**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.

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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.

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

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# REPLY BRIEF FOR APPELLANTS

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## INTRODUCTION AND SUMMARY

1. The Supreme Court held in this case that the district court lacks jurisdiction under the Administrative Procedure Act (APA) to order the National Institutes of Health (NIH) to continue performance under terminated biomedical research and training grants. *NIH v. American Pub. Health Ass'n*, 145 S. Ct. 2658, 2660 (2025). This decision follows another that likewise held the APA does not confer jurisdiction to reverse grant terminations. *Department of Educ. v. California*, 604 U.S. 650, 650-51 (2025) (per curiam). Those rulings are dispositive here.

Neither set of plaintiffs provides any basis for disregarding the Supreme Court's clear direction. Plaintiffs insist they are asserting statutory rather than contractual rights, yet they identify no statute or regulation that entitles them to the relief they seek, which is continued payment under a grant. And the injunction plaintiffs sought and obtained from the district court did not mandate compliance with any statute or regulation. Rather, it compelled NIH to carry out its obligations under the grant agreements. That is specific performance of a contract. Finally, plaintiffs complain the Court of Federal Claims could not award their desired remedy of specific performance. While true, that limitation is a deliberate feature of the remedial structure Congress established, not a basis to disregard the Supreme Court's jurisdictional analysis.

2. The district court's vacatur of NIH's guidance on grant priorities should also be vacated. Plaintiffs' challenge to that guidance is now moot because NIH has

since updated the guidance to address many of the concerns identified by the court. Although plaintiffs speculate that the guidance might be applied to them again in the future, any such application would involve the updated guidance, not the original version they challenged. In any event, plaintiffs cannot pursue a freestanding challenge to the guidance. Only the grant terminations supplied the injury necessary for standing and the final agency action required by the APA. Plaintiffs respond that the terminations remain relevant, but as explained above, the court lacks jurisdiction over those claims and therefore cannot provide any remedy for that alleged injury.

Plaintiffs' challenge to the guidance also fails on the merits. Decisions about which grants to fund are generally committed to agency discretion unless the agency violates a statute or regulation, and plaintiffs make no such showing here. The guidance was also appropriately tailored to its intended audience: internal agency experts expected to exercise their professional judgment. Moreover, the guidance clearly articulated the interests being advanced and NIH's reasons for its decisions. Plaintiffs' arguments to the contrary rest on the assertion that the grant terminations were indiscriminate and dictated by officials outside the agency. That contention has little to do with whether the guidance itself is unlawful. Instead, it would at most be relevant to a challenge to the specific termination decisions over which the court lacks jurisdiction.

## ARGUMENT

### I. The District Court Improperly Reversed the Termination of Grants

1. The Supreme Court's stay decision in this very case holds that the district court lacked jurisdiction to vacate the challenged grant terminations. *NIH v. American Pub. Health Ass'n*, 145 S. Ct. 2658, 2660 (2025). The Court explained that the APA's "limited waiver of [sovereign] immunity" does not permit adjudication of claims "based on" the research grants or allow relief that would enforce any "obligation to pay money" under those grants. *Id.* (alteration in original) (quotation marks omitted). That ruling—which was categorical and not couched in the language of likelihood of success—"squarely control[s]" even "like" cases, *Trump v. Boyle*, 145 S. Ct. 2653, 2654 (2025), and necessarily controls this case, which is the same proceeding. This conclusion was also not novel: it echoed an earlier decision to stay another district court order that also reversed grant terminations. *Department of Educ. v. California*, 604 U.S. 650, 650-51 (2025) (per curiam). This Court must therefore vacate the order reversing the grant terminations for lack of jurisdiction. *NIH*, 145 S. Ct. at 2664 (Gorsuch, J., joined by Kavanaugh, J., concurring in part and dissenting in part) ("That reasoning binds lower courts as a matter of vertical *stare decisis*."); *Hutto v. Davis*, 454 U.S. 370, 375 (1982) (per curiam) ("[A] precedent of this Court must be followed by the lower federal courts no matter how misguided the judges of those courts may think it to be.").

2. Plaintiffs are not entitled to prevail in this Court on the ground that the Supreme Court was simply wrong. But their arguments are in any event mistaken. Plaintiffs sued because their grants were terminated, A381 (APHA); A463 (States), and they seek to compel continued performance of those grants, A73 n.2 (States); A76 n.1 (APHA). "[B]oth . . . the source of the rights" and "the type of relief sought" arise from the grant agreements, which are contracts. *Megapulse, Inc. v. Lewis*, 672 F.2d 959, 968 (D.C. Cir. 1982). That makes the essence of the claim contractual. Consequently, the Tucker Act "impliedly forbids" proceeding under the APA. *Albrecht v. Committee on Emp. Benefits of the Fed. Rsrv. Emp. Benefits Sys.*, 357 F.3d 62, 67-68 (D.C. Cir. 2004) (quotation marks omitted).

Plaintiffs' contention that the source of their rights is the APA ignores that the APA authorizes review only for persons who "suffer[ed] legal wrong because of agency action." 5 U.S.C. § 702. Here, the "alleged legal wrong" was the government's failure to pay promised grant funds. *NIH*, 145 S. Ct. at 2664 n.2 (Gorsuch, J., joined by Kavanaugh, J., concurring in part and dissenting in part). The grants—not the APA—are therefore the true source of plaintiffs' asserted rights, and plaintiffs' challenges are "based on" the grants. *Id.* at 2660 (granting stay) (quotation marks omitted). Were it otherwise, the Tucker Act would be meaningless, as nearly any contract claim could be reframed as APA error. *See Megapulse*, 672 F.2d at 967 n.34 ("[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." (alteration in original) (quotation marks omitted)).

Plaintiffs fare no better in asserting that their rights arise from statute or regulation. States Br. 58; APHA Br. 26. They identify no such authority. At most, they suggest—while acknowledging that even the district court did not adopt this theory—that certain statutory or regulatory provisions govern the circumstances under which a grant may be terminated. But the provision they cite, 45 C.F.R. § 75.372, merely confers authority to terminate grants; it does not limit termination authority conferred elsewhere, which is the basis for NIH's action here. NIH terminated grants pursuant to the express terms incorporated through the NIH Grants Policy Statement. *See*, *e.g.*, A136. Those terms authorize termination "to the extent authorized by law, if an award no longer effectuates the program goals or agency priorities." A2449, 2460 (incorporating 2 C.F.R. § 200.340(a)(4)). The essential question, therefore, is whether NIH was entitled to terminate the agreements under that contractual term. That is fundamentally a contractual inquiry, and any dispute over it cannot be litigated in district court.

Even if plaintiffs' argument on that score were accurate, it would not suggest that they are enforcing contractual rights. In *Spectrum Leasing Corp. v. United States*, 764 F.2d 891, 894-95 (D.C. Cir. 1985), the D.C. Circuit rejected a plaintiff's attempt to seek an injunction in district court enforcing an asserted contractual right to payment under the guise of enforcing a statutory obligation. The fundamental problem with

that claim was that the right to the "payments [wa]s created in the first instance by the contract," rather than by any statute. *See id.* at 894. So too here. *See Sustainability Inst. v. Trump*, 2025 U.S. App. LEXIS 14121, at *7 (4th Cir. June 5, 2025) ("[I]t is the operative grant agreements which entitle any particular Plaintiff to receive federal funds.").

The relief ordered similarly underscores the contractual nature of this case. The district court ordered reversal of the grant terminations, A74 (States); A77 (APHA), thus effectively ordering specific performance of the grant agreements. Plaintiffs' observation that they must still meet other grant conditions, States Br. 60; APHA Br. 36, illustrates that the government is being held to its contractual obligations rather than some other obligation. "An order vacating the government's decision to terminate grants under the APA is in every meaningful sense an order requiring the government to pay those grants." *NIH*, 145 S. Ct. at 2664 (Gorsuch, J., joined by Kavanaugh, J., concurring in part and dissenting in part).

3. Plaintiffs' policy arguments provide no basis for ignoring the Supreme Court's direction on the relevant jurisdictional limits. Plaintiffs argue that applying the Tucker Act leaves them without full relief, and State plaintiffs point out that the terminated grants could never be reinstated. States Br. 63. But it has long been recognized by this Court, and others, that federal courts "do not have the power to order specific performance by the United States of its alleged contractual obligations." *See Coggeshall Dev. Corp. v. Diamond*, 884 F.2d 1, 3-4 (1st Cir. 1989). This is due to a

deliberate decision by Congress "to foreclose specific performance of government contracts" and preclude APA review of such claims. *Spectrum*, 764 F.2d at 893 n.2 (quotation marks omitted). Dissatisfaction with the remedies Congress provided is not a basis to avoid the jurisdictional framework Congress enacted. "If indeed the statute leads to incomplete relief, and if plaintiffs . . . are dissatisfied, they are free to direct their complaints to Congress." *United States v. Tohono O'odham Nation*, 563 U.S. 307, 317 (2011).

APHA plaintiffs likewise argue that some of its members lack standing to assert contract claims because they are not parties to the grant agreements. APHA Br. 40. But they do not, and cannot, suggest that no party may bring such claims such that judicial review is unavailable. Nor is there any support for plaintiffs' counterintuitive theory that nonparties enjoy greater entitlement to injunctive relief than the contracting parties themselves simply because only the latter may obtain damages. The far more sensible inference is that Congress chose to limit relief to damages available to the contracting parties. *See Block v. Community Nutrition Inst.*, 467 U.S. 340, 349 (1984) ("[W]hen a statute provides a detailed mechanism for judicial consideration of particular issues at the behest of particular persons, judicial review of those issues at the behest of other persons may be found to be impliedly precluded.").

State plaintiffs claim to have a "complex ongoing relationship" with NIH, but it is unclear how that observation is relevant. States Br. 61. The question under § 702 is whether another statute "expressly or impliedly forbids" the claim. *Bowen v.*

*Massachusetts*, 487 U.S. 879 (1988)—the only case plaintiffs cite and the source of the phrase—did not involve contracts and did not interpret that bar on APA claims, but rather involved the separate limitations on claims for money damages, 5 U.S.C. § 702, and on claims as to which an adequate remedy was available in a court, *id.* § 704. *See Great-West Life & Annuity Ins. Co. v. Knudson*, 534 U.S. 204, 212 (2002) (emphasizing that *Bowen* "did not involve a claim for" breach of contract or any "contractual obligation").

4. APHA plaintiffs' suggestion that the grants cannot be contracts because NIH lacked both the authority and the intent to "bind the government," APHA Br. 31-33, is mystifying. If that were the case, then the grants would have no legal effect at all—an assertion that would render this entire lawsuit pointless. APHA plaintiffs also argue that the grants are not contracts because they provide no "direct benefit" to the government and consideration is lacking. APHA Br. 33 (emphasis and quotation marks omitted). The Federal Circuit rejected that argument, holding that consideration exists where a grant recipient "agreed to comply with an array of requirements attached to the receipt, use, and distribution of the grant money." *Columbus Reg'l Hosp. v. United States*, 990 F.3d 1330, 1340 (Fed. Cir. 2021); *see also Vera Inst. of Just. v. U.S. Dep't of Just.*, 2025 U.S. Dist. LEXIS 128304, at *29 (D.D.C. July 7, 2025) (explaining that the contention that grants are not contracts is "at odds with authorities from the Federal Circuit"). The grants here likewise impose conditions, a point plaintiffs themselves concede. *See* States Br. 60; APHA Br. 36.

None of this is changed by the fact that NIH's public-facing website distinguishes contracts from grants. APHA Br. 32. The portion of the website cited by APHA plaintiffs provides only a general, colloquial description of NIH's funding mechanisms for public-education purposes, not a legally operative delineation of rights. A1499-1500. Indeed, if plaintiffs' view were correct, grants would never constitute contracts—an argument that courts have repeatedly rejected. *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985) (grants are "much in the nature of a contract" (quotation marks omitted)); *Columbus Reg'l Hosp.*, 990 F.3d at 1340. Moreover, the website itself underscores its imprecision; it lists only fixed-price and cost-reimbursement instruments as "contract types," even though procurement law recognizes others. *See*, *e.g.*, 48 C.F.R. § 16.500 (indefinite-delivery contracts). The website's simplified taxonomy cannot override established legal principles governing the contractual nature of grant agreements.

5. APHA plaintiffs likewise miss the point in asserting that the district court had authority to vacate the grant terminations because § 706 of the APA empowers courts to "set aside" agency action taken pursuant to unlawful guidance. APHA Br. 21. Justice Barrett's controlling concurrence squarely rejected that argument, holding that "if the [Court of Federal Claims] has exclusive jurisdiction over the grant terminations, the plaintiffs cannot end-run that limit simply by packaging them with a challenge to agency guidance." *NIH*, 145 S. Ct. at 2661-62 (Barrett, J., concurring) (citation omitted). That decision follows from general principles: if plaintiffs can

bring an APA action against one final agency action (here, the guidance), they have no right to bootstrap a challenge to a separate agency action as to which the district court lacks jurisdiction. No case on which plaintiffs rely suggests otherwise. *See Bridgeport Hosp. v. Becerra*, 108 F.4th 882, 884 (D.C. Cir. 2024) (resolving dispute about statutory Medicare reimbursement rates, not contractual obligations); *Independent U.S. Tanker Owners Comm. v. Dole*, 809 F.2d 847, 850 (D.C. Cir. 1987) (domestic tanker operations); *Montana Wildlife Fed'n v. Haaland*, 127 F.4th 1, 18 (9th Cir. 2025) (plaintiffs not asserting rights arising from contracts). As the Supreme Court held, if the district court concludes that agency guidance violates the APA, it may "vacate the guidance, preventing the agency from using it going forward"—but it may not reach, let alone set aside, contract actions that were taken under that guidance. *NIH*, 145 S. Ct. at 2662 n.2 (Barrett, J., concurring).

6. Given the foregoing, there is no basis for this Court to consider any other issue relating to the grant terminations. But if it did, more grounds for reversal would be unearthed. The terminations are lawful for the same reasons as NIH's guidance: they are committed to agency discretion and are neither arbitrary nor capricious. *See infra* Part II.D.

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

### A. Challenges to the Grant Guidance Are Moot

1. 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 elected to treat the guidance "as a whole," A154. But the "whole" of NIH's grant priorities guidance is materially different from what the court reviewed because NIH has since issued updated guidance that directly remedies the alleged shortcomings identified by the court.

The district court's analysis rested entirely on its conclusion that the agency's guidance failed to provide an operative definition of the term "DEI," rendering NIH's standards arbitrary. A165-170. With respect to guidance concerning "gender identity," the court similarly faulted the absence of a definition, A170, as well as a lack of evidentiary support, *id.* These concerns have been directly addressed by updated guidance issued by the NIH Director. NIH, *Advancing NIH's Mission Through a Unified Strategy* (Aug. 15, 2025), https://perma.cc/V5E2-4ED2 (NIH Director Statement).

Regarding "DEI," the updated guidance clarifies that the term refers to projects premised on "broad or subjective claims," including those attributing health disparities to imprecise or poorly measured constructs such as systemic racism. NIH Director Statement. And with respect to "gender identity," the Director identified a

recent literature review that both defined the types of studies encompassed by the term and supplied the evidentiary basis for NIH's approach. *Id.* (citing Dep't of Health & Hum. Servs., *Treatment for Pediatric Gender Dysphoria: Review of Evidence and Best Practices* (May 1, 2025), https://perma.cc/9LGM-ANGA). Accordingly, NIH's grant-priority guidance no longer contains the perceived deficiencies upon which the district court's order was predicated.

2. Plaintiffs principally contend that their challenge remains live because NIH "may apply" the vacated guidance to future grants. States Br. 42 (quotation marks omitted); APHA Br. 45. But plaintiffs identify no scenario—with or without the challenged injunction—in which NIH would apply the vacated guidance to them without the additional clarifications described above. There is therefore "no reasonable expectation of recurrence" of the agency action that the district court found deficient. *ACLU of Mass. v. U.S. Conf. of Catholic Bishops*, 705 F.3d 44, 56 (1st Cir. 2013).

Moreover, plaintiffs' argument underscores why the "conditions and circumstances" here warrant vacatur of the district court's order. *See In re Ruiz*, 83 F.4th 68, 77 (1st Cir. 2023) (per curiam) (quotation marks omitted). Plaintiffs assert that NIH may not rely on any guidance that incorporates any element of the original. States Br. 44; APHA Br. 46. But the court's reasoning did not sweep nearly so broadly. The court held the "DEI" portions of the guidance unlawful not because they established improper research priorities, but because the term was inadequately

defined. A165-170. Likewise, with respect to "gender identity," the court faulted the absence of supporting evidence, not any requirement that NIH fund research on that topic. A170. To the contrary, the court recognized that the "Administration has political priorities and enjoys the ability to make policy changes." A179. Nothing in the court's reasoning suggests that NIH could never determine that "DEI" or "gender identity" are disfavored research priorities. *See infra* Part II.D. Vacatur is therefore necessary to eliminate the unwarranted uncertainty that plaintiffs' position would otherwise create.

3. State plaintiffs also contend that the ongoing dispute over the grant terminations keeps their challenges to the guidance alive. States Br. 45. But those two sets of claims are "legally distinct." *NIH*, 145 S. Ct. at 2661 (Barrett, J., concurring). A challenge to the guidance could yield only one form of relief—"preventing the agency from using it going forward," *id.* at 2662 n.2—and that relief would be meaningless because the challenged guidance has been superseded.

4. Finally, APHA plaintiffs contend that the updated guidance is not properly before the Court because it cannot supply contemporaneous reasoning for the vacated directives. APHA Br. 46. But that contention merely reinforces why the challenge to the original guidance is moot. The NIH Director Statement is not offered as a post hoc justification for the prior guidance; it provides "additional guidance" that supersedes the vacated material. By supplying updated direction that

governs NIH's conduct going forward, the NIH Director Statement eliminates any live controversy regarding the original guidance and thus renders the challenge moot.

### B. Even at the Time the Complaint Was Filed, Plaintiffs Lacked Standing to Challenge the Guidance Because Their Only Injury Was the Grant Terminations

1. Once divorced from the grant terminations, plaintiffs' challenge to internal NIH guidance on grant priorities suffers from other threshold deficiencies. Plaintiffs lack standing because they cannot show that they suffered an injury "fairly traceable to the defendant's allegedly unlawful conduct" that is "likely to be redressed by the requested relief." *California v. Texas*, 593 U.S. 659, 669 (2021) (quotation marks omitted). Plaintiffs principally assert that the grant terminations supply the requisite injury. States Br. 37; APHA Br. 43. But the grant terminations are "legally distinct" from plaintiffs' challenges to the guidance. *NIH*, 145 S. Ct. at 2661 (Barrett, J., concurring). Even setting that distinction aside, the terminations do not confer standing in district court because the court lacks jurisdiction to redress that alleged injury. *Id.* at 2661-62; *California*, 593 U.S. at 668-69. An order prohibiting the agency from applying the guidance in the future would do nothing to redress any injury associated with the previous grant terminations. For that reason, plaintiffs can identify no form of relief the court could provide on the guidance that would remedy the grant terminations if, as here, the court lacks jurisdiction over them. *See Maine People's All. & Nat. Res. Def. Council v. Mallinckrodt, Inc.*, 471 F.3d 277, 283 (1st Cir.

2006) ("[A] would-be plaintiff must demonstrate . . . that prevailing in the action will afford some redress for the injury.").

2. Plaintiffs further contend that delays in processing their pending applications for new grants constitute the requisite injury. States Br. 39; APHA Br. 42. But the district court expressly declined to resolve plaintiffs' claims regarding alleged delays in awarding new grants, instead reserving that for a "Phase Two" of this proceeding that is still pending before it. A83. And for that reason, plaintiffs provided no evidence regarding pending applications at the phase of the proceeding that the court resolved. Instead, they complained that the agency had already taken action on their applications and grants. When "standing is reviewed after trial, the facts establishing standing must be supported adequately by the evidence adduced at trial," *Mallinckrodt*, 471 F.3d at 283 (quotation marks omitted), and plaintiffs have not met that burden here.

APHA plaintiffs are also wrong to claim that the risk of future grant terminations establishes standing. APHA Br. 43. Their reliance on the government's acknowledgment that NIH "may apply the Challenged Directives" to future applications "absent further Court order or judgment" does not show that plaintiffs hold any grants that face a non-speculative risk of future termination under guidance that had already been applied to them and not resulted in termination. Moreover, as noted above, plaintiffs identify no scenario where NIH would apply the vacated guidance, rather than the updated guidance, to them. *See supra* Part II.A. In any

event, injury from a future grant termination would be traceable to the future application of guidance to a particular grant, not to the guidance itself. Justice Barrett's controlling opinion does not alter that conclusion. Although she referenced the possibility of a district-court challenge to the guidance, she expressly confined her reasoning to the Tucker Act issue because the government had not briefed the guidance in its stay application. *NIH*, 145 S. Ct. at 2662 (Barrett, J., concurring).

### C. The Grant Guidance Is Not Final Agency Action

1. In any event, NIH's grant-priorities guidance is not final agency action because it neither "mark[s] the 'consummation' of the agency's decisionmaking process" nor constitutes 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)); *see also NIH*, 145 S. Ct. at 2662 (Barrett, J., concurring) ("It is not obvious, for instance, that NIH's guidance is final agency action."). The guidance instructed NIH staff to review existing grants for consistency with administration priorities, with the possibility that some might later be terminated. *See*, *e.g.*, A563 (ordering a "review of the overall contracts and grants"); A559 (ordering an "internal review"). It did not direct the termination of any specific grant. Instead, NIH staff were to rely on their "scientific background" and program expertise "to identify DEI activities." A104 n.8. The guidance therefore served only as 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 (emphasis omitted) (quoting *University of Med. & Dentistry of N.J. v. Corrigan*, 347 F.3d 57, 69 (3d Cir. 2003)). Such "investigatory measures are not final agency action" because they are "tentative or interlocutory [in] nature." *Id.* (quotation marks omitted).

2. Plaintiffs principally argue that the guidance constitutes final agency action because it allegedly forbids research on specified topics. States Br. 47; APHA Br. 47. That position sits uneasily beside their simultaneous claim that the guidance is too vague to have operative meaning, States Br. 29-30; APHA Br. 54, an assertion that implies that NIH must still exercise its judgment to determine whether particular grants fall outside the agency's stated priorities, A104 n.8. Indeed, the district court adopted this latter view, describing the guidance as merely the "paper trail" documenting the terminations rather than the cause of them. A155. The court likewise faulted the guidance for affording NIH purported latitude "to arrive at whatever conclusion it wishes." A166 (quotation marks omitted). If plaintiffs' and the court's characterizations were correct, the guidance could not itself establish "rights or obligations" or give rise to "legal consequences" as required to constitute final agency action. *Harper*, 118 F.4th at 116 (quotation marks omitted). Rather, the final agency action would occur when NIH determines that a grant contains impermissible terms under its priorities and works with recipients to remove them, A127-128, or, if the issue cannot be resolved through modification, when NIH decides to terminate the grant, A127.

State plaintiffs respond only that an agency action may be both final and arbitrary and capricious. States Br. 50. That point is indisputable, but immaterial. The district court's order rested entirely on the premise that the guidance established no definitive standards. A164-170. It is that case-specific premise that defeats plaintiffs claim of finality. The case on which plaintiffs rely illustrates the distinction. In *Firearms Regulatory Accountability Coalition, Inc. v. Garland*, the challenged rule rescinded prior classifications of certain weapons and included a slideshow specifically identifying which weapons were now deemed illegal. 112 F.4th 507, 516, 518 (8th Cir. 2024). The agency in that case conceded that the rule marked the "consummation of the agency's decisionmaking process," so the only remaining question was whether it altered legal rights or obligations. *Id.* At 518 (quotation marks omitted). The merits holding—that the agency's methodology for determining illegality was arbitrary and capricious—had no bearing on the finality analysis. *Id.* at 525. Nothing in that decision supports the remarkable proposition that guidance which, by plaintiffs' own telling, articulates no definitive standards and resolves no specific matters can nonetheless be deemed final agency action.

State plaintiffs further acknowledge that the guidance did not categorically direct the termination of grants that focused on, for instance, racial minorities. States Br. 14, 32 (noting that only some grants focusing on "Black churches" were terminated). For that reason, their reliance on *Biden v. Texas*, 597 U.S. 785, 808 (2022), is misplaced. In *Biden*, the agency issued an unequivocal directive terminating a

specific program, thereby producing immediate legal consequences. *See id.* NIH's guidance does not terminate any program or grant; it merely articulates policy priorities and leaves individual determinations for subsequent, case-specific agency processes.

### D. The Grant Guidance Is Lawful

NIH's grant priorities—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. The APA does not apply where agency action is "committed to agency discretion by law." 5 U.S.C. § 701(a)(2). One such circumstance is "[t]he allocation of funds from a lump-sum appropriation." *Lincoln v. Vigil*, 508 U.S. 182, 192 (1993). "[T]he 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 determine how "resources are best spent" and whether a particular program "best fits the agency's overall policies." *Id.* at 193 (quoting *Heckler v. Chaney*, 470 U.S. 821, 831 (1985)). Although Congress may impose outer limits through

"permissible statutory objectives," courts have "no leave to intrude" on an agency's judgment so long as it operates within those boundaries. *Id.*

NIH's grant-priorities guidance fits this bill because it governs the allocation of funds drawn from lump-sum appropriations. The relevant statutory limitations merely define broad categories of eligible recipients, *see* 42 U.S.C. § 241(a)(3), and require that each national research institute spend its appropriation on its designated topic, such as "cancer," Pub. L. No. 118-47, 138 Stat. 460, 656 (2024). That breadth of discretion is a necessary feature of the grant program, as NIH receives far more meritorious proposals than it can possibly fund. Congress sensibly did not attempt to decide which studies in areas like "dental and craniofacial diseases" merit support; it delegated that judgment to the expert discretion of the National Institute of Dental and Craniofacial Research. *Id.* "[T]he 'agency is far better equipped than the courts to deal with the many variables involved in'" prioritizing among competing scientific grant applications. *Lincoln*, 508 U.S. at 193 (quoting *Heckler*, 470 U.S. at 831-32).

2. Plaintiffs do not meaningfully dispute any of this. States Br. 51; APHA Br. 49. State plaintiffs instead attempt to sidestep the implications of the discretion Congress afforded NIH by asserting that they challenge not individual funding decisions, but agencywide policies. States Br. 51-52. But the challenged guidance simply explains how the agency will exercise its discretionary funding authority, and there is no basis for concluding that courts may review indirectly what they may not directly.

The only case State plaintiffs cite is *Union of Concerned Scientists v. Wheeler*, 954 F.3d 11 (1st Cir. 2020). States Br. 52. There, this Court considered an EPA rule disqualifying grant recipients from serving on an advisory committee. This Court held that the matter was not committed to agency discretion because Congress had imposed statutory constraints showing that "some fetters were needed." *Wheeler*, 954 F.3d at 18. No comparable statutory limitation exists here, and State plaintiffs identify none. They instead point to a footnote observing that the challenged action in *Wheeler* was an agencywide policy rather than an individual hiring decision. States Br. 52. But the breadth of the policy was not the reason the action was reviewable, it was rather Congress' explicit restriction. *Wheeler*, 954 F.3d at 18. No analogous statutory constraint applies to NIH's allocation of its lump-sum appropriations, so State plaintiffs' argument fails.

3. APHA plaintiffs take a different approach and cite statutes that prioritize certain research areas. APHA Br. 50. But none of those provisions conflict with the challenged guidance; they establish only broad programmatic objectives, and the district court notably declined to find any statutory violation. A178. APHA plaintiffs also invoke a regulation that they say limits the circumstances in which NIH may terminate a grant. APHA Br. 50 (citing 45 C.F.R. § 75.372(a)). But even if that were so—and it is not, as the provision neither restricts authority conferred elsewhere to terminate grants nor bars treating inconsistency with agency priorities as "cause"—any such limitation would pertain to the grant terminations, not the guidance.

These statutes and regulations might support judicial review if the guidance directed NIH not to fund any grants within a research institute's assigned subject-matter area, or if it required funding for entities that are ineligible under governing law. But that is not this case. *Amica Ctr. for Immigrant Rts. v. U.S. Dep't of Just.*, 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 (quotation marks omitted)).

### ii. The Grant Guidance Was Not Arbitrary and Capricious

1. 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"). 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 heavily debated issues that should not be subject to judicial second-guessing.

Moreover, the guidance contemplated a multi-step, expert-driven process. NIH staff were instructed to rely on their "scientific background" and familiarity with "their programs" to identify grants that might raise concerns under the revised priorities. A104 n.8. For any such grants, the guidance directed staff to work collaboratively with recipients to remove impermissible terms wherever feasible. A127-128. Only where a grant funded work that was wholly inconsistent with the agency's stated priorities would NIH proceed to issue a notice explaining why the project was no longer prioritized. A124-125. And any recipient who disagreed was expressly informed of the procedures for pursuing an administrative appeal. A125. These steps reflect precisely the kind of "reasonabl[e] expla[nation]" and deliberative process that are hallmarks of permissible agency decision-making. *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021).

2. Plaintiffs primarily contend the guidance was arbitrary and capricious for lacking supporting evidence. States Br. 29; APHA Br. 52. But it is unclear what additional evidence the agency needed to consider that would not be duplicative of what is already clear from the ongoing public, academic, and legal debate on these issues. The arguments for and against DEI programs are well documented, *see*, *e.g.*,

*Students for Fair Admissions, Inc. v. President & Fellows of Harvard Coll.*, 600 U.S. 181, 258 (2023) (Thomas, J., concurring), and were expressly addressed in the directives and associated Executive Orders, *see*, *e.g.*, A563 (explaining that studies focused on particular groups do not improve the health of all Americans); Exec. Order No. 14,173, 90 Fed. Reg. 8633 (Jan. 31, 2025) (criticizing DEI programs as wasteful and discriminatory). The same holds true for issues relating to "gender identity," which is "an evolving field" involving "fierce scientific and policy debates." *United States v. Skrmetti*, 605 U.S. 495, 525 (2025). Plaintiffs, for their part, provide no clarity on what evidence they think is necessary other than to acknowledge that studies are not. States Br. 33-34.

Plaintiffs provide no reason why the Executive Branch could not adopt a policy position on these questions consistent with the President's stated priorities and his articulated disagreement with the prior administration's approach. Exec. Order No. 14,151, § 1, 90 Fed. Reg. 8339, 8339 (Jan. 29. 2025); Exec. Order No. 14,168, § 7, 90 Fed. Reg. 8615, 8617-18 (Jan. 30, 2025). That constitutes a "satisfactory explanation for its action" and readily satisfies the APA's requirements. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). Indeed, the district court did not find the DEI-related directives unsupported by evidence; the court's evidentiary concerns arose only with respect to directives involving "gender identity," and, as discussed above, those concerns were resolved through subsequent guidance incorporating a scientific literature review. *See supra* Part II.A. And, even if the

agencies' explanations were inadequate, the proper remedy would be to remand for further explanation, not to enjoin the guidance altogether.

3. Plaintiffs also echo the district court's conclusion that the directives were unlawful because NIH had not defined terms such as "DEI." States Br. 29; APHA Br. 53. But NIH did supply a workable definition. The initial guidance explained that "DEI" programs included those grounded in "amorphous equity objectives." A108. As noted above, NIH subsequently refined that definition to clarify that "DEI" refers to projects premised on "broad or subjective claims," such as attributing health disparities to poorly measured concepts like systemic racism. NIH Director Statement. Although the term was not defined with mathematical precision, that level of specificity is more than sufficient given that it was intended for agency experts, not the public, and was issued in the context of "selective subsidies," which routinely rely on subjective criteria and perfect "clarity" "is not always feasible." *National Endowment for the Arts v. Finley*, 524 U.S. 569, 589 (1998).

Indeed, plaintiffs never contend that they lack any understanding of what constitutes "DEI." Their own materials demonstrate the opposite. *See*, *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. Their objections instead center on whether the specific grants that NIH terminated related to "DEI." States Br. 30 (questioning why certain health programs associated with Black churches were treated as "DEI

studies" while others were not); APHA Br. 53 (asserting that some terminated grants did not employ explicit racial preferences). Plaintiffs also assert that the terminations were executed too quickly and without adequate individualized review. States Br. 33; APHA Br. 53. But these contentions go to the propriety of the subsequent termination decisions, not to the legality of the overarching grant-priorities guidance, which is the only agency action properly before this Court.

4. Finally, plaintiffs contend that the directives were arbitrary and capricious because NIH failed to consider reliance interests. States Br. 34; APHA Br. 54. The record shows otherwise. The guidance expressly invited grantees to request transition funds "to support an orderly phaseout of the project," A652, which reflects the agency's recognition of the impacts of terminating an ongoing grant. Plaintiffs insist that this was insufficient because some of the terminations allegedly produced broader downstream effects. States Br. 35; APHA Br. 54-55. But to the extent that any individual termination might have caused more significant disruptions, that too is a challenge to the propriety of that specific termination, not the guidance. Nor does that argument negate the fact that the agency considered reliance interests in issuing its guidance and is permitted to conclude "that other interests and policy concerns outweigh any reliance interests." *Department of Homeland Sec. v. Regents of the Univ. of Cal.*, 591 U.S. 1, 32 (2020).

In any event, plaintiffs lack a valid reliance-interest claim. An express grant term expressly provides that a grant may be terminated when "an award no longer

effectuates the program goals or agency priorities." 2 C.F.R. § 200.340(a)(4). No grantee could reasonably rely on the assumption that agency priorities would remain static across administrations or that every award would continue notwithstanding a shift in those priorities.

## 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 6497 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.

*s/*
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## CERTIFICATE OF SERVICE

I hereby certify that on December 3, 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.

*s/*
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