IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA AB, and ASTRAZENECA UK LTD.,

Plaintiffs,

vs.

ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the U.S. Department of Health and Human Services; the U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; MEHMET OZ, in his official capacity as Administrator of the Centers for Medicare and Medicaid Services; and the CENTERS FOR MEDICARE AND MEDICAID SERVICES,

Defendants.

Civil Action No. 25-cv-4212

PLAINTIFFS' COMBINED RESPONSE TO DEFENDANTS' NOTICE OF SUPPLEMENTAL AUTHORITY AND NOTICE OF FURTHER AUTHORITY

AstraZeneca hereby responds to the Government's letter discussing the Supreme Court's recent decision in *Mullin v. Doe*, 609 U.S. __ (June 25, 2026) (*Doe*) (Ex. A), and further submits the D.C. Circuit's subsequent decision in *Ardelyx, Inc., v. Kennedy*, No. 24-5290 (June 26, 2026) (*Ardelyx*) (Ex. B). Together, *Doe* and *Ardelyx* strongly support AstraZeneca's argument that its statutory claim is reviewable under the Inflation Reduction Act (IRA).

1. In *Doe*, the Supreme Court applied the Immigration and Nationality Act's judicial review bar to "alleged procedural errors." *Doe* at 13. In doing so, the Court relied on specific language absent here. The statute in *Doe* precludes "review of any determination of the Attorney General *with respect to* the designation, or termination or extension of a designation, of a foreign state under this subsection." 8 U.S.C. § 1254a(b)(5)(A) (emphasis added). The Court found the italicized phrase to be "particularly" important, explaining that it "'generally has a broadening effect, ensuring that the scope of a provision covers not only its subject but also matters relating to that subject.'" *Doe* at 12 (citation omitted). That phrase justified inclusion of preliminary decisions leading up to a "final decision," the Court said, since "all the preceding decisions would be 'with respect to' that decision." *Id.* at 13. The IRA, by contrast, *does not* bar "any determination . . . with respect to" subsequent decisions. Rather, it shields only discrete "determinations" and "selections" "under" specific statutory subsections. 42 U.S.C. § 1320f–7(2). So CMS's attempt to *replace* a statutory definition is not one of those shielded determinations or selections.

Doe also distinguished *McNary v. Haitian Refugee Center, Inc.*, 498 U.S. 479 (1991), on grounds relevant here. The review bar in *McNary* differed from the one in *Doe* because the *McNary* provision "referred to 'a single act,' *i.e.*, a ruling on an individual application." *Doe* at 14 (citation omitted). Here, the IRA likewise bars review only of the "singular 'determination'" of "what 'drugs' are included in the list" that CMS must publish for each annual cycle. *Teva Pharms. USA, Inc. v. Kennedy*, 2025 WL 3240267, at *9 (D.D.C. Nov. 20, 2025); *see* Dkt. 35 at 13-17 (AstraZeneca explaining similarities between this case and *McNary*).

Finally, *Doe* did not address—let alone foreclose—the merger rule, because it did not involve the type of claim that is the prerequisite for the rule's application: a statutory challenge. There was no dispute in *Doe* that the Secretary had indeed made the relevant "determination" that the INA shielded from review; the plaintiffs merely objected to "*how* the Secretary went about making her determination." *Doe* at 11 (citation omitted); *see id.* at 13 (*Doe* plaintiffs raised "alleged procedural errors"). Here, by contrast, AstraZeneca's statutory claim "rests not on a review of a 'determination under' the subparagraph covered by the [judicial-review] provision, but rather [asks] whether [CMS] has made the kind of determination required by the statute." *Sw. Airlines Co. v. TSA*, 554 F.3d 1065, 1071 (D.C. Cir. 2009) (cleaned up); *see* Dkt. 35 at 3-11.

The Government asserts "*Doe* implicitly rejects this application of the so-called 'merger rule' because it applies the review bar even though it precludes review of agency determinations 'under' a specific subsection." Dkt. 46 at 2. But that misunderstands the nature of the rule. The statutory cross-reference in *Doe* did not implicate the merger rule because the plaintiffs did not dispute that the agency had made a decision "under" the cross-referenced INA provision; they raised only "allegations of procedural error," *Doe* at 13—*i.e.*, they argued that the "challenged agency decision" was "arbitrary, capricious, or procedurally defective," a type of claim that does not implicate the rule. *Knapp Med. Ctr. v. Hargan*, 875 F.3d 1125, 1128 (D.C. Cir. 2017) (cleaned up). Here, by contrast, AstraZeneca brings a *statutory* challenge to the agency's *failure* to apply the Qualifying Drug definition. This is a quintessential merger case. *See* Dkt. 35 at 3-11.

2. Indeed, the D.C. Circuit in *Ardelyx* has since underscored that very point, applying the merger rule in a context similar to this case and rejecting the Government's same arguments.

First, the D.C. Circuit applied the merger rule to a review bar similar to the IRA's, reaffirming that a "jurisdiction-stripping provision does not apply if the agency's action fails to qualify as the kind of action for which review is barred." *Ardelyx* at 12; *see* Dkt. 35 at 3-11 (AstraZeneca's similar argument).

Second, the D.C. Circuit rejected the Government's contention that the judicial-review bar applied so long as the agency "purported to" make the type of decision barred from review, explaining that an agency's authority "does not turn upon its say so," which indeed would be a "preposterous position." *Ardelyx* at 14; *see* Dkt. 40 at 10 (Government's similar argument here).

Third, the D.C. Circuit differentiated the merger rule from the question whether a "challenge to [a] regulation" is "'inextricably intertwined' with the challenge to" the agency's application of the regulation. *Ardelyx* at 18. The Court held that "even if" a facial "challenge to the regulation" *is* indeed "'inextricably intertwined' with [a] challenge" to CMS's decision to include a particular drug in a statutory category, the Court "would *still* have to consider whether the CMS had authority to include [that drug]" in the first place. *Id.* at 19 (emphasis added); *see* Dkt. 40 at 6 (Government making "inextricably intertwined" argument here).

Finally, the D.C. Circuit rejected the Government's central argument here, that applying the merger rule to a statutory claim would "render the judicial-review bar irrelevant." *Id.* at 16; *see* Dkt. 46 at 2 (Government making similar argument in its notice of supplemental authority); Dkt. 40 at 10 (Government making similar argument in its reply brief). The D.C. Circuit emphasized that the bar there—like the IRA's bar here—applies to *non*-statutory claims: It "still forecloses inquiry into whether the challenged agency decision is arbitrary, capricious, or procedurally defective." *Ardelyx* at 16. And again, the fact that the *Doe* plaintiffs raised only "allegations of procedural error," *Doe* at 13, rather than statutory claims, explains why the Supreme Court did not consider the merger rule there. *See* Dkt. 35 at 8 (AstraZeneca explaining that the review bar permits certain statutory claims but precludes claims that agency decision was "arbitrary, capricious, or procedurally defective") (cleaned up).

Dated: July 16, 2026

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that this document will be served on Defendants in accordance with Fed. R. Civ. P. 5(a).

/s/ Michael A. Pichini
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Exhibit A

Syllabus

NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States* v. *Detroit Timber & Lumber Co.,* 200 U. S. 321, 337.

SUPREME COURT OF THE UNITED STATES

Syllabus

MULLIN, SECRETARY, DEPARTMENT OF HOMELAND SECURITY, ET AL. *v.* DOE ET AL.

CERTIORARI BEFORE JUDGMENT TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

No. 25–1083. Argued April 29, 2026—Decided June 25, 2026*

The question presented is whether respondents, who challenge the termination of Temporary Protected Status (TPS) for aliens from Syria and Haiti, are entitled to orders postponing the terminations during litigation. Congress created TPS in 1990 to provide short-term humanitarian relief for aliens who cannot safely return to their home countries. Although designed to afford temporary relief, TPS designations in practice have often lasted for decades.

Syria received a TPS designation in 2012 because of "extraordinary and temporary conditions" related to the repressive regime of Bashar al-Assad, 77 Fed. Reg. 19027, and in September 2025, the Secretary of Homeland Security provided public notice that Syria's TPS designation would terminate, 90 Fed. Reg. 45402. Seven Syrian nationals sued in the Southern District of New York asserting claims under the Administrative Procedure Act (APA) to stop the termination. The District Court concluded that the plaintiffs were entitled to interim relief under 5 U. S. C. §705. The Second Circuit denied the Government's request for a stay.

Haiti received a TPS designation in 2010 after a devastating earthquake, 75 Fed. Reg. 3477, and in November 2025, the Secretary provided public notice that Haiti's TPS designation would terminate, 90 Fed. Reg. 54739. Five Haitian nationals sued in the District Court for the District of Columbia asserting claims under the APA and charging

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*Together with No. 25–1084, *Trump*, *President of the United States, et al.* v. *Miot et al.*, on certiorari before judgment to the United States Court of Appeals for the District of Columbia Circuit.

that the termination of Haiti's TPS designation violated the constitutional right to equal protection because it was motivated by race. The District Court granted interim relief, and a divided D. C. Circuit panel declined to issue a stay. The Government sought a stay and a writ of certiorari before judgment in both cases. This Court granted review, consolidated the cases, and deferred ruling on the stay applications.

Held:

1. The TPS statute bars judicial review of non-constitutional claims. Pp. 12–18.

(a) Section 1254a(b)(5)(A) provides that "[t]here is no judicial review of any determination of the [Secretary of Homeland Security] with respect to the designation, or termination or extension of a designation, of a foreign state." The term "determination" may mean either an individual decision or the process leading to a decision. Under either understanding, §1254a(b)(5)(A) bars all of respondents' non-constitutional claims. Further, 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 (internal quotation marks omitted). Pp. 12–13.

(b) Respondents and the courts below offer no sound theories to overcome the plain meaning of the judicial-review bar. Pp. 13–18.

(1) Respondents' argument that §1254a(b)(5)(A) applies only to substantive claims, not those based on alleged procedural errors, finds no support in the statutory language because a "determination" may concern procedural or substantive questions. Respondents' reliance on *McNary* v. *Haitian Refugee Center*, *Inc*., 498 U. S. 479, and *Bowen* v. *Michigan Academy of Family Physicians*, 476 U. S. 667, is misplaced because those decisions turned on the specific wording of different provisions and did not adopt the broad principle that the term "determination" applies only to substantive matters. Pp. 13–15.

(2) *Doe* respondents' argument that "determination" refers only to an assessment of country conditions finds no support in the statute's text or context and contravenes the principle that we give common terms their ordinary meaning. See *Yellen* v. *Confederated Tribes of Chehalis Reservation*, 594 U. S. 338, 353. Pp. 15–17.

(3) Respondents' attempt to limit the judicial-review bar to the Secretary's ultimate "determination"—not any subsidiary decision—is inconsistent with the plain meaning of the statutory text and contradicts the administrative-law principle that subsidiary decisions merge into final agency action. See *Army Corps of Engineers* v. *Hawkes Co*., 578 U. S. 590, 597–598. Pp. 17–18.

2. *Miot* respondents' equal protection claim—that Haiti's TPS designation was terminated because of race—is unlikely to succeed.

Ironically, respondents themselves offer a race-neutral explanation for the Government's action: namely, that the current administration, which has terminated every TPS designation that has come up for renewal, simply opposes the TPS program as it has been implemented in the past.

The Court assumes for the sake of argument that heightened scrutiny applies and that it must determine whether a "discriminatory purpose [was] a motivating factor in the decision" to terminate Haiti's TPS designation, *Arlington Heights* v. *Metropolitan Housing Development Corp*., 429 U. S. 252, 265–266. Because application of that standard calls for consideration of the context in which a challenged statement was made, *id*., at 267–268, the immigration context is an important factor.

None of the cited statements by either the President or the Secretary was overtly racial, and in substance all expressed policy views that could rest on race-neutral justifications. Viewing all the relevant evidence, *Miot* respondents are unlikely to prove that race was a motivating factor in the decision to terminate Haiti's TPS designation, and it follows that they are not entitled to interim relief on their equal protection claim. Pp. 20–24.

Reversed and remanded.

ALITO, J., announced the judgment of the Court and delivered the opinion of the Court except as to Part III–A. ROBERTS, C. J., and THOMAS and KAVANAUGH, JJ., joined that opinion in full, and GORSUCH and BARRETT, JJ., joined except for Part III–A. THOMAS, J., filed a concurring opinion. KAGAN, J., filed a dissenting opinion, in which SOTOMAYOR and JACKSON, JJ., joined.

NOTICE: This opinion is subject to formal revision before publication in the United States Reports. Readers are requested to notify the Reporter of Decisions, Supreme Court of the United States, Washington, D. C. 20543, pio@supremecourt.gov, of any typographical or other formal errors.

SUPREME COURT OF THE UNITED STATES

Nos. 25–1083 and 25–1084

MARKWAYNE MULLIN, SECRETARY, DEPARTMENT OF HOMELAND SECURITY, ET AL., PETITIONERS
25–1083 *v.*
DAHLIA DOE, ET AL.

ON WRIT OF CERTIORARI BEFORE JUDGMENT TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

DONALD J. TRUMP, PRESIDENT OF THE UNITED STATES, ET AL., PETITIONERS
25–1084 *v.*
FRITZ EMMANUEL LESLY MIOT, ET AL.

ON WRIT OF CERTIORARI BEFORE JUDGMENT TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

[June 25, 2026]

JUSTICE ALITO announced the judgment of the Court and delivered the opinion of the Court with respect to all but Part III–A, and an opinion with respect to Part III–A, in which THE CHIEF JUSTICE, JUSTICE THOMAS, and JUSTICE KAVANAUGH join.

In these cases, we consider whether respondents, who challenge the termination of Temporary Protected Status (TPS) for aliens from Syria and Haiti, are entitled to orders postponing the terminations during litigation. We hold that they are not.

The TPS statute plainly bars consideration of respondents' non-constitutional claims. It allows "no judicial review of any determination . . . with respect to the . . . termination" of a TPS designation. 8 U. S. C. §1254a(b)(5)(A). The term "determination" can be used to describe either an individual decision or the whole process leading to a final decision, and under either understanding of the term, §1254a(b)(5)(A) squarely bars all of respondents' non-constitutional claims.

The sole constitutional claim before us will likely fail. Citing statements made by President Trump and former Secretary of Homeland Security Kristi Noem, one set of respondents advances an equal protection claim that Haiti's TPS designation was terminated because of the racial makeup of that country's population. But, ironically, one of respondents' other arguments undermines the equal protection claim by offering a strong, race-neutral explanation for Haiti's termination: namely, that the current administration, which has terminated every TPS designation that has come up for renewal, simply opposes the TPS program, at least as it has been implemented in the past.

For these reasons, the District Courts erred in granting interim relief.

I

A

Congress created TPS in 1990 to provide short-term humanitarian relief for aliens who cannot safely return to their home countries due to events such as armed conflict or natural disaster. Before then, the Executive Branch sometimes provided similar relief as a matter of discretion without any express statutory authorization. Then, as now, the Immigration and Nationality Act (INA) permitted the Executive to defer the removal of an alien who agrees to leave this country voluntarily. See 8 U. S. C. §1229c(a)(1); §1252(b) (1958 ed.). Before Congress created TPS, aliens had 30 days to depart voluntarily, but the Government claimed discretionary authority to extend that deadline indefinitely.[1] Beginning in 1960, the Government used this mechanism to provide humanitarian relief similar to that now furnished by TPS. Under a program that came to be known as "Extended Voluntary Departure" (EVD), the Government authorized deferred departure for nationals from countries where living conditions had become unsafe. EVD allowed aliens from those countries to remain in the United States until the Government concluded that conditions had improved. The Government granted EVD to nationals of at least 14 countries. H. R. Rep. No. 98–1142, p. 4 (1984).

Under this regime, the grant and termination of humanitarian relief was purely a matter of executive discretion, and judges on the Court of Appeals for the District of Columbia Circuit concluded that the Executive's decision to withhold such relief was an unreviewable exercise of prosecutorial discretion. *Hotel & Restaurant Employees Union, Local 25* v. *Smith*, 846 F. 2d 1499, 1519–1520 (CADC 1988) (opinion of Silberman, J.); see also *id*., at 1510 (opinion of Mikva, J.) ("[T]he court has no meaningful standard against which to judge the agency's exercise of discretion to deny EVD status in this case"). Judge Silberman, joined by three other judges, observed that review of an EVD decision would raise separation-of-powers concerns because "[c]ontrol of the country's policy toward aliens is 'inherent in the executive power to control the foreign affairs of the nation,'" *id*., at 1520 (quoting *United States ex rel. Knauff* v. *Shaughnessy*, 338 U. S. 537, 542 (1950)), and "'[m]atters relating "to the conduct of foreign relations . . . are so exclusively entrusted to the political branches of government as to be largely immune from judicial inquiry or interference,"'" *Hotel & Restaurant Employees Union*, 846 F. 3d, at 1520. Judge Silberman therefore concluded that judicial review

[1] See H. R. Rep. No. 98–1142, p. 4 (1984); L. Oswald, Note, Extended Voluntary Departure: Limiting the Attorney General's Discretion in Immigration Matters, 85 Mich. L. Rev. 152, 155–156 (1986).

would be impermissible "in the absence of an extraordinarily precise statutory standard against which to measure the conduct in question." *Ibid.*

B

After critics objected that the Extended Voluntary Departure program lacked "'proper guidelines or standards,'"[2] Congress created TPS. This new regime provided standards to govern the grant and termination of TPS but maintained core features of the old EVD program. Three aspects of the new regime are noteworthy.

First, as with EVD, the Executive Branch retains discretion over whether to designate a country for TPS. Responsibility for TPS decisions rests with the Secretary of Homeland Security, 6 U. S. C. §§552(d), 557, and the statute provides that the Secretary "*may* designate" a country for TPS "after consultation with appropriate agencies of the Government" if certain conditions are met. 8 U. S. C. §1254a(b)(1) (emphasis added). These are:

1. "[T]here is an ongoing armed conflict within the state and, due to such conflict, requiring the return of aliens who are nationals of that state to that state (or to the part of the state) would pose a serious threat to their personal safety;"
2. "[T]here has been an earthquake, flood, drought, epidemic, or other environmental disaster in the state resulting in a substantial, but temporary, disruption of living conditions," "the foreign state is unable, temporarily, to handle adequately" the return of its nationals, and the state requests TPS designation; or
3. "[T]here exist extraordinary and temporary conditions in the foreign state that prevent aliens who are

[2] Congressional Research Service, J. Wilson, Temporary Protected Status and Deferred Enforced Departure 4 (2025).

> nationals of the state from returning to the state in safety, unless the [Secretary] finds that permitting the aliens to remain temporarily is contrary to the national interest." *Ibid.*

Once a country receives a TPS designation, certain nationals of that country living in the United States without another lawful immigration status qualify for work authorization and immunity from removal. See §§1254a(a)(1), (c).

The second notable feature of TPS is that the statute requires the Government to terminate a country's TPS designation if the Secretary determines that the country "no longer continues to meet the conditions for designation." §1254a(b)(3)(B). The Secretary generally makes such determinations as part of an ongoing review of all TPS designations. The Secretary is instructed to review each TPS designation at least every 18 months. §§1254a(b)(2)–(3). During this review, the Secretary must "consul[t] with appropriate agencies of the Government" and "determine whether the conditions for such designation under this subsection continue to be met." §1254a(b)(3)(A). If the Secretary takes no action, a TPS designation automatically extends for another six months. See §§1254a(b)(2)(B), (3)(C). These extensions continue until the Secretary publishes a termination notice. *Ibid*. Terminations take effect at least 60 days after the notice appears in the Federal Register. §1254a(b)(3)(B).

Finally, the Secretary's TPS designation decisions are not subject to judicial review. The relevant provision bars "judicial review of any determination of the [Secretary of Homeland Security] with respect to the designation, or termination or extension of a designation, of a foreign state." §1254a(b)(5)(A).

C

Although designed to afford "temporary" relief, TPS designations in practice have often lasted for decades. For example, the Secretary designated Somalia in 1991, and that designation remains in effect 35 years later. See 56 Fed. Reg. 46805 (1991); *African Communities Together* v. *Noem*, No. 26–cv–11201, 2026 WL 710666 (D Mass., Mar. 13, 2026). Three other countries retain designations that are more than 25 years old. See 64 Fed. Reg. 526 (1999) (Nicaragua); *id.*, at 524 (Honduras); 66 Fed. Reg. 14214 (2001) (El Salvador).[3]

The current administration objects to lengthy TPS designations and adopted a new, restricted approach shortly after the beginning of President Trump's second term in office. In Executive Order 14159, titled "Protecting the American People Against Invasion," the President directed Cabinet officers to "ensur[e] that designations of Temporary Protected Status are consistent with the provisions of" the TPS statute and that such designations "are appropriately limited in scope and made for only so long as may be necessary to fulfill the textual requirements of that statute." 90 Fed. Reg. 8446 (2025). Under this approach, the Secretary of Homeland Security has terminated every TPS designation that has come up for renewal, 13 in all. See *infra*, at 22–23.

Legal challenges to these decisions began almost immediately. In opposing those challenges, the Government's front line of defense has been the judicial-review bar in §1254a(b)(5)(A), but the lower courts have consistently rebuffed that argument. The Government once again led with that jurisdictional argument in asking us to stay two

[3] Not all TPS designations have lasted so long. Presidents Clinton, George W. Bush, and Obama terminated some TPS designations much more promptly. See, *e.g.*, 58 Fed. Reg. 7582 (1993) (Lebanon, terminated two years after initial designation); 62 Fed. Reg. 33442 (1997) (Rwanda, terminated three years after initial designation); 69 Fed. Reg. 40643 (2004) (Montserrat, terminated less than eight years after initial designation); 81 Fed. Reg. 66064 (2016) (Guinea, terminated less than three years after initial designation). None of these terminations were challenged in court.

District Court orders that postponed the termination of Venezuela's TPS designation, and we granted those requests. *Noem* v. *National TPS Alliance*, 605 U. S. 909 (2025) (*NTPSA I*); *Noem* v. *National TPS Alliance*, 606 U. S. 1062 (2025) (*NTPSA II*). Nevertheless, lower courts, including those in the cases now before us, have continued to block the Secretary's attempted terminations of other TPS designations. *E.g.*, 1 App. 33 (Syria); *id.*, at 40 (Syria); 818 F. Supp. 3d 126, 186 (DC 2026) (Haiti); 2 App. 719 (Haiti); *Doe* v. *Noem*, 822 F. Supp. 3d 893, 901 (ND Ill. 2026) (Burma); *African Communities Together* v. *Noem*, ___ F. Supp. 3d ___, 2026 WL 948591, *16 (D Mass., Apr. 8, 2026) (Ethiopia).

1

The Secretary designated Syria for TPS in 2012 because of "extraordinary and temporary conditions" related to the repressive regime of Bashar al-Assad. 77 Fed. Reg. 19027 (2012). The initial designation notice recounted horrific conditions in that country, including use of "excessive force against civilians, arbitrary executions, killing and persecution of protestors and members of the media, arbitrary detention, disappearances, torture, and ill-treatment." *Ibid.* The notice recounted that Syrian military units and mercenaries had "terrorized the population, targeting and killing small children, women, and other unarmed civilians." *Ibid.* These actions led military defectors and members of the population into armed resistance and, eventually, civil war. *Ibid.* For these reasons, the Secretary concluded that "Syrian nationals cannot return to Syria in safety due to extraordinary and temporary conditions." *Id.*, at 19028. The Secretary designated Syria for TPS for an initial period of 18 months. *Ibid.* In the 14 years since then, Syria has maintained its TPS designation through a series of extensions and re-designations. See 90 Fed. Reg. 45399 (2025).

In September 2025—several months after we stayed the District Court order in *NTPSA I*, the first case involving Venezuela—the Secretary provided public notice that Syria's TPS designation would terminate in 60 days. 90 Fed. Reg. 45402. She stated that she had "consult[ed] with appropriate U. S. Government agencies" and had "reviewed country conditions in Syria." *Id*., at 45399. She recognized that between 2011 and 2024 the Syrian civil war had caused more than 500,000 deaths, the displacement of millions, and extensive damage to infrastructure. *Id*., at 45400. But in 2024, the Assad regime fell, and a transitional government took its place. *Ibid*. The notice recounted that the United States had normalized relations with Syria's new government and had revoked sanctions. *Ibid*.

Even so, the termination notice acknowledged that serious problems remained. It noted that localized violence had replaced "nationwide hostilities" and that "insurgent flare-ups" continued. *Ibid*. The Secretary also recognized that "most Syrians require some form of humanitarian assistance," but she found that "this does not prevent nationals from returning in safety, as evidenced by the U. N. High Commissioner for Refugees' estimate that 'since 2024, over 1.2 million Syrians have returned to Syria.'" *Ibid*. In short, the termination notice described improved conditions in Syria but by no means painted a rosy picture. Based on her review, the Secretary determined that "termination of the Syria Temporary Protected Status designation [was] required." *Ibid*.

Asserting claims under the Administrative Procedure Act (APA), seven Syrian nationals who benefit from TPS sued in the Southern District of New York to stop the termination of Syria's TPS designation. The District Court concluded that these plaintiffs (respondents in No. 25–1083) were entitled to interim relief under 5 U. S. C. §705, which authorizes a reviewing court in appropriate circumstances to postpone the effective date of agency action. See 1 App. 6. The court rejected the Government's jurisdictional argument because of the "restrictive manner in which jurisdiction-stripping provisions are construed." *Id.*, at 9. It then held that the plaintiffs were likely to succeed on their APA claims that the termination of Syria's TPS designation was contrary to law and arbitrary and capricious. See §706.

The court claimed not to "opin[e] on the substance of the Secretary's termination decision or on her authority to make such a decision," but it proceeded to criticize the Secretary for "taking a hatchet to the TPS system." *Id.*, at 15–16. The court found that the Secretary's decision to terminate Syria's TPS designation constituted one aspect of the current administration's "anti-immigrant agenda." *Id.*, at 25. The court then indefinitely postponed the effective date of the termination of Syria's TPS designation and declined to stay its own order.

The Second Circuit also denied the Government's request for a stay. It concluded that it likely had jurisdiction, that the challengers had at least one strong APA claim (namely, that the Secretary acted contrary to law by failing to engage in adequate consultation with other agencies before terminating TPS), and that the other stay factors were not met. *Id.*, at 38–40.

Following the Second Circuit's ruling, the Government turned to this Court for relief. We granted certiorari before judgment and deferred ruling on the Government's request for a stay. 607 U. S. ___ (2026).

2

Haiti received a TPS designation in 2010 after a devastating earthquake killed or injured hundreds of thousands of residents, caused massive property damage, and severely worsened living conditions. 75 Fed. Reg. 3477 (2010). The Government re-designated Haiti for TPS and extended that designation several times. See 90 Fed. Reg. 54734 (2025).

In 2018, the Government attempted to terminate Haiti's TPS designation, but court orders prevented that termination from taking effect. 86 Fed. Reg. 41864 (2021). In 2021, following a change in administration, the Government redesignated Haiti for TPS, citing gang-related violence, human-rights abuses, poverty, inadequate healthcare, and food insecurity. *Id.*, at 41864–41867. Relying on these same grounds, the Government continued to extend Haiti's TPS designation. 90 Fed. Reg. 54734. The net effect was to allow Haitians who benefit from TPS to retain that status for 16 years.

In November 2025, the Secretary provided public notice that Haiti's TPS designation would terminate on February 3, 2026—the last day of the most recent extension. *Id.*, at 54739. Stating that she had "consult[ed] with appropriate U. S. Government agencies," *id.*, at 54735, she explained her assessment of the current situation in Haiti. "Certain conditions," she acknowledged, "remain[ed] concerning," especially gang violence and its "spillover effects." *Ibid.* But she asserted that certain areas "of the country [were] suitable to return to" and that the situation would further improve with the deployment of a multinational gang-suppression force. *Ibid.* Separately, she concluded that the ongoing designation of Haiti contravened the United States' national interests. She noted, among other things, that many Haitians in the United States had entered illegally, that Haitians who came here legally overstayed their visas at an exceptionally high rate, and that the Haitian Government was often unable to provide the information needed to identify its own nationals' criminal records or gang affiliations. *Id.*, at 54736–54737. The notice concluded by noting that the United States' "immigration policy must align with our foreign policy vision of a secure, sovereign, and self-reliant Haiti and not a country that Haitian citizens continue to leave in large numbers to seek opportunities in the United States." *Id.*, at 54738.

Before the termination took effect, a group of five Haitian nationals with TPS sued in the District Court for the District of Columbia to stop the termination of Haiti's designation. They asserted claims under the APA and charged that the termination of Haiti's designation violated the constitutional right to equal protection because it was motivated by race. The District Court granted interim relief. See *Miot*, 818 F. Supp. 3d, at 186. It found that the TPS judicial-review bar did not apply because plaintiffs challenged "*how* the Secretary went about making her determination," not the ultimate TPS termination decision itself. *Id.*, at 148 (emphasis in original). On the merits, the court ruled that several of the challengers' APA claims were likely to succeed, including the claim that the Secretary had not properly consulted other Government agencies and the claim that she had acted arbitrarily and capriciously by ignoring evidence of Haiti's true country conditions. The court also ruled that the challengers would likely succeed on the merits of their equal protection claim because both President Trump and Secretary Noem made statements that suggested racial animus against "Haitians and other nonwhite foreigners." *Id.*, at 177, 180. The court did not stay its order.

A divided D. C. Circuit panel likewise declined to issue a stay. It noted that many other courts had held that they had jurisdiction to consider similar claims, and it found that the Government had failed to show that it would suffer irreparable harm. According to the majority, the Government's assertion that the District Court had intruded on the Executive Branch's foreign-policy prerogatives was a mere "'generalized assertio[n] of injury'" and insufficient to support a stay. 2 App. 720.

Judge Walker dissented. In his view, the court lacked jurisdiction, and the Government was irreparably harmed by "'an improper intrusion by a federal court into the workings of a coordinate branch of the Government.'" *Id.*, at 726.

After this decision, the Government sought a stay and a writ of certiorari before judgment. We granted review, consolidated this case with *Doe*, and deferred ruling on the stay application. 607 U. S. ___ (2026).

II

A

We first consider respondents' non-constitutional claims and conclude that we are barred from reviewing them. A provision of the TPS statute, 8 U. S. C. §1254a(b)(5)(A), provides: "There is no judicial review of any determination of the [Secretary of Homeland Security] with respect to the designation, or termination or extension of a designation, of a foreign state under this subsection." This text is clear, and its plain meaning is very broad.

We start with the key term "determination," which may mean several different things. It may be used as a synonym for "decision." See, *e.g.*, 4 Oxford English Dictionary 548 (def. 2.b) (2d ed. 1989) (a "decision arrived at or promulgated"); Webster's Third New International Dictionary 616 (def. 4a) (1986) ("the act of deciding definitely and firmly"). The term may also be used to describe the chain of events leading up to a decision. See, *e.g.*, American Heritage Dictionary 359 (def. 1.a) (1981) (the "act of making or *arriving at* a decision" (emphasis added)); Random House Dictionary of the English Language 541 (def. 1) (2d ed. 1987) (the "act of *coming to* a decision or of fixing or settling a purpose" (emphasis added)).

Not only is it common to use the term "determination" in this broad sense, but other terms in the judicial-review bar—particularly the phrase "with respect to"—support this broad understanding. That phrase "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).

Under either of these definitions, §1254a(b)(5)(A) bars respondents' non-constitutional claims. Each claim concerns a discrete decision made by the Secretary—for example, her decision to consult the State Department in a particular manner and her decision that country conditions in Syria and Haiti justified termination of their TPS designations. And all those steps were part of the process that led to her final decision to terminate these countries' TPS designations. Indeed, the same result would follow if "determination" referred only to that final decision. In that event, all the preceding decisions would be "with respect to" that decision. So, under any dictionary definition of "determination," the judicial-review bar applies to respondents' non-constitutional claims.

We recognize that "when 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). But here, the text of the TPS judicial-review bar very clearly overcomes the general presumption in favor of judicial review.

B

Respondents and the courts below offer several theories to overcome the plain meaning of the judicial-review bar, but none is sound.

1

The most prominent theory is that §1254a(b)(5)(A) applies only to substantive claims, not those based on alleged procedural errors. 1 App. 10–11; 818 F. Supp. 3d, at 148; Brief for Respondents in No. 25–1083, pp. 30–31; Brief for Respondents in No. 25–1084, pp. 15–16. This argument finds no support in the language of §1254a(b)(5)(A) because a "determination" may concern procedural or substantive questions. Take *Doe* respondents' argument that the Secretary inadequately consulted the State Department about conditions in Syria. In proceeding as she did, the Secretary, either personally or through her subordinates, made a series of procedural determinations: to communicate with the State Department by email, to send a terse and unspecific email, and to proceed to terminate Syria's TPS designation after receiving a laconic answer.

In attempting to limit §1254a(b)(5)(A) to substantive determinations, respondents and lower courts have relied not on the statutory text but on several of our decisions, chiefly *McNary* v. *Haitian Refugee Center*, *Inc*., 498 U. S. 479 (1991), and *Bowen* v. *Michigan Academy of Family Physicians*, 476 U. S. 667 (1986). But they read far too much into those decisions.

McNary concerned the Special Agricultural Farmworker amnesty program. A provision of the governing statute barred "review of a determination respecting *an application* for adjustment of status under" that program except in removal proceedings. §1160(e)(1) (1988 ed.) (emphasis added). Because this provision referred to "a single act," *i.e.*, a ruling on an individual application, the Court held that alien farmworkers' broad claims about the procedures used in implementing the program could proceed. *McNary*, 498 U. S., at 492. Thus, the decision turned on the specific wording of the provision at issue. It did not adopt the broad principle that the term "determination" applies only to substantive matters.

Nor does *Bowen* support respondents' position. There, the Court held that two statutory provisions did not bar judicial review of a regulation that provided disparate Medicare Part B payments to allopathic and other physicians. The first provision did not bar review at all. Instead, it authorized judicial review of benefits awarded in hearings conducted by private insurance carriers. 42 U. S. C. §1395ff(b) (1982 ed.). The Government asked the Court to infer that this grant of a particular type of review implicitly barred review of the challenged regulation. *Bowen*, 476 U. S., at 673. But based on the language of this provision and its legislative history, the Court rejected that request. *Id.*, at 674–678. The *Bowen* Court's refusal to find an implicit preclusion of review in the specific language and legislative history of a differently worded provision in a particular statutory scheme hardly means that the term "determination" in 8 U. S. C. §1254a(b)(5)(A) is limited in the way respondents contend and lower courts have ruled.

The second statutory provision at issue in *Bowen* is no more helpful to respondents than the first provision. This provision in the Medicare Act incorporated a list of sections of the Social Security Act, and one of those sections prohibited certain actions against the Government or its officers. See 42 U. S. C. §13955ii (1982 ed., Supp. II) (referencing 42 U. S. C. §405(h) (1982 ed., Supp. II)). The Court held that this provision did not bar review of the challenged Medicare regulation because it was "incorporated *mutatis mutandis*," *i.e.*, with necessary and appropriate modifications, and because legislative history showed that the Medicare Act provision was not meant to bar review of important questions like the one at issue. *Bowen*, 476 U. S., at 680.

By contrast, the TPS judicial-review bar expressly restricts review; it is not a string cite that incorporates another provision to a limited degree. And even if we were disposed to consult legislative history to determine the meaning of 8 U. S. C. §1254a(b)(5)(A), the proponents of the substance-only interpretation cite no legislative history that supports their position.

2

Doe respondents, while agreeing that §1254a(b)(5)(A) applies to only substantive determinations, advance another argument that would reduce the reach of that provision even further. In their view, the statutory term "determination" in the judicial-review bar applies only to determinations about conditions in the country designated for TPS.

This argument, which gives the commonly used term "determination" a special meaning, runs headlong into our statutory-interpretation precedents. We are wary of giving common terms technical meanings. See *Yellen* v. *Confederated Tribes of Chehalis Reservation*, 594 U. S. 338, 353 (2021). Statutory interpretation proceeds on the assumption that those who draft and enact a provision generally intend its terms to mean what they mean in ordinary usage. Without that assumption, the entire endeavor would break down. Ordinary people could not understand what the law requires of them, and every word in a statute could be an unfathomable puzzle. Of course, a statute may provide expressly, or may signal in some other clear way, that it employs a common term in a way that departs from its ordinary meaning, but without strong proof of such a departure, commonly used terms should be given their common meaning. *Feliciano* v. *Department of Transp.*, 605 U. S. 38, 45 (2025).

Here, "determination" is a commonly used term, and therefore *Doe* respondents bear the burden of showing that, as used in §1254a(b)(5)(A), it carries a technical, TPS-specific meaning. But their effort to show that "statutory context" dictates adoption of their interpretation, *Yellen*, 594 U. S., at 351, falls short because the TPS statute uses "determination" in multiple ways that that have nothing to do with the assessment of country conditions. For example, the very first use of "determination" in the TPS statute refers to a "determination with respect to the alien's eligibility for . . . benefits." §1254a(a)(4)(B). In another provision, the statute refers to the "determination of an alien's admissibility." §1254a(c)(2)(A). Still another provision describes the effect of TPS on discretionary immigration benefits if the Secretary "determines that extreme hardship exists."

§1254a(e). These uses of "determination" or "determines" are plainly not references to country conditions.

Doe respondents counter that we need not look to how the TPS statute as a whole uses the term "determination" but can instead limit our examination to the use of the term in subsection (b), which contains the judicial-review bar. And there, they point out, the term refers only to the Secretary's evaluation of country conditions. Brief for Respondents in No. 25–1083, pp. 18–22.

This argument rests on a cramped view of statutory context. When we consider statutory context, we evaluate the provision at issue "with a view to [its] place in the *overall* statutory scheme," not just in a single subsection. *Utility Air Regulatory Group* v. *EPA*, 573 U. S. 302, 320 (2014) (internal quotation marks omitted; emphasis added). While the use of a term in nearby or closely related provisions may be entitled to more weight, there is no justification for limiting our examination as closely as *Doe* respondents urge. Once we expand our aperture, we see that the TPS statute uses "determination" in its ordinary sense, not to denote an assessment of country conditions.

3

Taking a different tack, respondents argue that only the Secretary's ultimate "determination"—not any subsidiary decision, such as whether to consult other agencies—is unreviewable. The dissent makes a similar argument. *Post*, at 4–6 (opinion of KAGAN, J.). For reasons already explained, this argument is inconsistent with the plain meaning of the statutory text. And that is true whether the term "determination" is understood to mean a discrete decision or a process leading up to a final decision.

This argument also contradicts general administrative-law principles. In APA cases, an agency's subsidiary decisions merge into the final agency action, which is then subject to review. See *Army Corps of Engineers* v. *Hawkes Co.*, 578 U. S. 590, 597–598 (2016). If the final agency action is unreviewable, then so too are subsidiary determinations. See *Amgen, Inc.* v. *Smith*, 357 F. 3d 103, 113 (CADC 2004); *DCH Regional Medical Center* v. *Azar*, 925 F. 3d 503, 506 (CADC 2019). This important principle ensures that challengers cannot avoid a judicial-review bar by creative pleading or clever lawyering.

Moving beyond the text and precedent, respondents contend that our interpretation of the judicial-review bar could protect many shocking abuses of TPS. For example, a rogue Secretary in one fell swoop could issue a 50-year TPS designation, contrary to the 18-month statutory cap. Or a Secretary could terminate a TPS designation based on a coin-flip. The Government responds to each of respondents' far-fetched hypotheticals and concludes that some but not all could in fact be redressed by the courts. See Reply Brief 9–10. But whether or not that assessment is correct, the fact remains that if a Secretary engaged in the sort of conduct that respondents imagine, Congress would have ample means to stop that abuse, including, for example, through the annual appropriations process. "Sometimes Congress decides that the political process is the proper forum for remedying improper conduct." *National TPS Alliance* v. *Noem*, 169 F. 4th 796, 807 (CA9 2026) (Bumatay, J., dissenting from denial of reh'g en banc).

* * *

In sum, we hold that the TPS statute's judicial-review bar applies to all non-constitutional claims.

III

We continue with *Miot* respondents' equal protection claim.[4]

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[4] *Doe* respondents brought a similar claim, but the District Court held that it was not likely to succeed. So that claim is not before us.

A

We have held that "where 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). In this case, we need not resolve whether the TPS statute meets that clear-statement rule because we conclude that *Miot* respondents' constitutional claim is unlikely to succeed on the merits.

Before proceeding further, we briefly explain why we may address the substance of *Miot* respondents' equal protection claim without deciding whether the District Court had jurisdiction to entertain it. It is a cardinal rule that a federal court may not consider the merits of a claim without first making a firm determination that it has jurisdiction. *Steel Co*. v. *Citizens for Better Environment*, 523 U. S. 83, 93–94 (1998).

When interim relief is sought, however, a court does not make a final decision on any matter necessary to the ultimate judgment. Instead, the court makes only a predictive—not a final—decision about the outcome of the case. And the likelihood that the court has jurisdiction over a claim and the likelihood that the claim is meritorious both bear on the claim's ultimate prospects. See *Arizona* v. *Biden*, 31 F. 4th 469, 479 (CA6 2022) (Sutton, C. J.). So in evaluating the likelihood-of-success question for the purpose of ruling on a request for interim relief, courts may consider both the likelihood that they have jurisdiction and the likelihood that the claim will succeed on the merits. If they conclude that a claim fails on either ground, they must deny interim relief. Similarly, a court with appellate jurisdiction may reverse on either jurisdictional or merits grounds a lower court order that granted interim relief. But courts need not always start with the jurisdictional ground if the claim for interim relief would also fail on the merits.

Here, we review the District Court's award of interim relief. Thus, in evaluating *Miot* respondents' likelihood of success on their equal protection claim, we may reverse the District Court's grant of interim relief on either jurisdictional or merits grounds.

B

We turn now to the merits of *Miot* respondents' equal protection claim. The parties dispute the proper standard for assessing this claim. The Government contends that we should apply the deferential test we used in *Trump* v. *Hawaii*, 585 U. S. 667 (2018), and it claims that many of the factors that informed the Court's identification of the proper standard of review in that case are also present here. Brief for Petitioners 46–47. These factors include the Executive's broad authority over the admission and exclusion of foreign nationals and the connection between immigration policy and foreign relations. *Ibid*. *Miot* respondents, on the other hand, urge us to apply heightened scrutiny under *Arlington Heights* v. *Metropolitan Housing Development Corp*., 429 U. S. 252 (1977). In their view, the *Hawaii* standard applies only to the exclusion of aliens seeking to enter the country, not to those who are already here. Brief for Respondents in No. 25–1084, p. 42.

We need not resolve this debate. We will assume for the sake of argument that the *Arlington Heights* standard applies and that we must therefore determine whether a "discriminatory purpose [was] a motivating factor in the decision" to terminate Haiti's TPS designation. 429 U. S., at 265–266. But because application of that standard calls for consideration of the context in which a challenged statement was made, *id*., at 267–268, the immigration context is an important factor.

In support of their claim that the termination of Haiti's TPS designation was based on race, respondents cite statements made by the President and former Secretary Noem.

The President's comments fall into four main categories. First, many express strong objections to the immigration that this country has experienced in recent decades and to many of the immigrants who have come here, particularly those who have come to or stayed in the United States illegally. These statements associate these immigrants with crime and other social ills. Second, some statements express great displeasure with TPS. They note, among other things, that TPS designations have often been far from temporary and that aliens who are allowed to stay in the United States under the program are not vetted like other aliens who seek admission. Third, some statements broadly denigrate the countries for which TPS designations have been granted—including Haiti—portraying them as hellish places in which to live. And fourth, some statements malign Haitians who have come to the United States.

Miot respondents also cite statements by former Secretary Noem that fall into three categories. Some expressed antipathy toward travelers from countries covered by a renewed travel ban, much like the one that was before us in *Hawaii*, 585 U. S, at 679–680. Others were derogatory comments about immigration and its effects. And still some others promised changes and criticized past implementation of TPS.

None of the cited statements by either the President or the Secretary was overtly racial, and in substance all expressed policy views that could rest on race-neutral justifications. For example, one may oppose TPS and favor tighter restrictions on immigration for economic or other reasons that have nothing to do with race. And a person without racial bias can provide a harshly unfavorable description of living conditions in some of the countries with TPS designations. The criteria for TPS designations guarantee that many, if not most, designated countries have such characteristics.

Haiti is no exception. It is a very poor country, and living conditions there are unquestionably difficult. Many Americans of all races would surely find those conditions intolerable. But poverty and deprivation are no reflection on character, and there is no justification for denigrating the character of Haitians who suffer from and bear no responsibility for their country's ills.

Due in large part to the difficult conditions at home, many Haitians have come to this country throughout our history. And beginning with the more than 500 Haitians who fought to support American independence at the Battle of Savannah in 1779,[5] Haitians have made many positive contributions to the United States from the very beginning, and they continue to do so today.

In offering the cited statements as proof that the termination of Haiti's TPS termination was motivated by race, *Miot* respondents seek to capitalize on the statements' heated language. Political discourse by prominent public figures is increasingly couched in terms that would have scandalized the public just a short time ago, and the statements cited by *Miot* respondents—especially those concerning Haiti and Haitian immigrants to this country—exemplify this development.

But whatever one may think of the cited statements, they are insufficient to show that the termination of Haiti's TPS designation was based on the race of the Haitian people. Ironically, both *Doe* and *Miot* respondents identify a strong, race-neutral explanation of these officials' statements: the present administration's general stance on immigration and its obvious antipathy toward past administrations' TPS policies. Respondents argue that the Secretary made a "preordained decision" to end TPS for all countries, Brief for Respondents in No. 25–1083, p. 49, and they stress that she terminated the TPS designations for every country that came up for review, 13 in all. *Id.*, at 9–10; Brief for Respondents in No. 25–1084, p. 10. Included are nations in

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[5] See G. Clark, The Role of the Haitian Volunteers at Savannah in 1779: An Attempt at an Objective View, 41 Phylon 356 (1980).

East Asia (Nepal and Burma), Central Asia (Afghanistan), the Middle East (Syria and Yemen), Africa (Somalia, Ethiopia, South Sudan, and Cameroon), Central America (Nicaragua and Honduras), South America (Venezuela), and the Caribbean (Haiti).

Most would regard this as a racially diverse group of countries, but *Miot* respondents see them all as "non-white" nations. *Ibid*. They claim that TPS has not been terminated for any predominantly white nation, and they therefore infer that the reason for the termination of the TPS designation for Haiti was having a predominantly non-white population.

Respondents' definition of a predominantly non-white nation is broad, apparently encompassing major European countries. See Tr. of Oral Arg. 106–108. It may be that only the termination of a TPS designation for a Nordic or Germanic country would be sufficient in their judgment to show that the Secretary's unbroken record of TPS terminations was race-neutral. However, no such test case has come up during the present administration. Only one European nation—Ukraine—had a TPS designation when the President began his second term, and that country's TPS designation has not yet come up for review. See 90 Fed. Reg. 5936 (2025) (extending Ukraine TPS designation through October 19, 2026). The only other European states ever designated for TPS were the war-torn provinces of Kosovo and Bosnia-Herzegovina.[6] The great majority of countries granted TPS have ranked among the poorest nations of the world, and no European nation falls into that category.

Viewing all the relevant evidence, we conclude that *Miot* respondents are unlikely to prove that race was a motivating factor in the decision to terminate Haiti's TPS

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[6] 63 Fed. Reg. 31527 (1998) (designating Kosovo for TPS); 65 Fed. Reg. 33356 (2000) (terminating Kosovo's TPS designation); 57 Fed. Reg. 35604 (1992) (designating Bosnia-Herzegovina for TPS); 65 Fed. Reg. 52789–52790 (2000) (terminating Bosnia-Herzegovina's TPS designation).

designation. It follows that they are not entitled to interim relief on their equal protection claim.[7]

* * *

The judgments of the United States District Courts for the Southern District of New York and the District of Columbia are reversed. The cases are remanded for further proceedings consistent with this opinion.

It is so ordered.

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[7] On June 16, *Miot* respondents filed a motion to dismiss the writ of certiorari as improvidently granted. They claim that newly discovered evidence provides further support for their equal protection claim. This evidence is cumulative of other evidence in the record, and the motion is denied.

SUPREME COURT OF THE UNITED STATES

Nos. 25–1083 and 25–1084

MARKWAYNE MULLIN, SECRETARY, DEPARTMENT OF HOMELAND SECURITY, ET AL., PETITIONERS
25–1083 *v.*
DAHLIA DOE, ET AL.

ON WRIT OF CERTIORARI BEFORE JUDGMENT TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

DONALD J. TRUMP, PRESIDENT OF THE UNITED STATES, ET AL., PETITIONERS
25–1084 *v.*
FRITZ EMMANUEL LESLY MIOT, ET AL.

ON WRIT OF CERTIORARI BEFORE JUDGMENT TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

[June 25, 2026]

JUSTICE THOMAS, concurring.

I join the opinion of the Court in full. I write separately to address two more fundamental problems with the *Miot* respondents' suit. First, their equal protection claim, while meritless under the Court's precedents, was also beyond the District Court's jurisdiction. Second, even assuming jurisdiction, the equal protection claim fails for the additional reason that aliens have no equal protection rights against the Federal Government.

I

Title 8 U. S. C. §1254a(b)(5)(A) precludes district courts from reviewing terminations of Temporary Protected Status (TPS) designations. It provides that "[t]here is no judicial review of any determination of" the Secretary of Homeland Security "with respect to the . . . termination" of a designation of a foreign country for purposes of Temporary Protected Status. See *ante,* at 12. As the Court explains, this bar precludes the statutory claims challenging the Secretary's "determination" that the TPS designations for Syria and Haiti should be terminated because they challenge "the process that led to [the Secretary's] final decision." *Ante,* at 13. The Court does not decide whether the *Miot* respondents' equal protection claim is barred as well.

In my view, this equal protection claim is barred by the statute. It falls within the plain text of §1254a(b)(5)(A)'s judicial-review bar. Respondents asked a federal court to "[s]et aside the termination of Haiti's . . . designation as . . . unconstitutional" because it "was, at least in part, improperly motivated by animus and discriminatory intent based on race and ethnicity." Amended Complaint in No. 25–cv–2471 (D DC), ECF Doc. 74, pp. 84–86. By asking for a court order invalidating the Secretary's decision to terminate Haiti's designation, respondents sought precisely what Congress barred: "judicial review of" the Secretary's determination "with respect to the . . . termination . . . of a designation . . . of a foreign state." §1254a(b)(5)(A). The statutory text does not distinguish statutory and constitutional claims; it bars all "judicial review." Judicial review, of course, means "a court's power to review the actions of other branches or levels of government," and it "esp[ecially]" refers to the "power to invalidate legislative and executive actions as being unconstitutional." Black's Law Dictionary 1011 (12th ed. 2024). Therefore, for the same reasons that their statutory claims are barred, their constitutional claim is also barred: It challenges "the process that led to" the "decision to terminate [Haiti's] TPS designatio[n]" at a minimum, and it likely is barred even under respondents' narrower view that the bar applies "only to substantive claims" respecting a termination. *Ante,* at 13.

Respondents suggest that the plain language of the statute should not apply. Brief for Respondents in No. 25–1084, p. 15. According to this Court's modern precedent, constitutional avoidance requires a clear statement to bar judicial review of constitutional claims. See *Webster* v. *Doe*, 486 U. S. 592, 603 (1988). Barring all judicial consideration of a constitutional challenge to the Secretary's TPS determination could, these precedents say, "rais[e] a serious constitutional question of the validity of the statute as so construed." *Weinberger* v. *Salfi*, 422 U. S. 749, 762 (1975). Accordingly, the argument goes, courts should avoid interpreting the statute to have barred such review unless its intent to do so was clear, which respondents appear to doubt. *Ibid.*

I am unconvinced for two reasons.

A

First, the statute makes Congress's intent to preclude judicial review clear. The canon of constitutional avoidance applies only if the statute is ambiguous. *Coney Island Auto Parts Unlimited, Inc.* v. *Burton Tr. for Vista-Pro Automotive, LLC*, 607 U. S. 155, 161 (2026). Congress's language—"no judicial review"—is not ambiguous. See *ante,* at 12–13. There is no indication in the text that reviewability may turn on the source of law for the underlying claim. It follows that constitutional avoidance has no role.

B

Second, even if §1254a(b)(5)(A) were ambiguous, a judicial-review bar would raise no "serious constitutional question" in the first place. *Weinberger*, 422 U. S., at 762. Because inferior federal courts are creatures of statute, U. S. Const., Art. I, §8, cl. 9, they "possess no jurisdiction but what is given them by the power that creates them," *United States* v. *Hudson*, 7 Cranch 32, 33 (1812); accord, *Trainmen* v. *Toledo, P. & W. R. Co.*, 321 U. S. 50, 63–64 (1944) (explaining that Congress has "plenary control over the jurisdiction of the federal courts"). So, Congress has the authority to deprive district courts of jurisdiction to decide particular kinds of claims.

It makes no difference that the *Miot* respondents alleged a violation of the Constitution. As Justice Scalia put it, "What could possibly be the basis for" doubting Congress's authority to bar judicial review of constitutional claims? *Webster*, 486 U. S., at 612 (dissenting opinion). "The very text of the Constitution refutes th[e] principle" that "*all* constitutional violations must be remediable in the courts." *Ibid.* In some cases, a question of constitutional law is "textually committed" to adjudication solely by another branch. *Nixon* v. *United States*, 506 U. S. 224, 228 (1993); see, *e.g.*, Art. I, §2, cl. 2 (setting the qualifications for House Members); §3, cl. 3 (setting qualifications for Senators); §5, cl. 1 (establishing that "[e]ach House shall be the Judge of the . . . Qualifications of its own Members," not any court). In other contexts, the "lack of judicially discoverable and manageable standards" has been taken to show that a claim of a constitutional violation cannot be addressed on the merits by federal courts. *Nixon*, 506 U. S., at 228.

Other familiar principles likewise bar judicial review of constitutional claims. An obvious one is sovereign immunity, "a monument to the principle that some constitutional claims can go unheard." *Webster*, 486 U. S., at 613 (Scalia, J., dissenting). Because of sovereign immunity, no one can sue the Federal Government for damages without a waiver, even if he brings a constitutional claim and even if damages are his only possible remedy. Likewise, "courts cannot examine" "the President's actions on subjects within his 'conclusive and preclusive' constitutional authority," regardless of whether he violates the Constitution in exercising that authority. *Trump* v. *United States*, 603 U. S. 593, 609 (2024). The Constitution thus does not require that courts be able to hear all constitutional claims.

* * *

Congress barred all judicial review of TPS termination decisions, including constitutional claims. Since nothing in the Constitution prohibits Congress from doing so, courts are obliged to simply "giv[e] effect to [§1254a's] ordinary meaning." *Guerrero-Lasprilla* v. *Barr*, 589 U. S. 221, 244 (2020) (THOMAS, J., dissenting).[1]

II

Respondents' equal protection claim also has no basis in the Constitution. The Constitution has only one Equal Protection Clause, and it applies only to the "State[s]," not the Federal Government. Amdt. 14, §1. Respondents, of course, sued the Federal Government. When asked at argument how the Equal Protection Clause could have anything to do with a suit against the Federal Government, respondents' counsel, drawing on precedents of this Court, stated that the claim "arises under . . . the Fifth Amendment's equal protection guarantee" because "the Fifth Amendment constrains the federal government in the same way that the Fourteenth Amendment constrains states." Tr. of Oral Arg. 118. Because the Fifth Amendment has no Equal Protection Clause, this Court was wrong to read equal protection into it in *Bolling* v. *Sharpe*, 347 U. S. 497 (1954). And, even if the Due Process Clause does prohibit some discrimination, it would not do so in a case about immigration status.

A

There is little evidence for the Court's modern assumption that "the Due Process Clause of the Fifth Amendment contains an equal protection component whose substance is

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[1] Although I would rule against respondents based on the judicial-review bar, I also agree with the Court that they are unlikely to succeed on the merits. Cf. *Jennings* v. *Rodriguez*, 583 U. S. 281, 314 (2018) (THOMAS, J., concurring in part and concurring in judgment).

'precisely the same' as the Equal Protection Clause of the Fourteenth Amendment." *United States* v. *Vaello Madero*, 596 U. S. 159, 166–167 (2022) (THOMAS, J., concurring) (quoting *Weinberger* v. *Wiesenfeld*, 420 U. S. 636, 638, n. 2 (1975)). The Clause says nothing about equal protection or discrimination. Reading an implicit "equal protection component" into the Fifth Amendment's language renders incomprehensible the Fourteenth Amendment's inclusion of both an identical Due Process Clause and the Equal Protection Clause. *Vaello Madero*, 596 U. S., at 170–171 (opinion of THOMAS, J.). History provides no basis for this atextual reading, either.[2] See *id.*, at 167–171.

Even if the Due Process Clause did include some nondiscrimination principle, it would have no application here. The Due Process Clause restricts the Federal Government's ability to "depriv[e]" people of "life, liberty, or property." U. S. Const., Amdt. 5. "The Due Process Clause protects rights, not privileges." *Learning Resources, Inc.* v. *Trump*, 607 U. S. 229, 323 (2026) (THOMAS, J., dissenting) (internal quotation marks omitted). "The founding generation understood the phrase 'life, liberty, or property' to refer to a relatively narrow set of core private rights that did not depend on the will of the government." *Sessions* v. *Dimaya*, 584 U. S. 148, 213 (2018) (THOMAS, J., dissenting).

The termination of Haiti's TPS designation does not deprive respondents of "life, liberty, or property," so they have no claim even if the words "due process" implicitly forbid discriminatory animus. The discretionary and limited status that a TPS designation provides, like any immigration status for aliens, is a government-created privilege, not a core private right. See *United States ex rel. Knauff* v.

[2] As I have explained, there is "substantial support for the proposition that . . . the Citizenship Clause guarantees citizens equal treatment by the Federal Government with respect to civil rights." *Vaello Madero*, 596 U. S., at 179 (THOMAS, J., concurring). But, respondents are not citizens, so the Citizenship Clause cannot guarantee them any rights.

Shaughnessy, 338 U. S. 537, 542 (1950) ("Admission of aliens to the United States is a privilege granted by the sovereign United States Government"); *Harisiades* v. *Shaughnessy*, 342 U. S. 580, 586–587 (1952) (explaining that even permanent residence is not a "right" but "a matter of permission and tolerance"); *United States ex rel. Turner* v. *Williams*, 194 U. S. 279, 290 (1904) ("[T]he deportation of an alien who is found to be here in violation of law is not a deprivation of liberty without due process of law"). So, a TPS determination does not implicate the Due Process Clause even if a discriminatory motive is inconsistent with "due process" in other contexts.

B

Perhaps for these reasons, this Court has never subjected even express racial classifications in immigration laws to scrutiny under the Due Process Clause. While foreigners have long been able to claim constitutional protection from racial discrimination by States, see *Yick Wo* v. *Hopkins*, 118 U. S. 356, 368–369 (1886), they have never been guaranteed a right to immigration status or citizenship based on equal protection principles, even when these laws were openly discriminatory, see Act of May 6, 1882, ch. 126, 22 Stat. 58–59 (severely restricting Chinese immigration); *Takao Ozawa* v. *United States*, 260 U. S. 178, 192–193 (1922) ("In all of the Naturalization acts from 1790 to 1906 the privilege of naturalization was confined to white persons (with the addition in 1870 of those of African nativity and descent)," and legislation up to 1922 had not changed that restriction). Congress only amended these laws to eliminate such discrimination in the middle of the 20th century,[3]

[3] The racial restrictions for naturalization were gradually removed from 1940 onward. See *Oyama* v. *California*, 332 U. S. 633, 635, n. 3 (1948). The last restrictions, however, were not removed until 1952. See *ibid.* (explaining that persons of Japanese descent were still ineligible in 1948); Immigration and Nationality Act of 1952, §311, 66 Stat. 239.

but not because the meaning of the Fifth Amendment has changed. See 8 U. S. C. §1427(a) (present naturalization statute).

If equal protection principles applied to immigration decisions, much of even our current immigration law would conflict with this Court's modern equal protection doctrine. This Court has interpreted the Equal Protection Clause to bar discrimination based on "country of origin." *Oyama* v. *California*, 332 U. S. 633, 640 (1948). But, our immigration laws have distinguished among aliens based on their national origin from the beginning. See, *e.g.*, Act of July 6, 1798, §1, 1 Stat. 577 (authorizing deportation of those who are subjects of hostile nations). Today, applicants for immigration are treated differently based on their nationality as a matter of course. 8 U. S. C. §1152(a)(2). And, respondents themselves seek a protection from deportation for people from Haiti, but not the neighboring Dominican Republic. If they are correct that the Court should apply equal protection precedents to immigration decisions, then the program that they benefit from may, ironically, be unconstitutional.

SUPREME COURT OF THE UNITED STATES

Nos. 25–1083 and 25–1084

MARKWAYNE MULLIN, SECRETARY, DEPARTMENT OF HOMELAND SECURITY, ET AL., PETITIONERS
25–1083 *v.*
DAHLIA DOE, ET AL.

ON WRIT OF CERTIORARI BEFORE JUDGMENT TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

DONALD J. TRUMP, PRESIDENT OF THE UNITED STATES, ET AL., PETITIONERS
25–1084 *v.*
FRITZ EMMANUEL LESLY MIOT, ET AL.

ON WRIT OF CERTIORARI BEFORE JUDGMENT TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

[June 25, 2026]

JUSTICE KAGAN, with whom JUSTICE SOTOMAYOR and JUSTICE JACKSON join, dissenting.

For over a decade, the Government has provided humanitarian relief to Haitian and Syrian nationals in the United States through the Temporary Protected Status (TPS) program. The Secretary of Homeland Security first designated Haiti for the program in 2010 after an earthquake devastated the country; the Secretary designated Syria in 2012 because of the government and military's brutal repression of the country's civilian population. Since those initial designations, Secretaries have repeatedly examined the conditions in the two countries, and have repeatedly determined that they remain too dangerous to permit safe return. As a result, those countries' TPS designations have been extended year after year, and hundreds of thousands of Haitians and Syrians have been able to live and work here.

But that is no longer so, and the suits before us challenge that change. Last year, then-Secretary Kristi Noem, at the instigation of President Trump, terminated Haiti's and Syria's TPS designations, declaring the countries now safe. Haitian and Syrian TPS holders brought these cases, and sought interim relief allowing them to stay here while the litigation progressed. The District Courts granted that relief, finding (among other things) that the terminations were likely unlawful. Both courts concluded that the Secretary probably violated the TPS statute by ordering the terminations without first consulting with other agencies about current country conditions. And the District Court in the Haiti litigation found as well that the plaintiffs had a likely successful equal protection claim, in part because statements made by the President showed that a racially discriminatory purpose had entered into the TPS termination.

Today the Court undoes that preliminary relief—insisting that the terminations take effect now—based on two mistakes about the plaintiffs' likelihood of success. First, the majority asserts that the Secretary's compliance with the TPS statute is in every respect unreviewable by the courts. But in fact the statute allows judicial review of whether the Secretary adhered to the procedures it mandates—which is what the plaintiffs dispute here. Second, the majority claims to see *no* evidence that race played *any* role in the Haiti decision. But the evidence is there, plain to see, in the President's statements, which the majority (and for that matter, his own lawyers) cannot even bear to repeat. Once that much is established, the case for interim relief is made: There is no dispute that the plaintiffs will suffer irreparable harm absent postponement of the TPS decisions. So the plaintiffs are entitled to stay in this country while these suits go forward. Respectfully, I dissent from the Court's decision that they may instead be put on the next plane.

I

Start with how the TPS program works—or, at least, is supposed to. The governing statute authorizes the Secretary to "designate" a country for the program if it is suffering from specified dangerous or harmful conditions, such as may arise from armed conflicts or natural disasters. 8 U. S. C. §1254a(b)(1). When the Secretary makes a designation, she also announces how long it will last—anywhere from six to eighteen months. At the end of that period, the designation does not just go away; nor is its fate left to the Secretary's unfettered discretion. Rather, the statute mandates a "[p]eriodic review" process: "At least 60 days before [the] end" of the chosen period, the Secretary, "after consultation with appropriate agencies of the Government, shall review the conditions in the foreign state" and "shall determine whether the conditions for such designation under this subsection continue to be met." §1254a(b)(3)(A). If the Secretary determines the statutory criteria are no longer met, she "shall" terminate the designation; otherwise, the designation "is extended." §§1254a(b)(3)(B), (C). Either way, "[t]he [Secretary] shall provide on a timely basis for the publication of notice" in the Federal Register. §1254a(b)(3)(A). So in all, the statute tells the Secretary to complete four steps to terminate a TPS designation: (1) consult with appropriate agencies about the country's conditions, (2) review those conditions, (3) determine whether those conditions are still bad enough to meet the statutory criteria, and (4) publish a notice in the Federal Register. All agree those steps are mandatory. See *ante*, at 5.

The first question in these cases is whether a federal court can review a claim that the Secretary failed to take one of the four mandated steps—here, that before terminating TPS for Haiti and Syria, she failed to consult with appropriate agencies about country conditions. The plaintiffs' failure-to-consult claims are brought under the Administrative Procedure Act, which means judicial review is available unless "a relevant statute precludes it" or the challenged "action is committed to agency discretion by law." *Department of Commerce* v. *New York*, 588 U. S. 752, 771 (2019); see 5 U. S. C. §701(a). Neither the Government nor the majority contends that the actions in dispute are committed to the agency's discretion, so the issue here is whether the TPS statute prevents courts from reviewing the Secretary's compliance with its mandatory procedures.

The statute does no such thing. Its judicial-review bar applies not to everything the Secretary does under the law, but only to her "determination" "with respect to the designation, or termination or extension of a designation, of a foreign state." 8 U. S. C. §1254a(b)(5)(A). To preclude review of those determinations is of course to insulate critical matters from judicial scrutiny. Suppose the Secretary determines that a country no longer qualifies for a TPS designation even though the record shows the opposite—that country conditions are as dire as ever. Under the statute, no court may second-guess that determination. But still, the review bar has limits. It does nothing to stop courts from reviewing things *other* than the Secretary's "determination[s]" concerning TPS designations. *Ibid*. And those other things include the procedural steps the Secretary must undertake prior to making any determination about country conditions.

For that reason, the judicial-review bar does not preclude the plaintiffs' failure-to-consult claims. Those claims are narrow. They do not assert that the Secretary made the wrong call when she determined that Haiti and Syria no longer meet the criteria for TPS (although the plaintiffs surely think that too). Instead, the claims are that the Secretary failed to comply with a pre-determination procedural mandate—more specifically, that she failed to consult with appropriate agencies about country conditions. A court can adjudicate those claims without reviewing—or even thinking about—the Secretary's later "determination[s]" concerning (*i.e.*, "with respect to") the "termination" of Haiti's and Syria's TPS "designation[s]." *Ibid*. That is because the claims concern a distinct matter—whether the Secretary did what the statute demands before she made her unreviewable decision.

The majority's contrary conclusion rests on what it self-describes as a "very broad" view of the term "determination." *Ante*, at 12. According to the majority, that term can "be used as a synonym for 'decision'" *or* "to describe the chain of events leading up to a decision." *Ibid.* So when the judicial-review bar refers to a "determination," the majority posits, it means not only the actual determination of whether a country still qualifies for TPS, but also the "chain of events leading up to" that decision. *Ibid.* And the latter includes, the majority says, the statutorily required consultations—which (*voila*!) brings them within the judicial-review bar.

"[V]ery broad" might be one description for that reading of the term "determination"; very strange is another. Just last Term, this Court observed that the word "determination" is a "term[] of everyday usage," and then said what it means: the "settling and ending of a controversy"; "the resolving of a question by argument or reasoning"; "[t]he decision arrived at or promulgated"; or "a determinate sentence, conclusion, or opinion." *EPA* v. *Calumet Shreveport Refining, L.L.C.*, 605 U. S. 627, 643 (2025). Missing from those definitions (or any other you, as an English speaker, would naturally come up with) is any suggestion that events preceding a determination—including required procedural steps—are properly referred to as the "determination" itself. See *McNary* v. *Haitian Refugee Center, Inc.*, 498 U. S. 479, 492 (1991) (construing the word "determination" in another judicial-review bar as "describ[ing] a single act," rather than the "procedure employed in making decisions"). In ordinary English, a "determination" means, well, a determination—not a determination plus anything and everything the decisionmaker does or is required to do beforehand. And then, so too in this statute—which even the majority does not think uses the word "determination" as some special term of art. See *ante*, at 16.[1]

And even if the matter is less certain than I think, the "strong presumption" in favor of judicial review should decide it the plaintiffs' way. *Mach Mining, LLC* v. *EEOC*, 575 U. S. 480, 486 (2015). That presumption applies even when we interpret the scope, rather than the existence, of a judicial-review bar. See *Cuozzo Speed Technologies, LLC* v. *Lee*, 579 U. S. 261, 273 (2016). In that context, as in all others, we "presume that Congress intends the executive to obey its statutory commands and, accordingly, that it expects the courts to grant relief when an executive agency violates such a command." *Bowen* v. *Michigan Academy of Family Physicians*, 476 U. S. 667, 681 (1986). The majority concedes as much, mouthing all the right words: "[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." *Ante*, at 13

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[1] The majority briefly states that it would reach the same conclusion if "determination" means only the "final decision" to terminate TPS because (it says) all the prior consultative steps—which, somewhat confusingly, it also labels "decisions"—would be "with respect to" that ultimate TPS determination. *Ante*, at 12–13. The problem with that argument is that it jumbles the order of the words in the statute. The statute does not speak of decisions (or steps) "with respect to" a determination—whatever that would mean. Instead, the statute speaks of a determination "with respect to" "the designation, or termination or extension of a designation, of a foreign state." 8 U. S. C. §1254a(b)(5)(A). So if a "determination" is indeed only the Secretary's "final decision," as the majority here accepts, then the phrase "with respect to," however broad, does it no good.

(quoting *Guerrero-Lasprilla* v. *Barr*, 589 U. S. 221, 229 (2020)). And then the principle gets ignored. If the meaning of "determination" is *not* "reasonably susceptible to divergent interpretations," it is only because, as I maintain, a "determination" is a determination. But the majority's view that a "determination" includes as well all the steps and processes and actions in "the chain" leading up to the determination? *Ante*, at 12. That is reasonably contestable by any measure.

Indeed, the consequences of today's holding could be Exhibit A in the case for why we have adopted a presumption favoring judicial review. The TPS statute makes plain that Congress insulated the Secretary's designation determinations from review—that it did not want judges overriding secretarial decisions (made with proper consultation) about conditions in foreign countries. But the majority's holding makes *everything* in the statute precatory, including procedural requisites whose enforcement would seem to fall smack in the middle of the judicial wheelhouse. After today, a Secretary can announce to the world that she didn't consult with anyone—more, that she didn't evaluate country conditions at all—before making, extending, or terminating a TPS designation. And the courts will be powerless to intervene, even though Congress loaded up the TPS statute with requirements about the (altogether different) way the Secretary is supposed to make her decision. If it means anything to "presume that Congress intends the executive to obey its statutory commands," *Bowen*, 476 U. S., at 681—to think that Congress does not want all its work to go for naught—then the majority has gone wrong.

And the claims that the majority refuses to review are in fact meritorious, because the Secretary did not consult (as the statute demands) with "appropriate agencies of the Government" about "the conditions" in Haiti and Syria. §1254a(b)(3)(A). As everyone agrees, the only relevant communications here were brief email exchanges between an aide to the Secretary and an official at the State Department (a clearly "appropriate" agency). The aide stated (in two separate emails) that Haiti's and Syria's TPS designations were up for review; the official then replied as to each that the State Department had "no foreign policy concerns" with a termination of TPS. 2 App. 763; Administrative Record in No. 25–cv–8686 (SDNY), ECF Doc. 72–2, p. 156. The problem with those exchanges is that they were not about the right thing. The statute insists on consultations about whether country conditions are safe, not about whether ending TPS raises "foreign policy concerns." While there might be overlap between the two subjects, they are hardly coextensive. It could well be that terminating TPS for even an unsafe country raises no foreign policy concerns because it does not threaten U. S. relations with any significant foreign nation. Of course, the State Department is free to opine on that matter, as part of its job of overseeing foreign affairs. But the TPS statute mandates that it also advise on something else: whether, since an earlier TPS designation, the conditions in a country (here, Haiti and Syria) have become safe. The State Department did not do that here, so the Secretary did not fulfill her consultation requirement.[2]

The Government's opposing argument—that the required consultation occurs whenever the Secretary *asks* about country conditions—is underwhelming. According to

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[2] One might wonder why a State Department official asked about TPS would weigh in on "foreign policy concerns" when the statute insists on consultations about country conditions. Perhaps it was just a miscommunication or mistake. But perhaps it was purposeful avoidance of an inconvenient topic. At the relevant time, the Department's travel advisories stated that Haiti was unsafe due to "kidnapping, crime, terrorist activity, civil unrest, and limited health care," and that "[n]o part of Syria [was] safe from violence" due to "terrorism, civil unrest, kidnapping, hostage taking, and armed conflict." 2 App. 771; 1 *id.*, at 447. So it would have been hard for a State Department official to provide the Secretary with the relevant country-condition assurances.

the Government, "consultation" just means "[t]o seek advice or input," not to receive it. Tr. of Oral Arg. 41; see *id*., at 38 ("[I]f you've asked, you've consulted"). So once the Secretary reaches out to an appropriate agency, the statute is satisfied, even if a response never comes back, or if the one that does is "completely unresponsive" like "wasn't that baseball game tonight great?" *Id.*, at 38–39. But sorry, that is not what "consultation" means. See, *e.g*., Black's Law Dictionary 316 (6th ed. 1990) (defining "[c]onsultation" as "[d]eliberation of persons on some subject"). If your doctor tells you, "After consulting with a specialist, I've determined that you should have this procedure," you would think he had an exchange with an expert about your condition. If it turned out the doctor emailed a specialist but never heard back, or the specialist's reply was about a baseball game, you would think the doctor had lied. The emails here are in the same vein. The consultation required by law never took place because there was no two-way communication about the right subject.

II

The Haiti plaintiffs have yet another claim that is likely to succeed: that race entered into the decision to terminate Haiti's TPS designation, in violation of equal protection.

Our decision in *Arlington Heights* v. *Metropolitan Housing Development Corp.*, 429 U. S. 252 (1977), supplies the standard for assessing that claim. The Haiti plaintiffs must show (here, must show as a likelihood) that a racially "discriminatory purpose" was "a motivating factor" in the termination of Haiti's TPS designation.[3] *Id.*, at 265–266.

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[3] The majority assumes without deciding that *Arlington Heights* provides the right framework. See *ante*, at 20. But of course it does. *Arlington Heights* is the framework we have always used to examine discriminatory purpose in equal-protection cases—including six years ago in another lawsuit involving a challenge to immigration policy. See *Department of Homeland Security* v. *Regents of Univ. of Cal.*, 591 U. S. 1, 34 (2020) (plurality opinion). The Government's argument that we

Critically, "a motivating factor" does not mean the sole factor, or even "the dominant or primary one." *Id.*, at 265. One factor among many is enough when the factor is racial to presumptively establish an equal protection violation. See *ibid*. And in determining whether such a factor exists, a court must undertake a "sensitive inquiry" into whatever "circumstantial and direct evidence of intent" is available. *Id.*, at 266. It should consider "[t]he historical background of the decision"; the "sequence of events leading up" to it; and, most relevant here, "contemporary statements" by decisionmakers. *Id.*, at 267–268.

This Court must also take account of a deferential standard of appellate review. The discriminatory-purpose inquiry is predominantly factual, so a lower court's conclusion must stand unless clearly erroneous. See *Anderson* v. *Bessemer City*, 470 U. S. 564, 573 (1985). Here, the District Court found that the existing record (which future discovery could supplement) "strongly suggests that [the] decision to terminate Haiti's TPS designation was motivated, at least in part, by racial animus." 2 App. 703; see *id.*, at 698 (observing that the President's statements "repeatedly invoked racist tropes of national purity," and evinced "anti-black" animus). Under clear-error review, that finding governs so long as it is "plausible." *Anderson*, 470 U. S., at 574.

It is more than plausible: Even putting the clear-error standard aside, the Haiti plaintiffs have carried their burden. The evidence they have offered includes statements by the President so repellent and racially inflected that the majority declines to put them in print. (Indeed, one measure of the President's way of speaking about Haitians is to compare it with the majority's, which is unfailingly

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should apply the deferential test the Court used in *Trump* v. *Hawaii*, 585 U. S. 667 (2018), seeks both a significant extension of *Hawaii* and a massive change in equal-protection law—neither of which is warranted.

respectful.[4]) So here are some of those statements. Haitians are "eating the dogs . . . . They're eating the cats. They're eating—they're eating the pets of the people that live [in Springfield, Ohio]." 2 App. 802; see *id.*, at 644. And: Haitians are also eating "other things too that they're not supposed to be." *Id.*, at 698–699. And: Haitians in the United States "probably have AIDS." *Id.*, at 698. And: Haiti is a "shithole country," which is "filthy, dirty, [and] disgusting." *Id.*, at 698–699. And: Haitian immigration is "like a death wish for our country." *Id.*, at 698. And: Haitians, along with some others, are "poisoning the blood" of our country. *Id.*, at 698. And: "Why is it we only take people from shithole countries" like "Haiti [and] Somalia"? "Why cannot we have some people from Norway [and] Sweden?" *Id.*, at 699. The majority briefly replies that those remarks are not "overtly racial," *ante,* at 21, but it is hard to know what that means. Haitians are Black. (Norwegians and Swedes not so much.) The references—of filth, disease, and primitiveness—are shot through with racial stereotypes and tropes. It is hard to imagine the statements being made today of any White community. No very "sensitive inquiry," of the kind *Arlington Heights* compels, is needed to see them for what they are, 429 U. S., at 266; judges, as we often say, are "not required to exhibit a naiveté from which ordinary citizens are free," *Department of Commerce*, 588 U. S., at 785. The statements fairly shout, in their racial undertones and overtones alike, that race entered into the President's resolve to remove Haitians from this country.

The majority's opposing argument is at odds with the *Arlington Heights* standard. On the majority's view, there is a more plausible "race-neutral explanation[]" of the

[4] For example: "[P]overty and deprivation are no reflection on character, and there is no justification for denigrating the character of Haitians who suffer from and bear no responsibility for their country's ills." *Ante*, at 22.

termination of Haiti's TPS designation: "the present administration's general stance on immigration and its obvious antipathy toward past administrations' TPS policies." *Ante*, at 22; see *ante,* at 2. But the *Arlington Heights* test is not in the nature of an "either/or" inquiry. It does not ask a court to identify which is the single cause, or even the primary cause, of an official action. To the contrary, that test recognizes a "both/and" world: that causes are usually multiple (and often intertwined). I have no doubt that, as the majority says, the current administration is generally hostile toward immigration and prior TPS policies. I also have no doubt, again with the majority, that those views may be held for reasons "hav[ing] nothing to do with race." *Ante*, at 21. But under *Arlington Heights*, that is not the end of the matter. If in addition to race-neutral reasons, race entered into the picture—even as a subsidiary factor—the Haiti TPS decision is irretrievably tainted. And here, the President's own statements show that race did enter in—that, within what was surely a multi-cause decision, it was *a* motivating factor. Because that is all the Haiti plaintiffs need to show on their equal protection claim, the District Court was right to find that it is likely to succeed.

III

Once the merits are thus established, the requested interim relief must follow, given the harm the plaintiffs will otherwise suffer. See *Nken* v. *Holder*, 556 U. S. 418, 426 (2009) (considering "whether the applicant will be irreparably injured"). Indeed, neither the Government, in its briefing here, nor the majority contests the point. Without a postponement of the TPS terminations, hundreds of thousands of Haitians and Syrians living in this country will lose their legal status and work authorization. Most will have no legal option except to leave the country, even at the price of leaving family behind; otherwise, they will likely be detained or removed. Some may be eligible to apply for asylum, but they will not be able to work here, so as a practical matter may also have to relocate. And where will any of those individuals go? Haiti and Syria are countries that the State Department continues to list as too dangerous for travel; they may be yet more perilous for a former inhabitant. Nor would there be much hope for an eventual return to this country, given statutory bars on reentry and TPS requirements of continuous presence. Hundreds of thousands of lives will be uprooted, most permanently, while this litigation to annul the Secretary's (likely illegal) termination orders proceeds.

Take as examples two of the individual plaintiffs here. Fritz Emmanuel Lesly Miot is a Haitian national who has held TPS for fifteen years. He lives in California where he works in a laboratory researching Alzheimer's, a job he can hold only because of his TPS work authorization. Miot suffers from Type 1 diabetes, which is easily treated in the United States. But in Haiti, the same disease can be a death sentence, given that country's collapsed health-care infrastructure (attributable to both natural disasters and political conditions). And beyond those health issues, Miot believes his long-term residency in the United States would make him a prime target in Haiti for a kidnapping. Or consider Laila Doe, who fled Syria with her daughter in 2013 after her neighborhood was bombed. Today, Doe lives in Illinois where she works as a behavioral technician for individuals with disabilities and cares for her elderly mother, a U. S. citizen. Without TPS, she will have to leave her mother and return to a still ravaged, violent, and dangerous country. Doe fears that as a single woman living alone, she will be robbed or even killed there. And she is afraid that her now 17-year-old daughter, who has lived in this country almost all her life, will have no future in Syria because she speaks little Arabic.

Miot, Doe, and the other plaintiffs before us deserve better than today's decision. True enough that TPS is a temporary program, and that it did not promise the plaintiffs never-ending humanitarian protection. But the law prevents the program from ending as it likely did here—without the required consultations about country conditions and, as to Haiti, with impermissible race-based considerations tainting the decision. At this juncture, both sets of plaintiffs ask for only one thing: that they may stay in this country while they continue to litigate their claims. For all the reasons given, they are entitled to that relief, and should not instead be consigned to devastating, and indeed life-threatening, injury.

Exhibit B

United States Court of Appeals
FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued September 25, 2025 Decided June 26, 2026

No. 24-5290

ARDELYX, INC., ET AL.,
APPELLANTS

v.

ROBERT F. KENNEDY, JR., SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.,
APPELLEES

Appeal from the United States District Court
for the District of Columbia
(No. 1:24-cv-02095)

Michael E. Bern argued the cause for appellants. With him on the briefs were *James E. McCollum, Jr.*, *Amit K. Sharma*, *Christine C. Smith*, *Alexander G. Siemers*, *Delia Tasky*, and *Nicholas L. Schlossman.*

Caroline D. Lopez, Attorney, U.S. Department of Justice, argued the cause for appellees. With her on the brief were *Yaakov M. Roth*, Acting Assistant Attorney General, *Michael S. Raab*, Attorney, and *David L. Hoskins*, Deputy Associate General Counsel for Litigation, U.S. Department of Health and Human Services. *Anna O. Mohan*, Attorney, U.S. Department of Justice, entered an appearance.

Before: CHILDS and PAN, *Circuit Judges*, and GINSBURG, *Senior Circuit Judge*.

Opinion for the Court filed by *Senior Circuit Judge* GINSBURG.

GINSBURG, *Senior Circuit Judge*: In 2008 the Congress directed the Secretary of Health and Human Services to "implement a payment system" that would provide a "single payment" for the reimbursement of "renal dialysis services" under Medicare, a federal health insurance program. *See* 42 U.S.C. § 1395rr(b)(14)(A)(i). In 2010 the Secretary, acting through the Centers for Medicare & Medicaid Services, defined "renal dialysis services" to include drugs with "only an oral form" — *i.e.*, oral-only drugs — furnished for the treatment of end-stage renal disease. 42 C.F.R. § 413.171(3) (2011). In 2024 the CMS identified XPHOZAH, an oral-only drug manufactured by Ardelyx, Inc., as a renal dialysis service covered by the new payment system starting on January 1, 2025. Before then, XPHOZAH, along with other orally administered drugs, had been reimbursed separately from the bundled payment under Medicare Part D.

Ardelyx, together with a healthcare research and advocacy organization and an organization representing the interests of kidney patients, challenged the CMS's definition of "renal dialysis services" as including oral-only drugs and the identification of XPHOZAH as a renal dialysis service.[*] The district court dismissed Ardelyx's complaint for lack of jurisdiction on the ground that the challenged actions were "identification[s] of renal dialysis services" within the meaning of 42 U.S.C.

[*] The Department of Health and Human Services, the Secretary of Health and Human Services, the CMS, and the Administrator of the CMS are all defendants and appellees in this lawsuit. For simplicity we refer to them collectively as the CMS.

§ 1395rr(b)(14)(G), which bars judicial review of such actions by the Secretary. *Ardelyx, Inc. v. Becerra* (*Ardelyx I*), 757 F. Supp. 3d 37, 46-47 (D.D.C. 2024). We agree and affirm the dismissal of Ardelyx's complaint.

I. Background

End-stage renal disease (ESRD) is a form of chronic kidney disease in which an individual's kidneys can no longer function on their own. Patients with ESRD who do not receive a kidney transplant will die unless they receive dialysis treatment several times per week. Medicare covers the cost of dialysis for patients suffering from ESRD. *See* 42 U.S.C. §§ 426-1, 1395rr(a).

A. Statutes and Regulations

In 1981 the Congress established a prospective payment system for the reimbursement of renal dialysis services in order to curb runaway costs. *See* Omnibus Budget Reconciliation Act of 1981, Pub. L. No. 97-35, § 2145, 95 Stat. 357, 799-800. Under this system, renal dialysis facilities and other providers of renal dialysis services would receive a prospective payment per treatment at a prescribed rate, regardless of their actual costs. *See* 48 Fed. Reg. 21254, 21260/3 (1983). This payment covered services including "routinely provided drugs, laboratory tests, and supplies." 75 Fed. Reg. 49030, 49032/1 (2010). A facility could retain any amount of the prospective payment that exceeded its actual costs. 48 Fed. Reg. at 21261/1. Certain items, such as erythropoiesis stimulating agents (ESAs), orally administered drugs, and most injectable drugs were reimbursed separately under Medicare Parts B or D.

The Congress believed this system would "encourage the more efficient delivery of dialysis services." 42 U.S.C. § 1395rr(b)(7). The system, however, also gave facilities an incentive to use the separately reimbursed items to treat ESRD because doing so allowed them to increase their total reimbursement. By 2010 these separately reimbursed items accounted for "40 percent of total spending for outpatient maintenance dialysis." 75 Fed. Reg. at 49032/2.

In order to bring that spending under control, the Congress enacted the Medicare Improvements for Patients and Providers Act of 2008, Pub. L. No. 110-275, § 153, 122 Stat. 2494, 2553. The MIPPA instructed the Secretary to "implement a payment system under which a single payment is made under this subchapter to a provider of services or a renal dialysis facility for renal dialysis services (as defined in subparagraph (B)) in lieu of any other payment." 42 U.S.C. § 1395rr(b)(14)(A)(i). Subparagraph (B), § 1395rr(b)(14)(B), defines "renal dialysis services" as follows:

For purposes of this paragraph, the term "renal dialysis services" includes--

(i) items and services included in the composite rate for renal dialysis services as of December 31, 2010;

(ii) erythropoiesis stimulating agents and any oral form of such agents that are furnished to individuals for the treatment of end stage renal disease;

(iii) other drugs and biologicals that are furnished to individuals for the treatment of end stage renal disease and for which payment was (before the application of this paragraph) made separately under this subchapter, and any oral equivalent form of such drug or biological; and

(iv) diagnostic laboratory tests and other items and services not described in clause (i) that are furnished to individuals for the treatment of end stage renal disease.[†]

Subparagraph (B) goes on to exclude vaccines from the definition of "renal dialysis services."

The Congress also limited review of the Secretary's actions with respect to the services covered by the new payment system. As relevant here, the Congress provided that

[†] For consistency with the district court's opinion, we refer to these categories as "subparts" of subparagraph (B).

"[t]here shall be no administrative or judicial review" of the Secretary's "identification of renal dialysis services included in the bundled payment." Subparagraph (G).

In 2009 the CMS published a notice of proposed rulemaking to implement the new prospective payment system. *See* 74 Fed. Reg. 49922. The CMS explained that it believed subpart (B) (iii) required it to include in the bundled payment "all drugs and biologicals formerly payable under either Medicare Part B or Part D used to treat ESRD, regardless of the route of administration," one effect of which was to include oral-only drugs. *Id.* at 49928/2-3. The CMS acknowledged that one could read "any oral equivalent form of such drug or biological" at the end of subpart (B)(iii) as "limit[ing] the scope of the drugs and biologicals included in the bundle to only oral versions of injectables (or other non-oral routes of administration)." *Id.* at 49928/3. Still, the CMS rejected that reading as "unduly constrained" because it would undermine the Congress's intent to include "all renal dialysis services furnished to ESRD patients in a comprehensive payment bundle." *Id.* The CMS alternatively invoked subpart (B)(iv), which covers "other items and services not covered in [subpart (B)] (i)," to support its inclusion of oral-only drugs in the bundled payment. *Id.*

In 2010 the CMS published the final rule implementing the bundled payment system. 75 Fed. Reg. 49030. In response to the "[m]any comments" it had received disagreeing with its reading of "renal dialysis services" to include oral-only drugs, *see id.* at 49038/2, the agency explained its view that the reference to oral equivalents in subpart (B)(iii) "pertains to the oral versions of injectable drugs." *Id.* at 49039/1. The CMS construed the reference earlier in subpart (B)(iii) to "other drugs [covered] under this [subchapter]" as including oral-only drugs in the definition of "renal dialysis services." *Id.* (cleaned up). In case the agency was wrong about the scope of subpart

(B)(iii), it again invoked subpart (B)(iv) in further support of its decision, characterizing that subpart as a "residual or catch all category for drugs which do not fall under the scope of those specified renal dialysis services identified" in subparts (ii) and (iii). *Id.* As a result, the final rule defines "renal dialysis services" reimbursed under the bundled payment to include:

> Other drugs and biologicals that are furnished to individuals for the treatment of ESRD and for which payment was (prior to January 1, 2011) made separately under Title XVIII of the Act (including drugs and biologicals with only an oral form).

42 C.F.R. § 413.171(3).

The CMS set an effective date of January 1, 2014 for the inclusion of oral-only drugs in the bundled payment to allow facilities, providers, pharmacies, and Medicare Part D plans to make necessary adjustments. 75 Fed. Reg. at 49044/1. Before the regulation went into effect, the Congress thrice delayed implementation of the bundled payment with respect to oral-only drugs, making the effective date January 1, 2025. *See* American Taxpayer Relief Act of 2012, Pub. L. No. 112-240, § 632(b), 126 Stat. 2313, 2354 (2013) (delaying implementation until January 1, 2016); Protecting Access to Medicare Act of 2014, Pub. L. No. 113-93, § 217(a), 128 Stat. 1040, 1061 (extending the delay until January 1, 2024); Achieving a Better Life Experience Act of 2014, Pub. L. No. 113-295, § 204, 128 Stat. 4010, 4065 (extending the delay until January 1, 2025). Along the way, the Congress also imposed other requirements related to the inclusion of oral-only drugs in the bundled payment. *See* § 632(b), 126 Stat. at 2354 (ordering the CMS to monitor the bone and mineral metabolism in ESRD patients "[w]ith respect to the implementation of oral-only ESRD-related drugs in the ESRD prospective payment system"); § 632(d), 126 Stat. at 2354-55 (directing the Government Accountability Office to report on "the Secretary's preparations to implement payment for oral-only ESRD-related drugs in the bundled prospective payment system"); § 217(d)(3), 128 Stat. at 1062-63 (requiring the CMS to establish performance measures for facilities regarding the quality of patient care "that are specific to the conditions treated with oral-only drugs").

B. The Identification of XPHOZAH

XPHOZAH is an oral-only drug manufactured by Ardelyx to treat hyperphosphatemia, a condition characterized by an abnormally high level of phosphate in the blood. Advanced kidney failure is the leading cause of hyperphosphatemia, which occurs in 80% of ESRD patients on maintenance dialysis. Patients with ESRD may begin treating hyperphosphatemia with phosphate binders, which prevent phosphate from entering the bloodstream by attaching to phosphate in the gastrointestinal tract. Of those patients with ESRD on maintenance dialysis who have hyperphosphatemia, however, 70% experience an inadequate response to phosphate binders and cannot maintain their target phosphate level.

In a declaration filed in support of its motion for a preliminary injunction, Ardelyx describes XPHOZAH as a "novel treatment option" for those patients. XPHOZAH blocks phosphate from entering the bloodstream through a different mechanism of action than phosphate binders. According to its FDA-approved label, XPHOZAH is indicated for use only by "adults with chronic kidney disease . . . on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy." The label also tells prescribers to "[i]nstruct patients not to take XPHOZAH right before a hemodialysis session."

In August 2023 — with the inclusion of oral-only drugs in the bundle still more than a year away — Ardelyx submitted a letter to the CMS asking it to continue excluding oral-only drugs such as XPHOZAH from the definition of "renal dialysis services" beyond January 1, 2025. Two months later, XPHOZAH received FDA approval and first became available to patients. XPHOZAH was initially covered under Medicare Part D and reimbursed separately from the bundled payment.

On May 13, 2024 the CMS notified Ardelyx that it had "identified XPHOZAH™ [as] a renal dialysis service under 42 C.F.R. 413.171, because it is furnished to individuals to treat a condition associated with ESRD and is essential to the delivery of maintenance dialysis." The letter informed Ardelyx that XPHOZAH would be included in the bundled payment for renal dialysis services beginning January 1, 2025.

C. Procedural History

On July 17, 2024 Ardelyx and the other appellants filed suit challenging both (1) the CMS's rule defining "renal dialysis services" to include oral-only drugs furnished for the treatment of ESRD, 42 C.F.R. § 413.171(3), and (2) the CMS's identification of XPHOZAH as a "renal dialysis service" included in the bundled payment. Ardelyx alleged these actions were arbitrary and capricious, an abuse of discretion, not in accordance with law, violative of statutory right, and in excess of the CMS's statutory authority, in violation of the Administrative Procedure Act, 5 U.S.C. § 706(2)(A), (C). The CMS moved to dismiss the complaint, arguing that sub-paragraph (14)(G) deprived the district court of authority to review the challenged actions. Ardelyx then moved for a preliminary injunction or, alternatively, for expedited summary judgment.

The district court granted the CMS's motion to dismiss. *Ardelyx I*, 757 F. Supp. 3d at 41. The district court first explained that in order to determine whether the bar to judicial review in subparagraph (14)(G) precluded it from reviewing the challenged actions, it had to determine whether the disputed actions were of the sort subparagraph (14)(B) authorized the Secretary to take. *Id.* at 48. The district court concluded they were.

The court first determined that defining "renal dialysis services" to include oral-only drugs was an "identification" within the meaning of the bar to judicial review in subparagraph (G), *id.* at 47, and was consistent with the definition of "renal dialysis services" in subparagraph (B), *id.* at 52-56. Specifically, the district court held that subpart (B)(iii) "directly incorporates into 'renal dialysis services' oral-only drugs by covering 'drugs and biologicals,' other than ESAs, that were previously reimbursed separately from the bundle." *Id.* at 52. The court also read subparagraph (B), which lists four types of things included in the definition of "renal dialysis services," as providing a non-exhaustive definition of that term. *Id.*

The district court next determined the CMS had the authority to identify XPHOZAH as a "renal dialysis service." The district court reasoned that XPHOZAH was furnished "for the treatment of" ESRD because it treats a condition "*caused by* or at least closely associated with kidney disease." *Id.* at 58. Having thus held the CMS had acted within its statutory authority, the district court did not consider Ardelyx's other arguments. *Id.*

Ardelyx moved to alter or amend the judgment or, alternatively, for an injunction pending appeal. The district court denied that motion. *Ardelyx, Inc. v. Becerra* (*Ardelyx II*), No. 24-cv-2095, 2024 WL 5186613 (D.D.C. Dec. 20, 2024). Ardelyx filed a timely notice of appeal and sought an injunction pending appeal, which we denied. As a result, the challenged portion of the rule went into effect on January 1, 2025, and XPHOZAH was included in the bundled payment.

II. Analysis

We review the district court's dismissal of Ardelyx's complaint de novo. *See Amgen, Inc. v. Smith*, 357 F.3d 103, 108 (D.C. Cir. 2004). On questions of statutory interpretation, this court "must exercise [its] independent judgment in deciding whether an agency has acted within its statutory authority." *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 412 (2024).

A. The Judicial-Review Provision, Subparagraph (14)(G)

Ardelyx challenges the Secretary's inclusion of oral-only drugs generally, and XPHOZAH specifically, in the bundled payment for renal dialysis services. At the outset, we must determine the scope of our authority to review the challenged actions. Recall that subparagraph (14)(G) bars judicial review of "the identification of renal dialysis services included in the bundled payment." According to the CMS, we lack the authority to review the challenged actions because they are "identification[s] of renal dialysis services" within the meaning of (14)(G). Ardelyx argues that (14)(G) does not cover the challenged actions because the CMS lacked authority to take those actions.

"We begin with the strong presumption that Congress intends judicial review of administrative action." *Bowen v. Mich. Acad. of Fam. Physicians*, 476 U.S. 667, 670 (1986).

This presumption is "particularly strong" where, as here, a party claims an agency has acted "in excess of delegated authority." *Amgen*, 357 F.3d at 111. As we have explained, the Congress "rarely intends to foreclose review of action exceeding agency authority." *Id.* at 112. To overcome the presumption, the party invoking the purported bar to judicial review must provide "clear and convincing evidence that Congress intended to preclude the suit." *Id.* at 111 (cleaned up); *cf. McLaughlin Chiropractic Assocs., Inc. v. McKesson Corp.*, 606 U.S. 146, 159 (2025) ("When Congress wants to bar a district court in an enforcement proceeding from reviewing an agency's interpretation of a statute, Congress can and must say so"). Most relevant here, the presumption can be overcome by "specific language" evincing a "congressional intent to preclude judicial review." *Ascension Borgess Hosp. v. Becerra*, 61 F.4th 999, 1003 (D.C. Cir. 2023) (cleaned up).

At first blush, (14)(G) seems to be precisely that. It simply says there "shall be no administrative or judicial review" of "the identification of renal dialysis services included in the bundled payment." As the district court observed, "[t]his stripping of judicial review . . . could not be clearer." *Ardelyx I*, 757 F. Supp. 3d at 47.

As the district court also realized, however, the judicial inquiry does not end there. A "jurisdiction-stripping provision does not apply if the agency's action fails to qualify as the kind of action for which review is barred." *Am. Hosp. Ass'n v. Azar*, 964 F.3d 1230, 1238 (D.C. Cir. 2020) (cleaned up). Consequently, in order "to determine whether the judicial-review bar applies in this case, we must decide whether the challenged agency action[s]" are the sort of actions shielded from review by (14)(G). *Id.*

We have previously applied this approach to another bar to judicial review involving prospective payments under Medicare. In 42 U.S.C. § 1395*l*(t)(12)(A), the Congress provided that "[t]here shall be no administrative or judicial review" of "the establishment of . . . other adjustments, and methods described in paragraph 2(F)." In *Amgen* we considered whether we had authority to review a challenge to a rule adjusting certain rates under Medicare Part B. 357 F.3d at 106-08. The CMS said it made the adjustments under § 1395*l*(t)(2)(E), which authorized it to establish "other adjustments as determined to be necessary to ensure equitable payments." *Id.* at 107. The CMS argued that subparagraph (12)(A) barred judicial review of the adjustments. Before dismissing the complaint, we had first to determine whether the equitable adjustments authorized by subparagraph (2)(E) qualified as "other adjustments" for purposes of the bar to judicial review in (12)(A) and, if so, whether (2)(E) authorized the Secretary to make the challenged adjustments. *Id.* at 111. These determinations were necessary, we explained, because the bar to judicial review "prevent[ed] review only of those 'other adjustments' that the Medicare Act authorizes the [CMS] to make." *Id.* at 112.

Similarly, in *American Hospital Association* we considered whether we had authority to review a challenge to a rate reduction implemented by the Department of Health and Human Services for a particular outpatient service. 964 F.3d at 1237. The agency had implemented the reduction pursuant to § 1395*l*(t)(2)(F), which authorized it to "develop a method for controlling unnecessary increases in the volume of covered [outpatient] services." *Id.* at 1235. HHS again invoked the bar to judicial review in (12)(A), which precludes review of "the establishment of . . . methods described in paragraph (2)(F)." *Id.* at 1237. The agency asked us to "dispose of the case on that basis at the threshold without examining HHS's authority to implement the rate reduction." *Id.* at 1237-38. We declined, noting that the premise of the plaintiffs' claim was that the challenged reduction was "*not* a 'method described in paragraph (2)(F)' within the meaning of the statute." *Id.* at 1238 (cleaned up). Pursuant to the reasoning in *Amgen*, we held (12)(A) barred us from reviewing the reduction only if it "qualified as a 'method for controlling unnecessary increases in volume' under subparagraph (2)(F)." *Id.* at 1238-39 (cleaned up). We then proceeded to consider that question. *See id.* at 1239-45.

The same reasoning applies here. Ardelyx claims the CMS exceeded its statutory authority by including oral-only drugs, including XPHOZAH, in the payment bundle. In order to determine whether we have authority to review Ardelyx's claims, we must decide whether the agency's actions qualify as an "identification of renal dialysis services" within the meaning of the bar to judicial review in subparagraph (14)(G). This, in turn, requires us to consider the meaning of "renal dialysis services" in subparagraph (14)(B).

The CMS insists we need not look past subparagraph (14)(G) in order to dismiss Ardelyx's challenge. According to the CMS, the only question is whether the CMS purported to identify or to "recognize" a drug as a renal dialysis service, which it indisputably did in the May 13, 2024 letter to Ardelyx. Needless to say, the CMS's authority to include a particular drug in the bundled payment does not turn upon its say-so. Indeed, we have previously described this as a "preposterous position" because a "bald assertion of power by an agency cannot legitimize it." *COMSAT Corp. v. FCC*, 114 F.3d 223, 227 (1997) (cleaned up); *see Amgen*, 357 F.3d at 113-14 (relying upon *COMSAT* to determine the scope of the bar to judicial review); *Am. Hosp.*, 964 F.3d at 1238 (same). "Otherwise, agencies could characterize reviewable or unauthorized action as falling within the scope of no-review provisions whose application to such action Congress did not intend." *Amgen*, 357 F.3d at 113.

We are also unpersuaded by the CMS's attempt to distinguish the reasoning of *Amgen* and *American Hospital Association*. The CMS claims the bar to judicial review in those cases expressly cross-referenced another provision, and reasons that we needed to consider the cross-referenced provisions only to determine the scope of the bar. Because (14)(G) does not cross-reference any other provision, the agency says, we need not look elsewhere.

As an initial matter, the CMS's description of the bar to judicial review we encountered in *Amgen* and in *American Hospital Association* is not entirely accurate. Although that provision included a specific cross-reference for "methods," it did not include one for "other adjustments" — the term at issue in *Amgen*. Even without an applicable cross-reference, we observed the use of "other adjustments" in the bar to judicial review "matches the language . . . in § 1395*l*(t)(2)(E), implying that Congress intended to reference adjustments made pursuant to that subsection." 357 F.3d at 113.

In this case, the CMS's argument fails for a simpler reason: The Congress expressly tied the bar to judicial review in (14)(G) to the definition of "renal dialysis services" in (14)(B) by defining that term "[f]or purposes of this paragraph" — *i.e.*, paragraph (14). As the district court observed, this "obviate[s] a need for an additional express link in" (14)(G) because that provision also refers to "renal dialysis services." *Ardelyx I*, 757 F.3d at 50. The term "renal dialysis services" has the same meaning in both provisions, so we must look to the definition in (14)(B) to determine the scope of (14)(G).

To be sure, this approach may "merge consideration of the legality of the [agency]'s action with consideration of this court's jurisdiction." *COMSAT*, 114 F.3d at 227 (cleaned up). Here, for example, the question whether the CMS exceeded its authority by including oral-only drugs and XPHOZAH in the bundled payment coincides with the question whether each of those actions qualifies as an "identification of renal dialysis services." This inquiry does not, however, render the judicial-review bar irrelevant. That bar "still forecloses inquiry into whether the challenged agency decision is arbitrary, capricious, or procedurally defective." *Am. Hosp.*, 964 F.3d at 1239 (cleaned up). If the CMS acted within its authority by including oral-only drugs and XPHOZAH in the bundled payment, then we lack authority to review whether those actions were "reasonable and reasonably explained," as required by the APA. *FCC v. Prometheus Radio Proj.*, 592 U.S. 414, 423 (2021). We review the merits of Ardelyx's challenge, therefore, only "to the extent necessary to determine whether the challenged agency actions fall within the scope of the preclusion of judicial review." *Amgen*, 357 F.3d at 113 (cleaned up).

B. Ardelyx's Challenge to the Regulation, 42 C.F.R. § 413.171(3)

In this section we consider whether the CMS's inclusion of oral-only drugs in the bundled payment constitutes an "identification of renal dialysis services." Subparagraph (14)(G).[‡] Recall that the CMS has defined "renal dialysis services" to include drugs furnished for the treatment of ESRD that have "only an oral form." 42 C.F.R. § 413.171(3). Ardelyx

[‡] The CMS erroneously implies that Ardelyx's complaint did not challenge the regulation defining "renal dialysis services" to include oral-only drugs. Ardelyx's complaint plainly challenges § 413.171(3). *See* Compl. ¶¶ 212-15 (arguing the CMS's promulgation of § 413.171(3) was "arbitrary, capricious, an abuse of discretion, not in accordance with law, in excess of statutory jurisdiction and authority, and short of statutory right").

offers two reasons the bar to judicial review does not preclude its challenge to this aspect of the rule. First, Ardelyx argues the CMS's promulgation of the rule was not an "identification" for purposes of subparagraph (14)(G). Second, Ardelyx claims the definition of "renal dialysis services" does not include oral-only drugs, so the CMS lacks authority to include such drugs in the bundled payment.

1. "Identification"

Ardelyx asserts that an "identification" within the bar to review in (14)(G) means the selection of a particular drug rather than a category of drugs. Because 42 C.F.R. § 413.171(3) speaks of a category, Ardelyx argues (14)(G) does not preclude us from reviewing its challenge to the regulation.

The statute does not define "identification," so we give that term its ordinary meaning. *Taniguchi v. Kan Pacific Saipan, Ltd.*, 566 U.S. 560, 566 (2012). The parties offer several definitions of "identify." The CMS refers us to the Oxford English Dictionary, which defines to "identify" as to "recognize as belonging to a particular category or kind." Ardelyx points to the Merriam-Webster Dictionary, where to "identify" means to "state the identity of . . . something," and to the Federal Circuit, which has defined to "identify" as to "recognize or establish an object as being a particular thing," *Apple Inc. v. Omni MedSci, Inc.*, No. 2023-1034, 2024 WL 3084509, at *5 (June 21, 2024); *see also Ardelyx I*, 757 F. Supp. 3d at 47 (defining to "identify" as to "recognize something and say or prove what that thing is" (cleaned up)).

Each of these definitions is broad enough to cover the CMS's determination that oral-only drugs furnished for the treatment of ESRD qualify as renal dialysis services. The CMS has recognized something (oral-only drugs furnished for the treatment of ESRD) as being a particular thing or as belonging to a particular category, namely, renal dialysis services. The CMS's promulgation of the regulation thus fits comfortably within the meaning of "identification" in (14)(G). Nothing in the statute or in the definitions offered by Ardelyx supports its narrower reading, which would preclude the CMS from making categorical determinations about which drugs to include in the bundle.

A contrary conclusion would too easily allow a plaintiff to circumvent subparagraph (G) and challenge the inclusion of a particular drug in the bundle. As the CMS notes, Ardelyx does not challenge the regulation "in a vacuum"; it also challenges the inclusion of XPHOZAH in the bundle "consistent with this regulation." Ardelyx does not argue that the May 13, 2024 letter selecting XPHOZAH for the bundle was not an "identification." Under Ardelyx's reading of "identification," however, "almost any challenge to an [identification of a particular drug] could be recast as a challenge to [the] underlying [regulation]," *DCH Reg. Med. Ctr. v. Azar*, 925 F.3d 503, 506 (D.C. Cir. 2019), an artful dodge we cannot allow. *Accord Palisades Gen. Hosp. Inc. v. Leavitt*, 426 F.3d 400, 405 (D.C. Cir. 2005) ("[W]hen a procedure is challenged solely in order to reverse an individual . . . decision" covered by a bar to judicial review, "judicial review is not permitted").

For this reason, the CMS argues we lack jurisdiction to consider Ardelyx's challenge to the regulation because that challenge is "inextricably intertwined" with the challenge to the identification of XPHOZAH. Yet Ardelyx raises distinct arguments as to why each action does not qualify as an "identification of renal dialysis services." For example, as just discussed, Ardelyx argues the CMS's promulgation of § 413.171(3) was not an "identification" for purposes of the bar to judicial review; it does not raise that argument with respect to XPHOZAH. Moreover, even if we viewed Ardelyx's challenge to the regulation as "inextricably intertwined" with its challenge to XPHOZAH, we would still have to consider whether the CMS had authority to include XPHOZAH in the bundle for the reasons discussed. We therefore consider both of Ardelyx's challenges below.

2. "Renal dialysis services"

Ardelyx's principal challenge to 42 C.F.R. § 413.171(3) is that the definition of "renal dialysis services" in (14)(B) excludes oral-only drugs. That subparagraph lists four categories that the Congress "include[d]" in the definition of "renal dialysis services." Ardelyx maintains those categories provide an exhaustive definition of "renal dialysis services," and none of them includes oral-only drugs that are not provided by dialysis facilities during dialysis. The CMS justifies its inclusion of oral-only drugs in the bundle in three ways. First, it argues oral-only drugs fit within the definition of "renal dialysis services" in the third enumerated category, subpart (B)(iii). Second, it interprets the fourth enumerated category, subpart (B)(iv), as a catchall provision covering "newly developed items and services that are not otherwise covered by the prior [subparts]." Third, it claims it has discretion to include in the bundle drugs that are not expressly covered by the four categories in subparagraph (14)(B) because that subparagraph is a non-exhaustive definition of renal dialysis services. Because we agree with the agency's first point, we do not reach its other arguments.

Subpart (iii) defines "renal dialysis services" to include:

> [(1a)] other drugs and biologicals that are furnished to individuals for the treatment of end stage renal disease and [(1b)] for which payment was (before the application of this

> paragraph) made separately under this subchapter, and [(2)] any oral equivalent form of such drug or biological.

Based upon the plain text of this subpart, we hold the CMS has the authority to include oral-only drugs in the bundled payment. The first clause in the subpart establishes two criteria for inclusion in the definition of a renal dialysis service. The first, which we have denominated [1a], includes in the definition "other drugs and biologicals" furnished for the treatment of ESRD, of which the CMS claims XPHOZAH is one (a matter we take up later); it does not exclude drugs based upon their form of administration. Oral-only drugs also satisfy the second criterion in the first clause [1b] if they were paid for "separately under this subchapter" and "before the application of this paragraph." *Id.* As the district court said, "'this subchapter' refers to Subchapter XVIII, which includes Medicare Parts A, B, C, *and* D," and thus "'separately under this subchapter' includes all drugs paid [for] separately under any reimbursement system." *Ardelyx II*, 2024 WL 5186613, at *10. Ardelyx does not challenge that conclusion on appeal. Ardelyx also acknowledged in its complaint that under the prior payment system, "orally administered ESRD drugs were generally covered separately under Medicare Part D." Compl. ¶ 65. Therefore, payment for certain oral-only drugs was "made separately under this subchapter" and "before the application of" the new bundled payment system. It follows, as the district court said, that subpart (iii) "directly incorporates" oral-only drugs in the definition of "renal dialysis services." *Ardelyx I*, 757 F. Supp. 3d at 52.

Resisting this conclusion, Ardelyx focuses on the second clause [2] of subpart (iii), which includes in the definition "any oral equivalent form of such drug or biological" covered by the first clause. Ardelyx argues that the express inclusion of oral drugs in this clause implies the Congress intended to exclude oral drugs from the first clause.

The CMS rejected this interpretation of the statute as "unduly constrained." 74 Fed. Reg. at 49928/3. We agree. The Congress spoke clearly when it wanted to address drugs administered in a certain form and when it wanted to omit particular items from the definition of "renal dialysis services." It did so by referring to oral drugs in both subparts (B)(ii) and (B)(iii), and by expressly excluding vaccines from subparagraph (B). The Congress did not exclude oral-only drugs from the first clause of subpart (iii), and we may not read that limitation into the statute. *See Lomax v. Ortiz-Marquez*, 140 S. Ct. 1721, 1725 (2020) ("Court[s] may not narrow a provision's reach by inserting words Congress chose to omit"); *Centro de Trabajadores Unidos v. Bessent*, 167 F.4th 1218, 1231 (D.C. Cir. 2026) (declining to read "address" to mean "*current* address" in a statute authorizing the disclosure of taxpayer information because the statute did "not specify what address must be included").

For similar reasons, we are unpersuaded by Ardelyx's contention that "renal dialysis services" include only drugs "provided by dialysis facilities during dialysis." That limitation appears nowhere in the subpart (B)(iii) definition of "renal dialysis services," which instead refers broadly to drugs furnished "for the treatment of" ESRD without regard to where or when they are furnished. In the medical context, "treatment" means "medical application of remedies so as to effect a cure," WEBSTER'S II DICTIONARY (3rd ed. 2005), and "management and care to prevent, cure, ameliorate, or slow progression of a medical condition," MERRIAM-WEBSTER DICTIONARY ONLINE. That definition easily encompasses a drug furnished to treat ESRD even if it is administered outside of a dialysis treatment.

This reading also accords with the Congress's intent to bring more services into the bundled payment.

Ardelyx erroneously contends this reading renders the second clause of subpart (iii) superfluous because the first clause would cover all oral drugs and because there cannot be an "oral equivalent form" of an oral-only drug. In fact, however, the first clause covers only drugs furnished to treat ESRD — regardless the form of administration — that were separately reimbursed "before the application of" paragraph (14). The second clause thus brings in any oral equivalent form of a drug covered by the first clause that became or becomes available after the application of paragraph (14). If an injectable drug is covered by the first clause, then the second clause would cover a subsequently developed oral-equivalent form of that drug. In those instances, the second clause is not superfluous. That some drugs covered by the first clause will not have an oral equivalent does not, as Ardelyx suggests, compel a different reading of the statute. "Language in a statute is not rendered superfluous merely because in some contexts that language may not be pertinent." *United States v. Turkette*, 452 U.S. 576, 583 n.5 (1981).

In a last gasp, Ardelyx notes that if the Congress had intended subpart (B)(iii) to include oral-only drugs, then it could have done so "using far fewer and simpler words." Perhaps so, but providing for the inclusion of "other drugs and biologicals" is one clear and reasonably succinct way of including certain drugs regardless of their form of administration. "[T]he mere possibility of clearer phrasing cannot defeat the most natural reading of a statute." *Caraco Pharm. Lab'ys, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 416 (2012).

We believe subpart (B)(iii) on its face defeats Ardelyx's challenge to the regulation. Seeking help elsewhere, Ardelyx cites one failed bill introduced in the House of Representatives that would have expressly added oral-only drugs to subpart (B)(iii), as though they were not already included in that subpart. *See* America's Affordable Health Choices Act of 2009, H.R. 3200, 111th Cong. § 1232(b)(1). Because the bill did not pass, Ardelyx believes this shows the Congress did not intend for subpart (B)(iii) to cover oral-only drugs. "Failed legislative proposals," however, "are a particularly dangerous ground on which to rest an interpretation of a prior statute" because "several equally tenable inferences may be drawn from such inaction, including the inference that the existing legislation already incorporated the offered change." *United States v. Craft*, 535 U.S. 274, 287 (2002) (cleaned up); *see also Knapp Med. Ctr. v. Hargan*, 875 F.3d 1125, 1130 (D.C. Cir. 2017) ("We can infer nothing from the Congress's consideration and rejection of a differently worded provision in a separate piece of legislation").

Subsequent congressional enactments, on the other hand, have the force of law and reflect the Congress's understanding of the pre-existing state of the law. Consequently, these actions may inform our analysis because "the meaning of one statute may be affected by other Acts, particularly where Congress has spoken subsequently and more specifically to the topic at hand." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000). Indeed, "it is well established that a court can, and should, interpret the text of one statute in the light of text of surrounding statutes, even those subsequently enacted." *Vt. Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 786 n.17 (2000).

The relevant post-enactment history demonstrates that the Congress was aware of the CMS's position regarding oral-only drugs and subpart (B)(iii) and repeatedly acted in a manner consistent with that position rather than undermining or correcting it. *See Brown & Williamson*, 529 U.S. at 155-56. As we have seen in its notice of proposed rulemaking and in the final rule, issued in 2009 and 2010 respectively, the CMS interpreted subpart (B)(iii) as including all drugs furnished for the treatment of ESRD "regardless of the route of administration." 74 Fed. Reg. at 49928/3; *see* 75 Fed. Reg. at 49039/1. Consequently, the final regulation defined "renal dialysis services" to include "drugs and biologicals with only an oral form." 42 C.F.R. § 413.171(3).

Against this backdrop, the Congress passed legislation that reflected its awareness of the CMS's position. "When Congress revisits a statute giving rise to a longstanding administrative interpretation without pertinent change, the congressional failure to revise or repeal the agency's interpretation is persuasive evidence that the interpretation is the one intended by Congress." *CFTC v. Schor*, 478 U.S. 833, 846 (1986) (cleaned up).

On three occasions in 2013 and 2014 the Congress expressly acknowledged the CMS's inclusion of oral-only drugs in the bundle without disapproving or amending subparagraph (B). *See* § 632(b)(1), 126 Stat. at 2354 (2013) (delaying the implementation of the bundled payment system to oral-only drugs until January 1, 2016); § 217(a)(1), 128 Stat. at 1061 (2014) (extending the delay until January 1, 2024); and § 204, 128 Stat. at 4065 (2014) (extending the delay until January 1, 2025); *see also* § 632(a), 126 Stat. at 2354 (amending paragraph (14) by adding subparagraph (I), which refers to "oral-only ESRD-related drugs, as such term is used in the final rule promulgated by the Secretary" (citing 75 Fed. Reg. 49030)). At the same time, the Congress ordered additional agency action to collect data on and assess the effect of oral-only drugs and their treatment of ESRD. *See* § 632(b)(2), 126 Stat. at 2354 (ordering the CMS to monitor the bone and mineral metabolism in ESRD patients "[w]ith respect to the implementation of oral-only ESRD-related drugs in the ESRD prospective payment system"); § 632(d), 126 Stat. at 2354-55 (ordering the GAO to report on the Secretary's preparations for adding oral-only drugs to the bundled payment); § 217(c)(1), 128 Stat. at 1062 (ordering the CMS to "establish a process for . . . determining when a product is no longer an oral-only drug" as "part of the promulgation of [the] annual rule for the Medicare [ESRD] prospective payment system under [paragraph (14)] for calendar year 2016"); and § 217(d)(3), 128 Stat. at 1062-63 (directing the CMS to establish performance measures for facilities regarding the quality of patient care "specific to the conditions treated with oral-only drugs").

These congressional enactments not only left the CMS's definition of "renal dialysis services" unchanged; as the CMS notes, they would make no sense if the Congress had excluded oral-only drugs from the definition of "renal dialysis services." The only logical conclusion is that the Congress agreed with, and acted upon the basis of, the CMS's interpretation of the statute.

3. "Before the application of this paragraph"

Here we address briefly one remaining dispute regarding the scope of subpart (B)(iii). The first clause in that subpart covers a drug only if payment for that drug was made separately "before the application of this paragraph." The district court concluded that "before the application of this paragraph" in that provision means before January 1, 2025 for oral-only drugs such as XPHOZAH because the Congress delayed the implementation of 42 C.F.R. § 413.171(3) until then. *Ardelyx I*, 757 F. Supp. 3d at 53. The CMS seemed to agree with the district court in its brief in this court, whereas Ardelyx's brief argues that approach would create a "nonsensical patchwork" in which "before the application of this paragraph" takes on a different meaning based upon a drug's form of administration: before January 1, 2011 for non-oral drugs, and before January 1, 2025 for oral-only drugs. Ardelyx also asserts this reading of the statute would exclude from the bundle several injectable drugs approved after 2011 that the CMS has included and would preclude adding to the bundle any oral-only drugs launched after January 1, 2025. Ardelyx instead suggests "before the application of this paragraph" means before January 1, 2011 for all drugs.[§]

We need not decide the meaning of the disputed phrase. Despite the differing interpretations before us, we fail to see how its meaning affects the outcome of this appeal. Recall that the regulation applies to oral-only drugs "for which payment was (prior to January 1, 2011) made separately." § 413.171(3). If we accept Ardelyx's position that "before application of this paragraph" means before January 1, 2011, then the regulation uses the same date as the statute. If we adopt the district court's conclusion that "before the application of this paragraph" means before January 1, 2025 for oral-only drugs, then the regulation still works with the statute. As that court observed, "Any oral-only drug for which payment was made separately prior to January 2011, per § 413.171(3), is necessarily one for which payment was made separately . . . before January 1, 2025." *Ardelyx I*, 757 F. Supp. 3d at 54. Either way, the CMS acted within its delegated authority by promulgating the regulation.

[§] In a post-argument letter, the CMS offered an alternative interpretation: "at the time that the paragraph is actually applied to any newly developed drug, 'payment was . . . made separately under this subchapter' for that drug." We do not address the CMS's belated position below.

If Ardelyx had argued the CMS lacked authority to include XPHOZAH in the bundle because it was not available before January 2011, then we would need to resolve the meaning of "before the application of this paragraph" as applied to oral-only drugs, including XPHOZAH. Ardelyx did raise that argument in its motion asking the district court to alter the judgment, but it did not pursue the argument on appeal. Indeed, the only argument Ardelyx makes with respect to the identification of XPHOZAH is that the CMS exceeded its authority because XPHOZAH is not "furnished . . . for the treatment of" ESRD but rather "to treat hyperphosphatemia," to the merits of which we turn below. That argument does not depend on our resolution of Ardelyx's objections to the final rule or on the meaning of "before the application of this paragraph" in subpart (B)(iii).

We therefore have no need to address the precise meaning of "before the application of this paragraph." Insofar as the meaning of this phrase may matter for the identification of any other drugs as "renal dialysis services," those drugs are not before the court.

In sum, we conclude that subpart (B)(iii) defines "renal dialysis services" to include oral-only drugs furnished for the treatment of ESRD and for which payment was made separately "before the application of [that] paragraph." Because the regulation, 42 C.F.R. § 413.171(3), accords with the statutory definition, subparagraph (14)(G) precludes us from reviewing the regulation any further.

C. Ardelyx's Challenge to the Identification of XPHOZAH

Finally, as just mentioned, Ardelyx challenges the CMS's identification of XPHOZAH as a renal dialysis service covered by the bundled payment. Even if the CMS can include some oral-only drugs in the bundle, Ardelyx argues, the CMS cannot include XPHOZAH because it is not furnished for the treatment of ESRD. Again, "XPHOZAH is furnished to treat hyperphosphatemia, not ESRD."

Ardelyx relies upon an unduly narrow reading of the phrase "for the treatment of [ESRD]" in subpart (B)(iii). Consider subpart (B)(ii), which defines "renal dialysis services" to include "erythropoiesis stimulating agents and any oral form of such agents that are furnished to individuals for the treatment of [ESRD]." ESAs treat anemia, a condition often caused by renal disease. Subpart (B)(ii) thus indicates the Congress intended the phrase "furnished . . . for the treatment of [ESRD]" to cover drugs that treat a condition commonly caused by ESRD. To read that phrase differently in a neighboring provision would run afoul of the "presumption that a given term is used to mean the same thing throughout a statute." *Brown v. Gardner*, 513 U.S. 115, 118 (1994).

Also, as we have seen, above at 21, "treatment" as used in the definition of "renal dialysis services" in (B)(iii) includes the management and care of a medical condition. That definition includes not only drugs that treat ESRD specifically but also drugs such as XPHOZAH that treat conditions closely associated with ESRD.

Hyperphosphatemia, which is most commonly caused by ESRD, occurs in 80% of ESRD patients on maintenance dialysis. Of those patients, 70% cannot maintain their target phosphate levels with phosphate binders. This is where XPHOZAH comes in.

As the CMS emphasizes, XPHOZAH's only approved use is to treat hyperphosphatemia "in adults with chronic kidney disease (CKD) on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy." Indeed, Ardelyx itself said in a declaration supporting its motion for a preliminary injunction that XPHOZAH is "approved as an add-on therapy for patients with ESRD on maintenance dialysis." It is therefore unsurprising that even Ardelyx describes XPHOZAH, in that same declaration, as a "treatment option" for patients with ESRD on dialysis who experience an inadequate response to phosphate binders.

Finally, Ardelyx claims the CMS's identification of XPHOZAH "is at odds" with its exclusion of other drugs that treat conditions commonly associated with or caused by ESRD. This argument goes to the quality of the CMS's reasoning rather than the scope of its authority. Per subparagraph (14)(G), therefore, we lack jurisdiction to consider it.

III. Conclusion

For the foregoing reasons, the district court order dismissing Ardelyx's complaint is

Affirmed.