

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ABBVIE INC.,

Plaintiff,

v.

U.S. DEPARTMENT OF HEALTH AND
HUMAN SERVICES, *et al.*,

Defendants.

Case No. 1:26-cv-00431 (CJN)

NOTICE

Defendants respectfully write to notify this Court that on October 2, 2026, the Government petitioned the D.C. Circuit for rehearing en banc in *Teva Pharmaceuticals USA, Inc. v. Kennedy*, 187 F.4th 587 (D.C. Cir. 2026). *See* Appellees' Petition for Rehearing En Banc, *Teva Pharms. USA, Inc. v. Kennedy*, No. 25-5425 (D.C. Cir. filed Oct. 2, 2026) (attached as Ex. A).

Date: October 2, 2026

Respectfully submitted,

ERIC J. HAMILTON
Deputy Assistant Attorney General
Civil Division

MICHELLE R. BENNETT
Assistant Branch Director
Federal Programs Branch

/s/ Pardis Gheibi
STEPHEN M. PEZZI (D.C. Bar 995500)
Chief Litigation Counsel
PARDIS GHEIBI (D.C. Bar 90004767)
Trial Attorney

United States Department of Justice
Civil Division, Federal Programs Branch
1100 L Street NW
Washington, DC 20005
Tel: (202) 305-8576
Email: stephen.pezzi@usdoj.gov

Counsel for Defendants

EXHIBIT A

[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

Of Counsel:

ROBERT FOSTER

Acting General Counsel

ELIZABETH C. KELLEY

Deputy General Counsel

Chief Legal Officer for CMS

MICHAEL J. GERARDI

*Deputy Associate General Counsel
for Litigation*

JOCELYN S. BEER

KENNETH R. WHITLEY

Attorneys

*U.S. Department of Health and
Human Services*

ERIC J. HAMILTON

Deputy Assistant

Attorney General

MICHAEL S. RAAB

MAXWELL A. BALDI

Attorneys, Appellate Staff

Civil Division, Room 7513

U.S. Department of Justice

950 Pennsylvania Avenue NW

Washington, DC 20530

(202) 532-0211

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

TABLE OF CONTENTS

	<u>Page</u>
GLOSSARY.....	v
INTRODUCTION AND RULE 40(B)(2) STATEMENT.....	1
STATEMENT OF THE ISSUES.....	3
STATEMENT OF THE CASE.....	3
REASONS FOR GRANTING THE PETITION.....	7
I. Rehearing en banc is necessary to restore uniformity to preclusion-of-review doctrine.....	7
A. The panel diverged from the Third Circuit’s interpretation of § 1320f-7(2).....	8
B. The panel created and exacerbated conflicts with decisions of the Supreme Court, this Court, and other circuits.....	10
II. This case presents an issue of exceptional importance.....	19
CONCLUSION.....	21
CERTIFICATE OF COMPLIANCE	
ADDENDUM	

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,

ERIC J. HAMILTON
*Deputy Assistant
Attorney General **

Of Counsel:

ROBERT FOSTER
Acting General Counsel

ELIZABETH C. KELLEY
*Deputy General Counsel
Chief Legal Officer for CMS*

MICHAEL J. GERARDI
*Deputy Associate General Counsel
for Litigation*

JOCELYN S. BEER
KENNETH R. WHITLEY
Attorneys

*U.S. Department of Health and
Human Services*

MICHAEL S. RAAB

/s/ Maxwell A. Baldi
MAXWELL A. BALDI
*Attorneys, Appellate Staff
Civil Division, Room 7513
U.S. Department of Justice
950 Pennsylvania Avenue NW
Washington, DC 20530
(202) 532-0211
maxwell.baldi@usdoj.gov*

OCTOBER 2026

* 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.

/s/ Maxwell A. Baldi
Maxwell A. Baldi