets the definition of a QSSD. § 1320f-1(e)(1)(A)(iii).

2. Plaintiffs manufacture prescription drugs including Austedo, a treatment for involuntary muscle movement, which is available in both regular- and extended-release formulations. Add.11. Each formulation contains the same active ingredient. Add.11. CMS selected as a drug for negotiation both formulations of Austedo. Add.11. Plaintiffs also manufacture generic drugs, including some approved to compete against other name-brand drugs already selected for negotiation. Add.11.

Plaintiffs allege that CMS acted contrary to law in defining a QSSD to aggregate formulations approved by FDA through separate applications and in promulgating the bona-fide-marketing standard and that the Negotiation Program violates due process. Add.11.

The district court granted summary judgment to the government. JA204. It permitted Teva's statutory challenges to proceed despite the judicial-review bar. JA179. It declined to reach plaintiffs' bona-fide-marketing claim because it concluded the claim was unripe. JA192-97. It upheld CMS's aggregation policy for defining QSSDs, JA186-92, and rejected plaintiffs' due process claim, JA197-203.

3. On appeal, the panel affirmed in part, reversed in part, and remanded. Add.43.

The panel held that the judicial-review bar did not bar plaintiffs' statutory challenges because the statute precludes only challenges to whether a particular drug is a QSSD and because plaintiffs' challenge turned on a question of statutory interpretation. *See* Add.15-26. The panel held that the statute precludes only challenges to individual determinations of whether a drug is a QSSD—"a single, discrete act rather than 'a group of decisions or a practice or procedure employed in making decisions.'" Add.18 (quoting *McNary v. Haitian Refugee Ctr., Inc.*, 498 U.S. 479, 492 (1991)). The panel also relied on that language from *McNary* to distinguish the Supreme Court's decision in *Mullin*, which held that Congress had barred judicial review of both a determination to revoke temporary protected status (TPS) and the procedural steps antecedent to that determination, 609 U.S. at 344-45. The panel distinguished *Mullin* because the TPS statute used broader language. Add.20-21.

The panel understood the relevant "determination" here to be "deciding whether a particular drug satisfies" the statutory definition for QSSD, and concluded that "[m]aking the required drug-specific 'determination' and interpreting the [Act] are distinct tasks." Add.19. The panel thus rejected the government's argument that determining whether a

drug is a QSSD means interpreting the statute and generating a list of drugs such that the determination and the interpretation are inextricably intertwined. Add.22-25. The panel reasoned that “an agency cannot make its statutory interpretation unreviewable simply by using it in an unreviewable determination.” Add.22. This holding also applies to CMS’s bona-fide-marketing standard. *See* Add.21.

On the merits, the panel upheld CMS’s aggregation rule for QSSDs. Add.26-31. It held ripe plaintiffs’ challenge to the bona-fide-marketing requirement and remanded to allow the district court to consider that claim in the first instance. Add.31-34. And it rejected plaintiffs’ due process claim. Add.34-43.

REASONS FOR GRANTING THE PETITION

I. Rehearing en banc is necessary to restore uniformity to preclusion-of-review doctrine.

While courts presume that agency action is reviewable, when Congress “provides that ‘there shall be no administrative or judicial review’ of specified agency actions, its intent to bar review is clear.” *DCH Reg’l Med. Ctr. v. Azar*, 925 F.3d 503, 505-06 (D.C. Cir. 2019) (citation omitted). The only question in those circumstances is “whether the challenged action falls ‘within the preclusive scope’ of the statute.” *Id.* at 506.

Plaintiffs assert that CMS misinterpreted two aspects of the QSSD definition: which products can be considered a single QSSD and which drugs can be excluded as QSSDs due to generic competition. JA132-34. CMS's guidance defines the parameters for QSSDs. Thus, for plaintiffs' challenge to proceed, either CMS's "determination of [QSSDs]" must exclude setting the parameters of the term or some exception to the judicial-review bar must apply. By embracing both rationales, the panel came into conflict with decisions of other circuits, this Court, and the Supreme Court.

A. The panel diverged from the Third Circuit's interpretation of § 1320f-7(2).

In *Novo Nordisk*, the Third Circuit resolved a parallel challenge to CMS's QSSD guidance, but, unlike the panel here, it held that the judicial-review bar categorically precluded such suits. *See* 154 F.4th at 111-13. In that case, a pharmaceutical manufacturer challenged "CMS's decision to group products into a single potentially qualifying drug." *Id.* at 111. The Third Circuit held that it lacked jurisdiction to consider the manufacturer's challenge to CMS's "definition of qualifying single-source drug" because the Act precluded judicial review of "determination of negotiation-eligible drugs" including the process CMS used to make that determination. *Id.* at 111-12.

The panel's decision creates a direct conflict with the Third Circuit on how to interpret the scope of § 1320f-7(2) because a manufacturer may challenge CMS's guidance in this circuit but not in the Third Circuit. The panel suggested *Novo Nordisk* may be distinguishable because it understood Novo Nordisk to have challenged "a completed, drug-specific determination" rather than "legal standards announced in CMS's Guidance." Add.25-26. But the Third Circuit's opinion belies that understanding of Novo Nordisk's claim. It noted that "Novo Nordisk ... challenges an earlier step in the process: CMS's decision to group products into a single potentially qualifying drug" and rejected that argument because "when a statute prohibits review of a particular determination, the bar extends to the ultimate decision *and* the process by which the agency reaches this decision." 154 F.4th at 111-12 (cleaned up).

A split between the Third Circuit (home to many of the largest pharmaceutical manufacturers) and this Court (in which any manufacturer may sue CMS) is particularly problematic when it involves a pharmaceutical-sales statute. Moreover, as the panel acknowledged, the D.C. Circuit's "approach in construing review bars has long differed from our sister circuit's." Add.25; *see Castaneira v. Noem*, 138 F.4th 540, 550 (D.C. Cir. 2025).

The en banc Court should resolve this conflict and obviate the need for any further review.

B. The panel created and exacerbated conflicts with decisions of the Supreme Court, this Court, and other circuits.

The panel's decision implicates a broader series of conflicts as well. It cannot be reconciled with *Mullin*, which rejects the panel's reading of a key precedent. It dramatically expands and conflicts with this Court's precedents interpreting judicial-review bars. And it takes this Court further out of the mainstream on when statutory challenges may proceed notwithstanding an express preclusion of review.

1. The panel's reasoning is inconsistent with the Supreme Court's decision in *Mullin*, which held that "the TPS statute's judicial-review bar applies to all non-constitutional claims." 609 U.S. at 345. In so holding, *Mullin* expressly limited the Supreme Court's earlier decision in *McNary*, which permitted a due-process challenge despite a judicial-review bar, 498 U.S. at 494. The statute in *McNary* barred "review of a determination respecting an application for adjustment of status under [an amnesty program] except [in removal proceedings]." 8 U.S.C. § 1160(e)(1). *McNary* held that the bar applied only to "a single act rather than a group of decisions

or a practice or procedure employed in making decisions.” 498 U.S. at 492. As *Mullin* explained, however, lower courts have “read far too much into” *McNary* by permitting challenges to policies or procedures under differently worded judicial-review bars. *See* 609 U.S. at 341. The “single act” covered by the statute in *McNary* was “a ruling *on an individual application*,” leaving challengers free to sue over “the procedures used in implementing the program.” *Id.* (emphasis added). “Thus, the decision turned on the specific wording of the provision at issue.” *Id.* The case, *Mullin* explained, did not adopt a “broad principle” about the meaning of the word “determination.” *Id.*

Rather than heeding its obligation to treat as authoritative the “[c]arefully considered language of the Supreme Court,” *CREW v. FEC*, 971 F.3d 340, 351 (D.C. Cir. 2020), the panel adopted an unduly narrow reading of *Mullin*, Add.20-21, and held that the statute permitted challenges to CMS’s guidance. It treated *McNary* as articulating “the usual rule permitting review of the ‘practices and policies’ governing individual determinations.” Add.24 (quoting *McNary*, 498 U.S. at 492). The panel noted that the statute at issue in *Mullin* “barred review of ‘any determination’ made ‘with respect to’ the designation, extension, or termination of [TPS].” Add.20. Because § 1320f-7 does not contain that broadening language, the

panel distinguished *Mullin*. Add.20-21. In *Mullin*, however, the broadening language underscored an overdetermined conclusion. *See* 609 U.S. at 339 (noting that “is it common to use the term ‘determination’ in [the] broad sense” of “the chain of events leading up to a decision” and that “the phrase ‘with respect to’ ... support[s] this broad understanding”); *id.* at 334 (explaining that however “determination” is understood, “an agency’s subsidiary decisions merge into the final agency action”). *Mullin* thus made clear that *McNary* was a narrow decision turning on specific statutory text, *id.* at 341, and other courts have since adopted that understanding, *see Demir v. Mullin*, 185 F.4th 719, 726 (7th Cir. 2026) (per curiam). The panel erred in continuing to treat *McNary* as articulating “the usual rule.” Add.24.

2. The panel’s decision also dramatically expands this Court’s precedent governing when courts may review claims that an agency exceeded its statutory authority notwithstanding a judicial-review bar. This Court has sometimes held that a judicial-review bar allows *ultra vires* challenges to agency actions. *E.g., Railway Lab. Execs.’ Ass’n v. National Mediation Bd.*, 29 F.3d 655, 663 (D.C. Cir. 1994) (en banc) (permitting *ultra vires* challenge despite implicit preclusion of review). The Court later expanded that theory to include claims that an agency had exceeded its

authority despite an *express* bar on judicial review where the scope of a judicial-review provision and a merits question merge. *See COMSAT Corp. v. FCC*, 114 F.3d 223, 227-28 (D.C. Cir. 1997).

Here, however, the panel went beyond even those previously recognized exceptions to judicial-review bars. Plaintiffs did not assert an *ultra vires* claim in the court of appeals; they simply argued that the guidance was contrary to law. *Cf. Leedom v. Kyne*, 358 U.S. 184, 188-89 (1958) (articulating demanding standard for *ultra vires* claims). Nor did the panel suggest that the merits question and the jurisdictional question somehow merged in this case; instead, it addressed each question in separate sections of the opinion. *Cf. Add.*19-20 (holding that statutory interpretation was not an inextricable part of CMS's determination). That bifurcated framework makes sense here because the merits dispute concerns the meaning of "QSSD" not the the word "determination." The merger theory thus has no evident application to this challenge. But if the *Kyne* standard is not met and the merger rule does not apply, existing circuit precedent offers no justification for bypassing an express judicial-review bar.

The panel innovated a novel exception to a judicial-review bar. It reasoned that because courts must interpret statutes, an agency "cannot

make its statutory interpretation unreviewable simply by using it in an unreviewable determination.” Add.22; *see* Add.16 (citing *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 402 (2024)); Add.19-20 (rejecting argument that statutory interpretation is part of a determination). The panel correctly identified that statutory interpretation falls to courts by default, but that rule “is only a default, meaning that it applies only absent congressional indication otherwise.” *McLaughlin Chiropractic Assocs., Inc. v. McKesson Corp.*, 606 U.S. 146, 157 (2025). Here, Congress indicated otherwise by barring review over CMS’s determination of QSSDs. In bypassing Congress’s decision, the panel transformed the default rule into an irrebuttable presumption. *See* Add.16-17, 21. These analytical moves shatter Congress’s control over the jurisdiction of the federal courts by suggesting that run-of-the-mill contrary-to-law claims do not fall within an ordinary judicial-review bar.

Moreover, the Supreme Court has accepted that other judicial-review bars preclude ordinary contrary-to-law claims. In a pair of cases, it held that courts had no jurisdiction to second-guess “questions closely tied to the application and interpretation of statutes related to” certain Patent Office decisions. *Cuozzo Speed Techs., LLC v. Lee*, 579 U.S. 261, 275 (2016); *see*

Thryv, Inc. v. Click-To-Call Techs., LP, 590 U.S. 45, 54, 56 (2020) (applying *Cuozzo*). The panel's categorical assertion of authority to interpret statutes conflicts with *Cuozzo* and *Thryv*, which recognize that some statutory interpretation may be committed to agencies and shielded from judicial scrutiny.

Critically, neither party briefed the panel's unprecedented new statutory-interpretation exception to judicial-review bars. If this Court were to contemplate adopting such an extreme rule, it should do so only after robust adversarial presentation of the issues before the full Court.

3. The panel's rule also collapses the distinction between *ultra vires* review and ordinary statutory challenges. No other circuit has adopted that framework.

To start, it is unclear whether the *COMSAT* merger doctrine remains good law. As the Supreme Court and this Court have held, *ultra vires* claims are unavailable where a statute expressly forecloses judicial review. *See NRC v. Texas*, 605 U.S. 665, 681 (2025); *Global Health Council v. Trump*, 153 F.4th 1, 20 (D.C. Cir. 2025). And there is no reason Congress would have precluded break-glass-in-case-of-emergency *ultra vires* claims while permitting ordinary statutory challenges. Indeed, a prerequisite for *ultra vires* review is

that ordinary judicial review procedures are unavailable. *NRC*, 605 U.S. at 681. It follows that an express bar on judicial review must preclude both contrary-to-law and *ultra vires* challenges. Furthermore, *Mullin* forbade review of a claim that an agency acted unlawfully because statutory prerequisites for the action were missing—the same type of claim treated as reviewable in *COMSAT*. See *Mullin*, 609 U.S. at 338-45; *COMSAT*, 114 F.3d at 226-27. Even accepting *COMSAT* as the baseline, however, the merger doctrine generally requires an “obvious legal error.” *DCH Reg’l*, 925 F.3d at 510 (citing *COMSAT*, 114 F.3d at 225). But see *American Hosp. Ass’n v. Azar*, 964 F.3d 1230, 1238-39 (D.C. Cir. 2020) (holding that any legal error suffices under merger doctrine). In permitting a challenge based on an argument that CMS misinterpreted the scope of the statute, the panel erased the distinction between contrary-to-law claims and *ultra vires* claims. This innovation illustrates how far the merger doctrine has drifted from its theoretical foundations. Only the en banc court (or the Supreme Court) can bring clarity to this doctrinal morass.

Even before the panel’s decision, this Court’s merger doctrine stood as an outlier leaving this Court alone in a three-way split over when challenges to an agency’s exercise of statutory authority may proceed notwithstanding a

judicial-review bar. Five circuits hold that an express preclusion of judicial review bars *all* claims including *ultra vires* challenges. See *In re Financial Oversight & Mgmt. Bd.*, 916 F.3d 98, 113 (1st Cir. 2019); *Yale New Haven Hosp. v. Becerra*, 56 F.4th 9, 26-27 (2d Cir. 2022); *Novo Nordisk*, 154 F.4th at 112-13; *CE Design, Ltd. v. Prism Bus. Media, Inc.*, 606 F.3d 443, 448 (7th Cir. 2010), *abrogated on other grounds by McLaughlin*, 606 U.S. 146; *Ethanol Boosting Sys., LLC v. Ford Motor Co.*, 162 F.4th 1151, 1159 (Fed. Cir. 2025). Four circuits take an intermediate approach and permit themselves a quick peek at the merits when considering *ultra vires* challenges but do not entertain ordinary contrary-to-law arguments. See *U.S. Anesthesia Partners of Tex. v. HHS*, 126 F.4th 1057, 1064 (5th Cir. 2025); *Key Med. Supply, Inc. v. Burwell*, 764 F.3d 955, 961 (8th Cir. 2014); *Hanauer v. Reich*, 82 F.3d 1304, 1308-09 (4th Cir. 1996); *United States v. Bozarov*, 974 F.2d 1037, 1045 n.8 (9th Cir. 1992). But we are aware of no other circuit that allows ordinary challenges to statutory authority to proceed when Congress has expressly precluded review.² The panel here, however, did just that. En banc review is warranted to correct that error.

² *National TPS Alliance v. Noem*, 150 F.4th 1000, 1018 (9th Cir. 2025), reached a similar conclusion, but that case is no longer good law following *Mullin*.

4. Rehearing en banc is also warranted because this Court's own cases are split on how to apply judicial-review bars. Other panels have properly declined to review ordinary statutory-authority claims in the face of a judicial-review bar. For example, *Texas Alliance for Home Care Services v. Sebelius* held that a judicial-review bar precluded a range of claims including that a regulation was “ultra vires ... and otherwise not in accordance with law.” 681 F.3d 402, 408 (D.C. Cir. 2012); *see id.* at 411. And *Florida Health Sciences Center v. HHS* rejected an effort to evade a judicial-review bar through an *ultra vires* challenge because the agency's action was “not obviously beyond the terms of the statute.” 830 F.3d 515, 522 (D.C. Cir. 2016); *see also Saavedra Bruno v. Albright*, 197 F.3d 1153, 1164 (D.C. Cir. 1999) (consular-nonreviewability doctrine precludes statutory claims).

Furthermore, in *Global Health Council*, the Court accepted that a judicial-review bar prevented it from considering otherwise-precluded statutory claims dressed up in *ultra vires* garb. *See* 153 F.4th at 20. *Global Health Council* noted that *ultra vires* review is available only when “review is not expressly precluded by statute,” though the prohibition was implicit in that case, and it held that ordinary claims that an agency acted unlawfully do

not satisfy the *Kyne* standard. *Id.* Had this panel faithfully applied *Global Health Council*, it could not have found jurisdiction here.

Only the en banc Court can bring these divergent lines of cases into harmony.

II. This case presents an issue of exceptional importance.

The Negotiation Program creates billions of dollars in savings each year for the fisc and Medicare beneficiaries alike. Congress anticipated that the Negotiation Program would prompt a deluge of litigation and accordingly expressly foreclosed judicial review over certain categories of action CMS takes to implement the program. Congress thus enabled the program to produce lower prices without litigation-induced disruptions or delays. The panel's decision, however, eviscerates the bar on judicial review of QSSD determinations by allowing virtually any claim framed as a contrary-to-law challenge.

By subjecting the Negotiation Program to a litany of potential attacks, the panel's decision threatens CMS's ability to continue providing more affordable drugs to millions of Medicare patients. CMS will shortly finalize a rule to implement the Negotiation Program going forward. The panel's decision invites manufacturers to challenge various aspects of the rule as

contrary to law. Indeed, the panel's focus on programmatic challenges poses an even greater threat to the program than permitting challenges to individual determinations. As the panel made clear that it viewed vacatur to be an available remedy if it disagrees with CMS's statutory interpretation, *see* Add.15, a successful challenge has the potential to halt CMS's implementation of the Negotiation Program until it issues new guidance or goes through a new round of notice-and-comment rulemaking. Prices at pharmacy counters could rise overnight. This is exactly the sort of situation Congress sought to avoid when it enacted the judicial-review bar. The Court should review this critical jurisdictional question now rather than waiting to see if a manufacturer can successfully grind the Negotiation Program to a halt.

CONCLUSION

For the foregoing reasons, the petition should be granted.

Respectfully submitted,

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* The Assistant Attorney General is recused in this matter.

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 40(d)(3)(A) because it contains 3,889 words. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Word for Microsoft 365 in Century Expanded BT 14-point font, a proportionally spaced typeface.

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

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

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

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

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

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

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

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

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

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

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

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

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

I.

A.

1.

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

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

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

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

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

2.

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

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

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

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3.

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

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

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

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

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

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

4.

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

5.

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

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

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

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

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

B.

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

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

1.

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

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

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2.

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

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

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

C.

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

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

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

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

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

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

II.

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

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

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III.**A.**

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

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

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

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

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

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

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

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

B.

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

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

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

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

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

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

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

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

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

C.

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

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

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

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

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

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

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

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

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

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

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

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

D.

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

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1.

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

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

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

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

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

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

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

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

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

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

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

2.

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

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

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

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

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

IV.

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

A.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

B.

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

1.

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

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

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

2.

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

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

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

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

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

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

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

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

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

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

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

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

C.

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

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1.

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

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

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

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

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

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

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

2.

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

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

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

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

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

a.

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

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

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

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

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b.

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

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

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

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

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

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

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

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

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

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

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

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

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c.

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

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

* * * * *

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

So ordered.

42 U.S.C. § 1320f-7**§ 1320f-7. Limitation on administrative and judicial review**

There shall be no administrative or judicial review of any of the following:

- (1) The determination of a unit, with respect to a drug or biological product, pursuant to section 1320f(c)(6) of this title.
- (2) The selection of drugs under section 1320f-1(b) of this title, the determination of negotiation-eligible drugs under section 1320f-1(d) of this title, and¹ the determination of qualifying single source drugs under section 1320f-1(e) of this title the² application of section 1320f-1(f) of this title.³
- (3) The determination of a maximum fair price under subsection (b) or (f) of section 1320f-3 of this title.
- (4) The determination of renegotiation-eligible drugs under section 1320f-3(f)(2) of this title and the selection of renegotiation-eligible drugs under section 1320f-3(f)(3) of this title.

¹ So in original. The word “and” probably should not appear.

² So in original. Probably should be preceded by “, and”.

³ So in original.