Nos. 25-1611, 25-1612

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

AMERICAN PUBLIC HEALTH ASSOCIATION; IBIS REPRODUCTIVE HEALTH; INTERNATIONAL UNION, UNITED AUTOMOBILE, AEROSPACE, AND AGRICULTURAL IMPLEMENT WORKERS (UAW); BRITTANY CHARLTON; KATIE EDWARDS; PETER LURIE; NICOLE MAPHIS,

Plaintiffs-Appellees,

v.

NATIONAL INSTITUTES OF HEALTH; JAY BHATTACHARYA, in the official capacity as Director of the National Institutes of Health; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ROBERT F. KENNEDY, JR., in the official capacity as Secretary of the United States Department of Health & Human Services,

Defendants-Appellants.

COMMONWEALTH OF MASSACHUSETTS; STATE OF CALIFORNIA; STATE OF MARYLAND; STATE OF WASHINGTON; STATE OF ARIZONA; STATE OF COLORADO; STATE OF DELAWARE; STATE OF HAWAII; STATE OF MINNESOTA; STATE OF NEVADA; STATE OF NEW JERSEY; STATE OF NEW MEXICO; STATE OF NEW YORK; STATE OF OREGON; STATE OF RHODE ISLAND; STATE OF WISCONSIN,

Plaintiffs-Appellees,

v.

ROBERT F. KENNEDY, JR., in the official capacity as Secretary of Health and Human Services; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; JAY BHATTACHARYA, in the official capacity as Director of the National Institutes of Health; NATIONAL INSTITUTES OF HEALTH; NATIONAL CANCER INSTITUTE; NATIONAL EYE INSTITUTE; NATIONAL HEART LUNG AND BLOOD INSTITUTE; NATIONAL HUMAN GENOME RESEARCH INSTITUTE; NATIONAL INSTITUTE ON AGING; NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM; NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES; NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES; NATIONAL INSTITUTE OF BIOMEDICAL IMAGING AND BIOENGINEERING; EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT; NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION

DISORDERS; NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH; NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES; NATIONAL INSTITUTE ON DRUG ABUSE; NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES; NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES; NATIONAL INSTITUTE OF MENTAL HEALTH; NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES; NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE; NATIONAL INSTITUTE OF NURSING RESEARCH; NATIONAL LIBRARY OF MEDICINE; NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES; JOHN E. FOGARTY INTERNATIONAL CENTER FOR ADVANCED STUDY IN THE HEALTH SCIENCES; NATIONAL CENTER FOR COMPLEMENTARY AND INTEGRATIVE HEALTH; NIH CENTER FOR SCIENTIFIC REVIEW,

Defendants-Appellants.

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

BRIEF FOR APPELLANTS

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REASONS WHY ORAL ARGUMENT SHOULD BE HEARD

The district court entered a partial final judgment that ordered the government to continue funding research contrary to the President's policy priorities and vacated guidance implementing the President's policy priorities. The government respectfully requests that the Court hold oral argument. Argument will aid the Court in resolving the important issues presented by this appeal.

INTRODUCTION

The district court ordered the National Institutes of Health (NIH) to pay money to plaintiffs (or their instrumentalities or members) based on the government's alleged contractual obligation under certain grant for biomedical research and research training. The court lacked jurisdiction to issue such an order. As the Supreme Court explained in this case, the "Administrative Procedure Act[(APA)]'s 'limited waiver of [sovereign] immunity' does not provide the District Court with jurisdiction to adjudicate claims 'based on' the research-related grants or to order relief designed to enforce any 'obligation to pay money' pursuant to those grants." *NIH v. American Pub. Health Ass'n*, 145 S. Ct. 2658, 2659 (2025) (second alteration in original).

The district court also erred in vacating NIH's guidance on grant priorities. Plaintiffs' challenge is now moot, as NIH has since updated the guidance to address many of the court's concerns. Moreover, plaintiffs lack standing because they have not suffered any cognizable injury, and the guidance does not constitute final agency action subject to review under the APA. The court avoided these threshold issues by analyzing the guidance and the grant terminations together as part of a "wholesale effort to excise grants." A155. But that approach is no longer viable, as the court lacks jurisdiction over the terminations.

In any event, plaintiffs' challenge to the guidance fails on the merits. Decisions about what grants to fund are generally committed to agency discretion. Absent a violation of statute or regulation, which the district court did not find here, such

decisions are not subject to APA review. The guidance was also appropriately tailored to its intended audience: internal agency experts expected to exercise their professional judgment. It was never intended to have the same level of specificity as rules binding on the public. Moreover, the guidance clearly articulated the interests being advanced and NIH's reasons for its decisions.

STATEMENT OF JURISDICTION

Plaintiffs brought this action alleging that certain federal grants for biomedical research and research training were improperly terminated. The district court believed it had jurisdiction under 28 U.S.C. § 1331, but the court lacked jurisdiction over the grant terminations for the reasons stated in Part I below. The court issued partial final judgments that vacated NIH guidance and plaintiffs' grant terminations as arbitrary and capricious. A73; A75; *see* Fed. R. Civ. P. 54(b). The United States filed a timely notice of appeal. A550; A553; *see* Fed. R. App. P. 4(a)(1)(B) (60-day time limit). This Court has jurisdiction over the appeal under 28 U.S.C. § 1291.

STATEMENT OF THE ISSUES

1. Whether the district court properly granted relief on claims that plaintiffs are entitled to monetary payments under a grant program.

2. Whether the district court properly vacated internal agency guidance on grant funding priorities that has been materially changed by subsequent guidance and only directed a review of existing grants.

STATEMENT OF THE CASE

A. Statutory Background

These cases involve grant terminations at NIH, a subagency of the Department of Health and Human Services (HHS). NIH is made up of two dozen national research institutes and centers (ICs) that focus on specific diseases or body systems, like the National Institute of Allergy and Infectious Diseases. 42 U.S.C. § 281(b). NIH and its ICs have broad authority to award grants to fund research by universities, hospitals, laboratories, individuals, and other research institutions "relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man." *Id.* § 241(a)(1); *see id.* § 284(b)(1)-(2). Congress supports that research via lump-sum appropriations. *See generally id.* § 282a (allocating sums for certain fiscal years "[f]or purposes of carrying out this subchapter"). For example, in 2024 Congress appropriated $6.5 billion for the National Institute of Allergy and Infectious Diseases to carry out the Public Health Service Act "with respect to allergy and infectious diseases." Further Consolidated Appropriations Act, 2024, Pub. L. No. 118-47, div. D, tit. II, 138 Stat. 460, 656; *see* Full-Year Continuing Appropriations and Extensions Act, 2025, § 1101(a)(8), Pub L. No. 119-4, div. A, tit. I, 139 Stat. 9, 11 (carrying forward HHS's 2024 appropriation into 2025).

Because funding is finite, NIH grants are "highly competitive," and the agency approves only 20% of applications. NIH, *Grants & Funding* (Oct. 15, 2024), https://perma.cc/L93C-KSY4. The process begins with a public notice of funding

opportunity that outlines the program goals and the conditions for applying. A476-477. Interested entities submit a proposal, which undergoes three layers of review. First, a "study section," which is a group of non-federal scientists with expertise in the relevant field, reviews the proposal and eliminates some grant applications from further consideration and assigns a score to the rest. A477-479. Next, the proposal is reviewed by an advisory council for the relevant IC, which renders one of three decisions: recommended for funding, not recommended for funding, or deferred for re-review by the study section. A480. A recommendation for funding is a prerequisite for any grant of more than $50,000 but does not guarantee that the grant will be funded. 42 U.S.C. § 284(b)(2). Lastly, the proposal is reviewed by the head of the relevant IC, who has the discretion as to whether to fund the grant. A481; A399 (acknowledging that "[f]inal authority to make an award belongs to the Director of the [national research institute] responsible for the grant"); A90 (district court acknowledging same).

Once a grant is selected for award, the grant terms are memorialized in a Notice of Award (NOA)—a formal legal document issued by the funding IC to the recipient. A2451. The NOA sets out "the amount of funds awarded" and the "terms and conditions" of the award, which the recipient accepts "by drawing or requesting funds." A2453-2455.

The NOAs incorporate express caveats that awards can be terminated if they do not support agency objectives or policies. Specifically, all NIH grants incorporate

by reference the NIH Grants Policy Statement, which in turn incorporates Office of Management and Budget (OMB)'s guidance for federal financial assistance in 2 C.F.R. pt. 200. A2449, 2460. OMB's guidance states that a "Federal award may be terminated" by the agency, "to the extent authorized by law, if an award no longer effectuates the program goals or agency priorities." 2 C.F.R. § 200.340(a)(4). Further, all NIH grants are subject to HHS's uniform administrative requirements for federal awards. 45 C.F.R. § 75.101; *see, e.g.*, A786 (NOA incorporating the NIH Grants Policy Statement and 45 C.F.R. pt. 75). Those HHS requirements mandate that NIH grants be administered "so as to ensure that Federal funding is expended and associated programs are implemented in full accordance with U.S. statutory and public policy requirements," including those "prohibiting discrimination." 45 C.F.R. § 75.300(a).

B. Factual Background

1. Immediately after his inauguration, President Trump issued a trio of executive orders announcing policy directives relevant to the grants at issue in this case.

On January 20, 2025, the President issued Executive Order No. 14,151, 90 Fed. Reg. 8339 (Jan. 29, 2025), titled *Ending Radical and Wasteful Government DEI Programs and Preferencing*, to eliminate "illegal and immoral discrimination programs, going by the name 'diversity, equity, and inclusion' (DEI)" from the government, *id.* § 1, 90 Fed. Reg. at 8339. That Executive Order rescinded President Biden's Executive Order that mandated "an ambitious whole-of-government equity agenda" and

instructed federal agencies to "allocate resources to address the historic failure to invest sufficiently, justly, and equally in underserved communities," *i.e.*, "populations sharing a particular characteristic . . . that have been systematically denied a full opportunity to participate in aspects of economic, social, and civic life." *Advancing Racial Equity and Support for Underserved Communities Through the Federal Government*, Exec. Order No. 13,985, §§ 1, 2, 6, 86 Fed. Reg. 7009, 7009-10 (Jan. 25, 2021). President Trump instead directed "[e]ach agency, department, or commission head" to "terminate, to the maximum extent allowed by law, all . . . 'equity-related' grants or contracts." Exec. Order No. 14,151, § 2(b)(i), 90 Fed. Reg. at 8339.

On January 21, 2025, President Trump issued Executive Order No. 14,173, 90 Fed. Reg. 8633 (Jan. 31, 2025), titled *Ending Illegal Discrimination and Restoring Merit-Based Opportunity*, "to enforce our longstanding civil-rights laws and to combat illegal private-sector DEI preferences, mandates, policies, programs, and activities." *Id.* § 2, 90 Fed. Reg. at 8633. That Executive Order instructs each agency head to "include in every contract or grant award . . . [a] term requiring [the] counterparty or recipient to certify that it does not operate any programs promoting DEI that violate any applicable Federal anti-discrimination laws." *Id.* § 3(b)(iv)(B), 90 Fed. Reg. at 8634. And that Order directs the head of the OMB to "[e]xcise references to DEI . . . principles, under whatever name they may appear, from Federal acquisition, contracting, grants, and financial assistance procedures." *Id.* § 3(c)(ii), 90 Fed. Reg. at 8634.

On January 20, 2025, the President also issued Executive Order No. 14,168, 90 Fed. Reg. 8615 (Jan. 30, 2025), titled *Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government*. That Executive Order affirms "the immutable biological reality of sex" and rejects its replacement "with an ever-shifting concept of self-assessed gender identity" via "'[g]ender ideology.'" *Id.* §§ 1, 2(f), 90 Fed. Reg. at 8615. The Executive Order directs federal agencies to "take all necessary steps, as permitted by law, to end the Federal funding of gender ideology." *Id.* § 3(e), 90 Fed. Reg. at 8616. And the Order directs agencies to "ensure grant funds do not promote gender ideology." *Id.* § 3(g), 90 Fed. Reg. at 8616.

2. Beginning in February 2025, NIH moved to terminate grants that do not align with the Administration's policy priorities.

To guide this process, the Acting HHS Secretary on February 10, 2025, issued a "Secretarial Directive on DEI-Related Funding." A98-99 (capitalization altered). That directive ordered a review of all HHS payments "related to DEI and similar programs" to ensure that all payments were "consistent with current policy priorities" and "improv[ed] the health and well-being of all Americans." A98. Consistent with that directive, NIH temporarily paused all grants supporting "diversity, equity, and inclusion . . . initiatives or any other initiatives that discriminate on the basis of race, color, religion, sex, national origin, or any other protected characteristic." A103.

On February 21, 2025, the Acting NIH Director directed his staff to ensure that NIH grants "do not fund or support low-value and off-mission research activities

or projects - including DEI and gender identity research activities and programs." A108-109. As the Acting Director explained, "based on [his] expertise and experience" and "consistent with recent Executive Orders," "amorphous equity objectives[] are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness." A108. Likewise, gender-identity studies may "ignore . . . biological realities," "are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans." *Id.* Accordingly, "it is the policy of NIH not to prioritize such research programs." *Id.*

Ensuing guidance documents issued in March and May of 2025 directed NIH staff to review "the specific aims" of each project for compliance with NIH's priorities. A127; A143. Where "[t]he sole purpose of the project" contradicts those priorities, like a grant for a conference about "diversity," funding may not issue. A143. But if the project only "partially supports" impermissible activities, staff were directed to negotiate out those terms. A144-145. For example, if a scientific conference limited to specific racial groups sought funding, NIH would ask the conference hosts to remove the racially restrictive term and open the conference to all comers. A146. If they agreed, the grant could proceed. *Id.*

Using that guidance as a touchstone, NIH and HHS officials exercised their judgment to identify grants for termination. A138; A141-142; A153.[1] NIH sent letters to affected grant recipients explaining that the OMB guidelines incorporated into their grants permit termination "if an award no longer effectuates the program goals or agency priorities." A124. The letters identified why the grantees' projects "no longer effectuate[] agency priorities" using standardized language tracking the Acting Director's guidance. A124-125. For example, researchers working on DEI-related grants were informed that "it is the policy of NIH not to prioritize such research" because "[r]esearch programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry." *Id.* And those studying "[t]ransgender issues" were informed of NIH's conclusion that "[r]esearch programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans." A125. The letters explained how the grantees could appeal the decision to the NIH Director or his designee. *Id.*; *see* 45 C.F.R. § 75.374.

3. On August 15, 2025, and after the district court issued the order on appeal, the NIH Director issued a new statement on grant priorities that replaced his previous

[1] This Court's stay opinion incorrectly stated "that [Department of Government Efficiency (DOGE)] staffers (who had no affiliation with either NIH or HHS) decided which grants to terminate." *American Pub. Health Ass'n v. NIH*, 145 F.4th 39, 46 (1st Cir. 2025). The official was a detailee from DOGE who was employed by HHS.

statement of February 21, 2025. NIH, *Advancing NIH's Mission through a Unified Strategy* (Aug. 15, 2025), https://perma.cc/V5E2-4ED2 (NIH Director Statement). In this updated guidance, the Director explained that NIH is committed to "advance[ing] the health of all Americans, regardless of their age, race, ethnicity, sex, sexual orientation, or other characteristics" and that NIH would fund research that employs "specific and measurable concepts," uses "precise language to define [research] participant attributes," and considers "race or ethnicity" only when "scientifically justified." *Id.* As an example, "redlining and housing discrimination are clearly defined practices that can measurably impact the health of minority populations" while "broad or subjective claims" like those based on "systemic racism" are not. *Id.* The guidance also addressed research on care for "children and teenagers identifying as transgender," explaining that "studies that involve the use of puberty suppression, hormone therapy, or surgical intervention to treat gender dysphoria, gender identity disorder, or gender incongruence in minors" are not supported by the data and citing, in support, a recent literature review. *Id.*

C. Prior Proceedings

1. Two sets of plaintiffs challenged NIH's grant terminations in the District of Massachusetts. A80-81. Research and advocacy organizations, a union, and individual researchers (APHA plaintiffs) filed *American Public Health Ass'n v. NIH*, No. 25-cv-10787 (D. Mass. filed Apr. 2, 2025). And 16 States (State plaintiffs) filed *Massachusetts v. Kennedy*, No. 25-cv-10814 (D. Mass. filed Apr. 4, 2025), asserting the

rights of their public universities. Both suits alleged that the grant terminations were arbitrary and capricious in violation of the APA. A444-447 (APHA); A533-535 (States). And both sets of plaintiffs sought an injunction to prevent NIH from "terminating any grants" pursuant to the challenged guidance documents and "[o]rder NIH to restore the grant awards, retroactive to the respective termination date." A455; *accord* A545-546.

2. The district court informally consolidated the cases and issued a series of decisions:

a. First, the district court held that it had subject-matter jurisdiction in *Massachusetts*. A1-28. The court acknowledged that the Supreme Court in *California* had stayed a district-court decision "enjoining the Department of Education from terminating certain grants" because such contract disputes can likely only be brought in the Court of Federal Claims under the Tucker Act. A12-13. But in the court's view, *California* was "not binding on this Court" and "of little assistance to the district courts" because it was "an emergency interlocutory order." A9, A17, A20. The court instead "agree[d] with the Supreme Court dissenters" and followed the decision of this Court that was effectively overruled in *California*. A9, A23.

Separately, the district court rejected the government's argument that NIH funding decisions are committed to agency discretion by law and thus not reviewable under the APA. A27 (citing 5 U.S.C. § 701(a)(2)). In the court's view, there was "arguably" law to apply because plaintiffs alleged that the grant terminations "conflict

with authorizing statutes and applicable regulations." *Id.* (citation omitted). But the court did not identify what those statutory or regulatory requirements might be or conclude that the agency had violated them. *Id.*

b. In *American Public Health Ass'n*, the district court construed the parties' preliminary-injunction briefing as a motion to dismiss, which the court denied in relevant part. A29-72. The court rejected the government's Tucker Act argument for "substantially for the same reasons" as in *Massachusetts* and concluded that the organizational plaintiffs had standing. A42; A43-49. On the merits, the court held that plaintiffs had adequately pleaded an arbitrary-and-capricious claim under the APA because the termination notices read "more like a political statement than reasoning about the grants." A59.

c. The district court held a joint hearing and bench trial in the two cases that was limited to plaintiffs' arbitrary-and-capricious claims concerning NIH's termination of awarded grants. A83. The court deferred for "Phase Two" plaintiffs' claims that NIH was unreasonably delaying action on new grants. *Id.* At the end of the hearing the court orally vacated NIH guidance and plaintiffs' grant terminations as arbitrary and capricious and promised that "a full written opinion" would follow. A57. The court issued partial final judgments in both cases reflecting the court's oral ruling, A73-74 (States); A75-76 (APHA), and denied the government's request for a stay pending appeal, A181-186.

d. In its written decision, the district court relied on Justice Jackson's *California* dissent to conclude that NIH had engaged in "no reasoned decision-making . . . in the 'robotic rollout' of this grant-termination action." A164 (quoting *Department of Educ. v. California*, 604 U.S. 650, 664 (2025) (Jackson, J., dissenting)). That conclusion rested on the court's view that NIH had failed to provide a workable definition of "DEI," instead offering what the court characterized as a "purely circular" formulation. A164-172. The court applied the same critique to NIH's guidance on research concerning "gender identity," while further faulting NIH for supplying no evidentiary support for its determination that such research was not worthwhile. A170.

The district court also objected to NIH's reliance on OMB guidance permitting termination of grants that "no longer effectuate[] the program goals or agency priorities" because HHS had not yet adopted that guidance as its own. A176 (quoting 2 C.F.R. § 200.340(a)(4)). Nonetheless, the court did not dispute that the OMB guidance is incorporated by reference into all NIH grants. A176-177. Given its arbitrary-and-capricious holding, the court declined to resolve plaintiffs' statutory challenges to the terminations except for finding that NIH did not violate the statutory requirement for a sexennial plan outlining research priorities and objectives. A178-179.

3. This Court denied the government's motion for a stay pending appeal. *American Pub. Health Ass'n v. NIH*, 145 F.4th 39 (1st Cir. 2025). On jurisdiction, this Court treated the district court's vacatur of NIH's guidance and the grant

terminations separately. *Id.* at 50. This Court held that the government had waived any argument that the court lacked jurisdiction to vacate the guidance. *Id.* In any event, this Court held, "the district court clearly had jurisdiction to grant 'prospective relief' that will govern 'the rather complex ongoing relationships'" between the parties. *Id.* (quoting *Bowen v. Massachusetts*, 487 U.S. 879, 905 (1988)). This Court acknowledged that the challenges to the grant terminations posed "a closer question," but thought that the claims could proceed because the court provided "declaratory relief that is unavailable in the Court of Federal Claims" and does not "depend on the terms or conditions of any contract." *Id.* at 50-51. This Court distinguished *California* as limited to an order "to pay out past-due grant obligations." *Id.* at 51 (quoting 604 U.S. at 650). In this Court's view, the court here had "simply declared that the Department unlawfully terminated certain grants" without relying on any particular grant terms. *Id.*

This Court also rejected the government's argument that NIH funding allocations are committed to agency discretion by law. *American Pub. Health Ass'n*, 145 F.4th at 52-53. This Court deemed this argument forfeited because the government had not specifically reiterated it in its district-court stay motion. *Id.* at 52. But this Court went on to hold that "numerous statutory provisions" and an HHS regulation provide "'judicially manageable standards'" for review. *Id.* at 53.

Finally, this Court further held that the grant terminations were likely arbitrary and capricious. *American Pub. Health Ass'n*, 145 F.4th at 53-54. This Court saw "no

obvious error" in the district court's conclusion that NIH engaged in an unexplained "about-face" that "entirely ignored significant reliance interests." *Id.* at 54.

4. The Supreme Court granted in part the government's request for emergency relief and stayed the parts of the district court's order that reversed the grant terminations. *NIH v. American Pub. Health Ass'n*, 145 S. Ct. 2658, 2659 (2025). As the Court emphasized, the "Administrative Procedure Act's 'limited waiver of [sovereign] immunity' does not provide the District Court with jurisdiction to adjudicate claims 'based on' the research-related grants or to order relief designed to enforce any 'obligation to pay money' pursuant to those grants." *Id.* (alteration in original).

Several Justices explained their votes in separate writings. Four would have granted the government's application in full, and four would have denied it in full. *NIH*, 145 S. Ct. at 2660. Justice Barrett, whose approach carried the day, issued a concurring opinion concluding that the government was entitled to a stay of the judgment insofar as it set aside grant terminations, but not as to the vacatur of agency guidance. *Id.* at 2661-62 (Barrett, J., concurring in the partial grant of the application for stay). She explained that, although the Tucker Act did not bar the district court from considering claims challenging agency guidance, plaintiffs could not "end-run" the Court of Federal Claims' exclusive jurisdiction over grant-termination challenges "simply by packaging them with a challenge to agency guidance." *Id.*

Justice Barrett explained that staying the vacatur of agency guidance was unwarranted, however, because the government's "application largely ignores the

guidance, which suggests that this aspect of the judgment causes it no irreparable harm." *NIH*, 145 S. Ct. at 2662 (Barrett, J., concurring in the partial grant of the application for stay). At the same time, she cautioned that "whether claims about the guidance in this case will succeed is another question," noting that "it is not obvious, for instance, that NIH's guidance is final agency action." *Id.* Because those issues had not been fully presented, Justice Barrett underscored that the government "remains free to challenge the District Court's vacatur of the guidance before the First Circuit." *Id.*

SUMMARY OF ARGUMENT

The district court ordered NIH to reverse the termination of grants that do not advance agency goals or priorities. The court also vacated agency guidance on grant priories. Both were in error.

1. As to the grant terminations, the district court mistakenly determined it had jurisdiction. As the Supreme Court held in this case, the "Administrative Procedure Act's 'limited waiver of [sovereign] immunity' does not provide the District Court with jurisdiction to adjudicate claims 'based on' the research-related grants or to order relief designed to enforce any 'obligation to pay money' pursuant to those grants." *NIH v. American Pub. Health Ass'n*, No. 145 S. Ct. 2658, 2659 (2025) (alteration in original). That holding "squarely control[s]" here. *Trump v. Boyle*, 145 S. Ct. 2653, 2654 (2025). And the Supreme Court's reasoning reflects the longstanding jurisdictional principle that claims premised on, and requiring the government to

comply with, grant agreements are contract claims that must be brought in the Court of Federal Claims.

2. The district court's vacatur of NIH's grant priorities guidance should be vacated. As an initial matter, NIH has since updated its guidance, addressing the court's concerns. For example, the court criticized NIH for not adequately supporting its conclusions on "gender identity" research. A170. In response, NIH has now cited a recent literature review as evidentiary support for its position. NIH Director Statement (citing HHS, *Treatment for Pediatric Gender Dysphoria: Review of Evidence and Best Practices* (May 1, 2025), https://perma.cc/9LGM-ANGA). As a result, the deficiencies the court identified no longer exist. It would be inequitable to allow the court's judgment to stand in these circumstances, as doing so could interfere with the government's ability to rely on the updated guidance to the extent that it builds on what the court held to be inadequate.

The order also rests on legal error. Plaintiffs lacked standing to challenge the guidance at the time they filed suit, as they did not suffer any cognizable injury. Moreover, the guidance does not constitute final agency action subject to APA review. The district court bypassed these threshold defects by evaluating the guidance and the grant terminations together as part of the same "wholesale effort to excise grants." A155. But that approach is no longer viable in light of the Supreme Court's ruling that the court lacks jurisdiction over the terminations.

In any event, plaintiffs' claims fail on the merits. The guidance that informs which grants to fund falls within the agency's discretion when, as here, no statutory or regulatory limits have been violated. *Lincoln v. Vigil*, 508 U.S. 182, 193 (1993). In such circumstances, the APA "gives the courts no leave to intrude." *Id.* Even if the guidance were reviewable, it was neither arbitrary nor capricious. NIH offered reasonable justifications, including a shift in policy priorities and a desire to reallocate funds accordingly. The district court's objections regarding the lack of detailed definitions or the possibility of political influence are not reasons why the guidance would be considered unlawful. The APA does not require perfect clarity in discretionary funding decisions, nor does it prohibit political leadership from setting new priorities consistent with the President's agenda.

STANDARD OF REVIEW

This Court reviews the district court's decision de novo. *See BIW Deceived v. Local S6, Indus. Union of Marine & Shipbuilding Workers*, 132 F.3d 824, 830 (1st Cir. 1997) (de novo review of whether the district court had jurisdiction); *Atieh v. Riordan*, 797 F.3d 135, 138 (1st Cir. 2015) (de novo review of merits of APA claim). To the extent it reaches the merits, this Court, like the district court, applies the standard set forth in the APA under which agency action may be overturned only if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law, such as if it is unsupported by substantial evidence." *Atieh*, 797 F.3d at 138 (quoting 5 U.S.C. § 706(2)). "This standard is quite narrow: a reviewing court may not substitute

its judgment for that of the agency, even if it disagrees with the agency's conclusions." *Id.* (quotation marks omitted).

ARGUMENT

I. The District Court Improperly Reversed the Termination of Grants

1. The Supreme Court's stay decision in this case concluded that the district court lacks jurisdiction to vacate the challenged grant terminations. *NIH v. American Pub. Health Ass'n*, 145 S. Ct. 2658, 2659 (2025). The Court explained that the "Administrative Procedure Act's 'limited waiver of [sovereign] immunity' does not provide the District Court with jurisdiction to adjudicate claims 'based on' the research-related grants or to order relief designed to enforce any 'obligation to pay money' pursuant to those grants." *Id.* (alteration in original). That decision was unconditional and would "squarely control[]" even like cases. *Trump v. Boyle*, 145 S. 2653, 2643 (2025). But this is not just a like case; it is the *same* case. This Court therefore must vacate the reversal of the grant terminations for lack of jurisdiction.

2. The Supreme Court's ruling reflects black-letter jurisdictional principles. Given the federal government's sovereign immunity, federal courts generally lack jurisdiction over "suits against the United States absent Congress's express consent." *United States v. Miller*, 145 S. Ct. 839, 849 (2025). The APA provides a limited waiver of sovereign immunity, but "comes with an important carve-out": The waiver does not apply "'if any other statute that grants consent to suit expressly or impliedly

forbids the relief which is sought.'" *Match-E-Be-Nash-She-Wish Band of Pottawatomi Indians v. Patchak*, 567 U.S. 209, 215 (2012) (quoting 5 U.S.C. § 702).

One such other statute is the Tucker Act, which provides that the "United States Court of Federal Claims shall have jurisdiction to render judgment upon any claim against the United States founded" on "any express or implied contract with the United States." 28 U.S.C. § 1491(a). As such, the "Tucker Act 'impliedly forbids'" bringing "contract actions" against "the government in a federal district court" under the APA. *Albrecht v. Committee on Emp. Benefits of the Fed. Rsrv. Emp. Benefits Sys.*, 357 F.3d 62, 67-68 (2004). To determine which court has jurisdiction, the question is whether "an action is in 'its essence' contractual," *Perry Capital LLC v. Mnuchin*, 864 F.3d 591, 618-19 (2017), *cert. denied*, 583 U.S. 1115 (D.C. Cir. 2018), which "depends both on the source of the rights upon which the plaintiff bases its claims, and upon the type of relief sought," *Megapulse, Inc. v. Lewis*, 672 F.2d 959, 968 (D.C. Cir. 1982). Both factors point to this case being "in its essence contractual." *Perry Capital LLC*, 864 F.3d at 619 (quotation marks omitted).

More precisely, plaintiffs' core complaint—that their grant agreements were improperly terminated, A381 (APHA); A463 (States)—self-evidently arises from the grant agreements. The same holds true for the reversal of those grant terminations, which is the relief plaintiffs sought and received from the district court. A73-74 (States); A75-76 (APHA). Like "many . . . federal grant programs," these grant agreements take the form of contracts. *See Bennett v. New Jersey*, 470 U.S. 632, 638

(1985); *see also Columbus Reg'l Hosp. v. United States*, 990 F.3d 1330, 1338 (Fed. Cir. 2021) (treating "federal grant agreements as contracts when the standard conditions for a contract are satisfied, including that the federal entity agrees to be bound"). Plaintiffs' challenge to the grant terminations is thus, at its essence, contractual. Such a case is not a challenge to some regulatory action with monetary implications, but rather a suit for "past due sums" from the government that the Tucker Act "impliedly forbids" bringing in federal district court under the APA. *Great-West Life & Annuity Ins. Co. v. Knudson*, 534 U.S. 204, 212 (2002). Were it otherwise, virtually any contract dispute with the government could be repackaged as an APA claim simply by reframing the relief requested. As the D.C. Circuit has cautioned, "[i]t is hard to conceive of a claim falling no matter how squarely within the Tucker Act which could not be urged to involve as well agency error subject to review under the APA." *Megapulse*, 672 F.2d at 967 n.34 (alteration and quotation marks omitted)

As the Supreme Court's stay order makes clear, this Court's stay order misapplied these principles. That order reasoned that the district court had jurisdiction because plaintiffs' claims were analogous to those in *Bowen v. Massachusetts*, 487 U.S. 879 (1988), since both sought only "declaratory relief that is well within the scope of the APA." *American Pub. Health Ass'n v. NIH*, 145 F.4th 39, 50 (1st Cir. 2025). But the analogy fails. Bowen did not involve a contract claim and did not address the APA provision in 5 U.S.C. § 702 that bars suits "expressly or impliedly forbid[den]" by another statute. *See Great-West*, 534 U.S. at 212, 215 (emphasizing that

Bowen "did not involve a claim for" breach of contract or any "contractual obligation").

Instead, Bowen turned on two different provisions: 5 U.S.C. § 702's bar on claims for "money damages," and 5 U.S.C. § 704's requirement that APA review is available only when "no other adequate remedy in a court" exists. The Court held that a State's claim for adjusted Medicaid reimbursement rates was not one for "money damages" merely because it would result in the payment of money, *Bowen*, 487 U.S. at 891-901, and that a Tucker Act suit was not an "adequate remedy" that foreclosed APA review, *id.* at 901-08. But nothing in *Bowen* addressed § 702's distinct prohibition on suits foreclosed by other statutes—the operative issue here.

3. The district court lacked jurisdiction to review the grant terminations, and its judgment must therefore be vacated for that reason. In light of that threshold defect, there is no basis for this Court to address any of the remaining issues concerning the terminations. But even if this Court were to reach the merits, reversal would still be required. The grant terminations, for the same reasons as the guidance that informed those decisions, are committed to agency discretion by law and neither arbitrary nor capricious. *See infra* Part II.D.

II. The District Court's Judgment Regarding Grant Guidance Should Be Vacated

In addition to reversing certain grant terminations, the district court also purported to vacate seven pieces of guidance outlining NIH's grant priorities. A73

n.1; A76-77. The Supreme Court's stay decision did not endorse that aspect of the decision; it held only that the vacatur did not necessarily fall within the exclusive jurisdiction of the Court of Federal Claims. *NIH*, 145 S. Ct. at 2661. Indeed, Justice Barrett's controlling concurrence made clear that the government could raise other challenges to the vacatur in this Court and expressed skepticism that the guidance constituted final agency action. *Id.* at 2662 (Barrett, J., concurring in the partial grant of the application for stay). But this Court should not reach the issues left open by the Supreme Court because the challenge is now moot: NIH has since updated its grant priorities guidance, including revisions directly addressing the concerns that troubled the court.

Other threshold defects also abound. Plaintiffs lack standing to challenge the directives, as they faced no cognizable injury. Moreover, the directives are nonbinding guidance, not final agency action reviewable under the APA. The district court sidestepped these threshold issues by considering the guidance and the grant terminations as part of a "wholesale effort to excise grants." A155. That approach is untenable; as explained above, this Court lacks jurisdiction over the grant terminations. *See supra* Part I. Finally, the guidance was not unlawful; rather, it reflected a change in policy, and NIH adequately identified, explained, and pursued new funding priorities.

A. Challenges to the Grant Guidance Are Moot

The guidance vacated by the district court has since been superseded, and plaintiffs' challenge no longer presents a live controversy. Although the court nominally referred to seven separate pieces of guidance, A73 n.1; A76-77, it never analyzed them individually. The court dismissed that approach as only "superficially appealing," A155, and elected instead to treat the guidance "as a whole," A154. Indeed, the court conflated the guidance with the grant terminations into a single, "wholesale effort to excise grants." A155. That framing was problematic for several reasons, including obscuring the fact that plaintiffs could not challenge the grant guidance in isolation. *See infra* Part II.B-C. But relevant here, the "whole" of NIH's grant priorities guidance is materially different from what the court reviewed, confirming that no live dispute remains for this Court to resolve.

Since the district court's judgment, NIH has issued updated guidance to which agency officials now refer in making grant decisions. Some of the guidance documents at issue here have been formally rescinded or superseded. A568 ("This staff guidance rescinds the guidance provided in the February 13, 2025 . . . ."); A598 (directing staff to "save this guidance until we can clear the updated staff guidance"). And the rest have been effectively overridden or explicated such that the shortcomings that the court perceived in the scheme of guidance as a whole—as noted, the court did not analyze each guidance individually in any event—are plainly no longer an issue.

For example, the district court's analysis rested on its view that the prior guidance lacked operative definitions of key terms, such as "DEI," thereby rendering the agency's standards arbitrary. A165-166. That concern was addressed by updated guidance issued by the NIH Director on August 15, 2025. NIH Director Statement. The new guidance specifies that NIH will support research considering race or ethnicity only when "scientifically justified," such as studies of the measurable health effects of redlining and housing discrimination. *Id.* Conversely, NIH will not support projects based on "broad or subjective claims," such as attributing health disparities to poorly measured concepts like systemic racism. *Id.* By delineating the scope of permissible research, the updated guidance addresses the very deficiency the court identified.

The revised guidance likewise addresses the district court's concerns about research on "gender identity." *See* A170. There, the court faulted the agency for failing to provide evidentiary support for its assessment that "research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans." *Id.* (emphases and quotation marks omitted). The updated guidance directly addresses that critique, explaining that studies involving puberty suppression, hormone therapy, or surgical interventions in minors lack a sufficient evidentiary basis and citing a recent literature review. NIH Director Statement (citing HHS, *Treatment for Pediatric Gender Dysphoria: Review of Evidence and Best Practices*, *supra*.)

Because NIH has superseded the guidance on which the district court relied, plaintiffs' challenge is moot. *See Already, LLC v. Nike, Inc.*, 568 U.S. 85, 91 (2013). Nor can plaintiffs show that they "may be parties to the same sort of dispute in the future." *Missouri ex rel. Nixon v. Craig*, 163 F.3d 482, 485 (8th Cir. 1998) (alteration and quotation marks omitted). "To qualify for this exception," the future conduct must be "sufficiently similar to the past conduct such that it is permissible to say that the challenged conduct continues." *Corrigan v. Boston Univ.*, 98 F.4th 346, 353 (1st Cir. 2024) (alteration and quotation marks omitted). NIH's current grant priorities guidance is materially different from the version considered by the court, and any new challenge would therefore raise an entirely distinct dispute.

Accordingly, this court should vacate the district court's decision on the guidance. *McLane v. Mercedes-Benz of N. Am.*, 3 F.3d 522, 524 n.6 (1st Cir. 1993) ("As a general rule, when a case becomes moot on appeal, we vacate the district court's decision and remand with a direction to dismiss."). Although it was NIH's actions that mooted plaintiffs' challenge, the "conditions and circumstances" of this case warrant vacatur. *See Milk Indus. Regul. Off. v. Ruiz*, 83 F.4th 68, 77 (1st Cir. 2023) (per curiam). The court's imprecision in treating all guidance "as a whole," A154, creates uncertainty as to whether its judgment might be read to restrict reliance on the amended guidance to the extent it incorporates the original. There is no basis to impose that result, particularly because there is no reason to believe NIH would revert to the less-detailed guidance that the court found unlawful. Moreover, the court

never separately determined that vacatur of the guidance was appropriate; rather, it erroneously lumped the guidance together with grant terminations over which it lacked jurisdiction. A164 (referring to a unitary "grant-termination action"). Under these circumstances, the court's judgment should be vacated in relevant part.

B. Plaintiffs Lack Standing to Challenge the Grant Guidance Because Their Only Injury Is the Grant Terminations

1. Plaintiffs lacked Article III standing to mount a challenge to NIH's grant guidance apart from the grant terminations even at the time they filed their complaint. To establish standing, plaintiffs have the burden to demonstrate (1) that they suffered an injury (2) "fairly traceable to the defendant's allegedly unlawful conduct" and (3) "likely to be redressed by the requested relief." *California v. Texas*, 593 U.S. 659, 669 (2021) (quotation marks omitted). That injury must be "concrete, particularized, and actual or imminent; fairly traceable to the challenged action; and redressable by a favorable ruling." *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013) (quotation marks omitted); *Nulankeyutmonen Nkihtaqmikon v. Impson*, 503 F.3d 18, 26-27 (1st Cir. 2007) ("An injury in fact is an invasion of a legally protected interest which is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical." (quotation marks omitted)).

The related doctrine of ripeness "prevent[s] the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements." *National Park Hosp. Ass'n v. Department of the Interior*, 538 U.S. 803, 807 (2003)

(quotation marks omitted). A claim is unripe for judicial review if it depends on "contingent future events that may not occur as anticipated, or indeed may not occur at all." *Trump v. New York*, 592 U.S. 125, 131 (2020) (per curiam) (*quoting Texas v. United States*, 523 U.S. 296, 300 (1998)). The Supreme Court has repeatedly held that challenges to intra-governmental directives are not ripe because such a directive, by itself, "does not affect [anyone]'s primary conduct." *National Park*, 538 U.S. at 810; *see also Ohio Forestry Ass'n v. Sierra Club*, 523 U.S. 726 (1998); *Reno v. Catholic Soc. Servs., Inc.*, 509 U.S. 43, 58-61 (1993). It is, moreover, "too speculative whether the problem [plaintiffs] present[] will ever need solving." *Texas*, 523 U.S. at 302. Once divorced from the grant terminations, plaintiffs' challenges to internal NIH guidance on grant priorities raises both standing and ripeness concerns.

The only harm plaintiffs alleged relevant to the phase of the trial that produced the challenged order—claims regarding NIH's alleged delays in awarding new grants having been reserved for "Phase Two," A81—arose from the termination of existing grants. The State plaintiffs, for example, complained of the "termination of millions of dollars (and counting) in grants already issued to plaintiffs' public institutions." A463. Likewise, APHA plaintiffs claim they "bring this case because they have been harmed by Defendant's unlawful grant terminations," A381, and are thus "facing the loss of jobs, staff, and income," A384. And the "concrete injury" APHA claimed gave it standing was the "termination of Plaintiffs' and Members' Project-based and Pipeline Grants." A309 (Dkt. No. 41 at 13); *see also* A315 (Dkt. No. 79 at 2 (arguing

that "NIH's grant cancellations are causing layoffs and reduced hours and training opportunities among [United Automobile, Aerospace and Agricultural Implement Workers] members")).

Consistent with that understanding, plaintiffs each brought a single arbitrary-and-capricious claim aimed at NIH's guidance and the grant terminations together, on the theory that the guidance led to the termination of their grants (or those of their instrumentalities or members). A443-447 (APHA); A533-535 (States). Thus, apart from the claims of delay reserved for later proceedings, the only injury plaintiffs ever alleged was the termination of grants.

The district court's order reflected the same understanding. In finding a violation of the APA, it faulted the "abruptness in the robotic rollout of this grant termination action." A164 (quotation marks omitted). The guidance itself was, in the court's words, merely the "paper trail" of NIH's broader effort to cancel grants. *Id.* at 78. Accordingly, the court's order did not merely vacate the guidance but also separately reversed the grant terminations. A73-74 (States); A75-77 (APHA). As Justice Barrett explained, "[i]f one simply flowed from the other, the [d]istrict [c]ourt would have needed only" to enjoin the challenged provisions. *NIH*, 145 S. Ct. at 2661 (Barrett, J., concurring in the partial grant of the application for stay). The court itself also recognized that the real consequence of its order was the "forthwith [] disbursement of funds both appropriated by the Congress of the United States and allocated heretofore by the defendant agencies." A265. It further denied a stay

pending appeal out of concern that funds would be "sequester[ed] (probably forever) during the course of the appeal." A186. As Justice Gorsuch observed, the "alleged legal wrong the district court sought to remedy was the government's failure to pay promised grants." *NIH*, 145 S. Ct. at 2664 n.1 (Gorsuch, J., joined by Kavanaugh, J., concurring in part and dissenting in part). And Justice Jackson agreed, observing that plaintiffs' "injury and right to payment actually stem from the Government's allegedly arbitrary and capricious termination of their grant funding in violation of the APA." *Id.* at 2673 n.2 (Jackson, J. concurring in part and dissenting in part) (emphasis omitted). The grant terminations were thus always the core of this case.

2. Once the challenges to the grant terminations are set aside, no injury remains with respect to NIH's grant-priorities guidance. Nothing in the guidance prohibits or otherwise restricts plaintiffs' ability to research any topic. The only conceivable effect on plaintiffs is the theoretical possibility that NIH might terminate additional grants in the future. But any such injury would be traceable to the subsequent application of guidance to a particular grant, not the guidance. In any event, plaintiffs never allege that this possibility is anything more than speculation. A384 (asserting only that plaintiffs "with grants that have yet to be cancelled wonder if they are soon to receive another vague, boilerplate termination letter"); *see NIH*, 145 S. Ct. at 2665 n.2 (Gorsuch, J., joined by Kavanaugh, J., concurring in part and dissenting in part) ("The only injury that gave respondents standing to obtain that relief was the termination of pre-existing grants. . . . So all claims on which the

district court rendered judgment were 'based on' respondents' contracts with the government, and those judgments were thus entered without jurisdiction." (citations omitted)). If plaintiffs believe that a future termination is unlawful, they can challenge it in a concrete factual setting in the appropriate forum. But they cannot establish Article III standing "simply by claiming that they experienced a 'chilling effect' that resulted from a governmental policy that does not regulate, constrain, or compel any action on their part." *Clapper*, 568 U.S. at 419; *see also Laird v. Tatum*, 408 U.S. 1, 11 (1972) (The plaintiff alleging chilling effect lacks standing where government policy is not "regulatory, proscriptive, or compulsory in nature.").

The absence of any concrete harm from NIH's grant-priorities guidance is evident from the district court's reasoning. The court faulted the guidance precisely because it lacked definitions for the disfavored research areas, such as DEI or "gender identity." A164-171. In the court's view, "[r]eliance on an undefined term of DEI (or any other category) is arbitrary and capricious because it allows the [agency] to arrive at whatever conclusion it wishes without adequately explaining the standard on which its decision is based." A166 (quotation marks omitted). But if the guidance supplied no operative standards, then it could not have dictated which grants were terminated and thus could not have caused any injury. Plaintiffs accordingly lack standing to challenge the grant priorities guidance as an independent matter.

C. The Grant Guidance Is Not Final Agency Action

1. NIH's grant priorities guidance is not final agency action reviewable under the APA. The APA authorizes review only of "final agency action." 5 U.S.C. § 704. To qualify as "final," agency action must satisfy two conditions: (1) it must "mark the consummation of the agency's decision-making process," and (2) it must be an action "by which rights or obligations have been determined, or from which legal consequences will flow." *Harper v. Werfel*, 118 F.4th 100, 116 (1st Cir. 2024) (quoting *Bennett v. Spear*, 520 U.S. 154, 178 (1997)). NIH's guidance meets neither requirement. *NIH*, 145 S. Ct. at 2662 (Barrett, J., concurring in the partial grant of the application for stay) ("It is not obvious, for instance, that NIH's guidance is final agency action.").

First, the grant guidance marked only the commencement, not the consummation, of the agency's decision-making process. The guidance merely instructed NIH staff to review existing grants for consistency with administration priorities, with the possibility that some might later be terminated. For example, the February 10, 2025, directive ordered "a review of the overall contracts and grants to determine whether those contracts or grants are . . . consistent with current policy priorities," and noted that "after review," "such contracts may be terminated." A563. That was also what the Acting NIH Director ordered. A559 ("NIH personnel shall conduct an internal review . . . ."). Accordingly, the March 25, 2025, guidance instructed NIH institutes and centers to "review the specific aims/major goals of the project to assess whether the proposed project contains any DEI, gender identity or

other research activities that are not an NIH/HHS priority/authority." A600-606. Consistent with this, NIH's chief grants official testified that staff were expected to rely on their "scientific background" and program knowledge "to identify DEI activities." A104 n.8. Unlike guidance that constitutes the agency's last word, *see Sackett v. EPA*, 566 U.S. 120, 127 (2012) (finding final agency action where a compliance order was "not subject to further Agency review"), NIH's guidance only started a decision-making process.

Second, the guidance did not determine any rights or obligations or impose any independent legal consequences. It did not prohibit plaintiffs from conducting any research they wished. Nor did it terminate any grants or otherwise inflict injury on plaintiffs. *See supra* Part I.B. Indeed, under the district court's view, the guidance failed to provide any direction at all and was "untethered to anything." A170-171. The guidance was thus a "preliminary step[,] . . . leading toward the possibility of a final action in the form of an enforcement or other action." *Harper*, 118 F.4th at 116 (quoting *University of Med. & Dentistry of N.J. v. Corrigan*, 347 F.3d 57, 69 (3d Cir. 2003)). As this Court has made clear, such "investigatory measures are not final agency action" because they are "tentative or interlocutory in nature." *Id.* (quotation marks omitted).

2. The district court's analysis underscores that the guidance documents, standing alone, are not final agency action. The court treated the guidance together with the grant terminations, explaining that it did not consider the guidance "in

isolation," but only in the "context of a wholesale effort to excise grants in 8 categories over a period of less than 90 days." A155. In that context, the court expressly viewed the guidance as the "paper trail" for the terminations. *Id.* If the guidance was only the justification for other agency decisions, it cannot also be final agency action carrying independent and binding legal effect.

Other aspects of the district court's analysis drive the point home. The court faulted the guidance for permitting the agency "to arrive at whatever conclusion it wishes . . . ." A166. That reasoning confirms that the guidance itself did not establish "rights or obligations" or produce "legal consequences," as required for reviewable final agency action. *Harper*, 118 F.4th at 116 (quotation marks omitted). The notion that the guidance could be treated as final action is particularly untenable here since the court lacked jurisdiction over the only agency actions—the grant terminations—that indisputably carried legal consequences. *See supra* Part I.

D. The Grant Guidance Is Lawful

Even if NIH's grant priorities guidance were independently reviewable, it is lawful. The guidance—like the underlying funding decisions it informs—is "committed to agency discretion by law" and not subject to APA review. 5 U.S.C. § 701(a)(2). And even were APA review appropriate, the guidance was manifestly proper under settled APA precedents.

i. The Grant Guidance Is Committed To Agency Discretion by Law

1. Consistent with the "'basic presumption of judicial review,'" the APA "instructs reviewing courts to set aside agency action that is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'" *Department of Com. v. New York*, 588 U.S. 752, 771 (2019) (first quoting *Abbott Labs. v. Gardner*, 387 U.S. 136, 140 (1967); and then quoting 5 U.S.C. § 706(2)(A)). But that presumption comes with a key caveat: The APA does not apply when agency action is "committed to agency discretion by law." 5 U.S.C. § 701(a)(2). That exception applies when a "statute is drawn so that a court would have no meaningful standard against which to judge the agency's exercise of discretion." *Heckler v. Chaney*, 470 U.S. 821, 830 (1985).

One paradigmatic decision "traditionally regarded as committed to agency discretion" is "[t]he allocation of funds from a lump-sum appropriation." *Lincoln v. Vigil*, 508 U.S. 182, 192 (1993). "After all, the very point of a lump-sum appropriation is to give an agency the capacity to adapt to changing circumstances and meet its statutory responsibilities in what it sees as the most effective or desirable way." *Id.* Lump-sum appropriations thus leave it to the agency to decide how "'resources are best spent'" and "whether a particular program 'best fits the agency's overall policies.'" *Id.* at 193 (quoting *Heckler*, 470 U.S. at 831). While Congress may set outer guardrails on "permissible statutory objectives," courts have "no leave to intrude" so long as agencies adhere to those limits in allocating funding. *Id.*

The grant guidance here falls squarely in that exception as it applies to the allocation of funds from lump-sum appropriations. *See* p. 3, *supra*. The relevant statutory limitations extend only to defining broad categories of eligible recipients, *e.g.*, 42 U.S.C. § 241(a)(3) ("universities, hospitals, laboratories, and other public or private institutions"), and requiring that each national research institute spend the money on its assigned topic, like "cancer" or "neurological disorders and stroke," *e.g.*, Pub. L. No. 118-47, 138 Stat. at 656. That level of discretion makes sense given that NIH receives five times as many proposals as it could possibly fund. NIH, *Grants & Funding*, *supra*. Congress did not decide for itself which studies on "dental and craniofacial diseases" warrant federal support, instead delegating that decision to the unreviewable discretion of the National Institute of Dental and Craniofacial Research. Pub. L. No. 118-47, 138 Stat. at 656. "[T]he 'agency is far better equipped than the courts to deal with the many variables involved in'" prioritizing competing scientific grant applications. *See Lincoln*, 508 U.S. at 193 (quoting *Heckler*, 470 U.S. at 831-32).

2. This Court previously reasoned that NIH's grant funding decisions were not committed to agency discretion because of the "statutory provisions that direct NIH to prioritize or to consider certain research objectives" and regulations providing "an exclusive list of reasons that NIH can unilaterally terminate grants." *American Pub. Health Ass'n*, 145 F.4th at 53. But those provisions could, at most, support claims that specific conditions were not satisfied. What those provisions do not support is an

unbounded arbitrary-and-capricious review of NIH's discretionary funding judgments in which the district court engaged.

That conclusion follows directly from *Lincoln*, 508 U.S. 182, where Congress identified broad "permissible statutory objectives" and the Court held that, within those objectives, the agency retained unreviewable discretion to allocate lump-sum appropriations. *Id.* at 193. The same is true here. The district court expressly declined to find any departure from Congress's statutory directives. A178-179 (refusing to "dive into the contours of the statutory overlap"). And the only statutory provision the court did address—the requirement that NIH maintain a sexennial strategic plan under 42 U.S.C. § 282(m)—it found satisfied. *Id.* Thus, NIH operated squarely within the statutory framework and its guidance on which grants to fund is an area into which "§ 701(a)(2) gives the courts no leave to intrude." *Lincoln*, 508 U.S. at 193.

In any event, none of the statutes or regulations invoked by this Court, the district court, or plaintiffs are inconsistent with the guidance. *American Pub. Health Ass'n*, 145 F.4th at 53. The cited statutes only set forth broad programmatic objectives: to disaggregate data by race, sex, and age, 42 U.S.C. § 282(b)(4)(B); to support "basic research" on "pathogens of pandemic concern," *id.* § 285f-5(b)(1); to "develop affordable new and improved vaccines," *id.* § 283d; and, "as appropriate," to encourage research on "sexual and gender minority populations," *id.* § 283p. Similarly, the cited regulation provides only that grant "may be terminated . . . for

cause." 45 C.F.R. § 75.372(a)(2). That regulation does not purport to displace NIH's broader termination authority under other regulations, such as 2 C.F.R. § 200.340(a)(4), or to preclude NIH from treating inconsistency with agency priorities as "cause." Those provisions might support judicial review if the guidance directed NIH to not fund any grants on a research institute's assigned topic or to award them to entities flatly ineligible under statute or regulation, but that is not this case. *See Amica Ctr. for Immigrant Rts. v. U.S. Dep't of Just.*, No. 25-298, 2025 U.S. Dist. LEXIS 127513, at *45 (D.D.C. July 6, 2025) (holding that an agency "has discretion to discontinue its use of the earmarked funds for that specific program" where "no statute or regulation" required continued funding).

ii. The Grant Guidance Was Not Arbitrary and Capricious

Even were APA review appropriate, the grant priorities guidance was manifestly proper under settled APA precedents. *See NIH*, 145 S. Ct. at 2665 (Kavanaugh, J., concurring in part and dissenting in part) (observing that "plaintiffs are unlikely to succeed on the merits of their arbitrary and capricious challenge to the guidance").

1. Under the APA, courts set aside agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). The arbitrary-and-capricious "standard is deferential." *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021). The court's only role is to "ensure[] that the

agency has acted within a zone of reasonableness," taking care not to "substitute its own policy judgment for that of the agency." *Id.* So long as the agency action "is rational, based on consideration of the relevant factors and within the scope of the authority delegated to the agency by the statute," the action will be upheld. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42 (1983).

The guidance here fell well within that wide band of reasonableness. The Acting Secretary explained that DEI initiatives—which focus on specific groups—"are inconsistent with the Department's policy of improving the health and well-being of *all* Americans." A563 (emphasis added). And the Acting NIH Director explained, "based on [his] expertise and experience," that DEI and gender-identities studies are "low-value and off-mission." A558. He added that the categories underlying DEI can be "artificial and non-scientific" and, at worst, may be "used to support unlawful discrimination on the basis of race and other protected characteristics." *Id.* He further reasoned that gender-identity research does "nothing to enhance the health of many Americans" and ignores "biological realities." *Id.*

Those decisions reflect quintessential policy judgments on hotly contested issues that should not be subject to judicial second-guessing. It is not irrational for agencies to conclude that paeans to "diversity" often conceal invidious racial discrimination. *E.g.*, *Students for Fair Admissions, Inc. v. President & Fellows of Harv. Coll.*, 600 U.S. 181, 258 (2023) (Thomas, J., concurring). And transgender issues are "an evolving field" involving "fierce scientific and policy debates." *United States v. Skrmetti*,

145 S. Ct. 1816, 1837 (2025). The Executive Branch was entitled to take a side on those questions in line with the President's policy pronouncements and clearly articulated disagreement with his predecessor's approach. Exec. Order No. 14,151, § 1, 90 Fed. Reg. at 8339; Exec. Order No. 14,168, § 7, 90 Fed. Reg. at 8617-18.

The guidance reasonably implemented those democratically accountable policy decisions. The guidance described the Administration's general priorities on research funding and instructed implementation on a grant-by-grant basis. A558-559, A651-680. The guidance contemplated that NIH staff would use their "scientific background" and knowledge of "their programs" to identify problematic grants. A104 n.8. Once problematic grants were identified, the guidance directed staff to work with grant recipients to excise impermissible grant terms wherever possible. A127-128. But where the grant solely funded initiatives inconsistent with the agency's stated priorities, the guidance provided that the affected grant recipient would be sent a letter explaining why NIH had chosen not to prioritize that research. A124-125. If any grantee disagreed, the termination notice explained how to pursue an administrative appeal. A125. Such "reasonabl[e] expla[nations]" for the agency's decision are exemplars of *permissible* agency decision-making. *Prometheus Radio*, 592 U.S. at 423.

2. The district court's principal objection was that NIH had not defined "DEI" or provided evidentiary support for its judgments. A164-173. But the APA does not require agencies to define every term in internal guidance, particularly where

the guidance directs highly discretionary judgments about allocating limited resources. Nor does the APA impose a "general obligation on agencies to conduct or commission their own empirical or statistical studies." *Prometheus Radio*, 592 U.S. at 423. Indeed, when another district court declared the President's direction to terminate "equity-related" grants impermissibly vague, the court of appeals stayed that preliminary injunction. *National Ass'n of Diversity Officers in Higher Educ. v. Trump*, 767 F. Supp. 3d 243, 277-80 (D. Md.), *stay granted*, No. 25-1189 (4th Cir. Mar. 14, 2025). When the government provides "selective subsidies," which frequently rely on subjective criteria, perfect "clarity" "is not always feasible." *National Endowment for the Arts v. Finley*, 524 U.S. 569, 589 (1998). In any event, plaintiffs seem to know what "DEI" is. *E.g.*, Cal. Gov't Operations Agency, *Diversity, Equity and Inclusion*, https://perma.cc/JR3N-YR82; Comm. on Health Equity, APHA, *Equity Diversity & Inclusion Survey* (Oct. 2021), https://perma.cc/3UFG-JTPE.

The district court also cast aspersions on having "partisan appointed public officials" help draft termination letters and identify grants inconsistent with the Administration's priorities. A166. But none of that has anything to do with the guidance. In any event, courts may not set aside agency action under the APA just "because it might have been influenced by political considerations or prompted by an Administration's priorities." *Department of Com.*, 588 U.S. at 781. "Under our Constitution, the 'executive Power'—all of it—is 'vested in a President.'" *Seila Law LLC v. CFPB*, 591 U.S. 197, 203 (2020). It is entirely appropriate that politically

accountable officials shift an agency's priorities after a change in Administration to reflect the new President's policy priorities. That the court treated shifting policy preferences and the involvement of political appointees as evidence of an APA violation is itself a ground for reversal.

Lumping the guidance and the grant terminations together, the district court also criticized NIH's use of "boilerplate language" in termination letters. A128, A130, A168. But that actually supports, rather than undermines, the agency's compliance with the APA because it demonstrates that NIH treated like cases alike. *See National Cable & Telecomms. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 981 (2005) ("Unexplained inconsistency is, at most, a reason for holding an interpretation to be an arbitrary and capricious change from agency practice under the Administrative Procedure Act."); *Grayscale Invs., LLC v. SEC*, 82 F.4th 1239, 1242 (D.C. Cir. 2023) ("It is a fundamental principle of administrative law that agencies must treat like cases alike."). The APA does not require agencies to gratuitously alter verbiage when implementing a uniform policy across multiple cases.

Lastly, this Court opined that the government insufficiently considered grantees' reliance interests. *American Pub. Health Ass'n*, 145 F.4th at 54. But the guidance invited grantees to request transition funds "to support an orderly phaseout of the project," mitigating any reliance concerns. A652. Moreover, there is no valid basis for a claim for reliance interests. The grant contracts authorize termination when "an award no longer effectuates the program goals or agency priorities." 2

C.F.R. § 200.340(a)(4). Grantees can hardly claim unfair surprise that the agency's priorities changed with a new Administration.

CONCLUSION

For the foregoing reasons, the judgment of the district court should be reversed.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 10567 words. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Word for Microsoft 365 in Garamond 14-point font, a proportionally spaced typeface.

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CERTIFICATE OF SERVICE

I hereby certify that on October 10, 2025, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the First Circuit by using the appellate CM/ECF system. Service will be accomplished by the appellate CM/ECF system.

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