IN THE

### Supreme Court of the United States

NATIONAL INSTITUTES OF HEALTH, et al.,

—v.—

AMERICAN PUBLIC HEALTH ASSOCIATION, et al.,

Respondents.

ROBERT F. KENNEDY, Jr., et al.,

—v.—

COMMONWEALTH OF MASSACHUSETTS, et al.,

TO THE HONORABLE KETANJI BROWN JACKSON, ASSOCIATE JUSTICE OF THE SUPREME COURT OF THE UNITED STATES AND CIRCUIT JUSTICE FOR THE FIRST CIRCUIT

### APHA RESPONDENTS' OPPOSITION TO APPLICATION FOR STAY

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### CORPORATE DISCLOSURE STATEMENT

In accordance with United States Supreme Court Rule 29.6, Respondents American Public Health Association, Ibis Reproductive Health, and International Union, United Automobile, Aerospace, and Agricultural Implement Workers state that they have no parent corporation, nor have they issued any stock owned by a publicly held company.

#### INTRODUCTION AND SUMMARY OF ARGUMENT

Beginning in February 2025, Defendants-Applicants, the National Institutes of Health ("NIH") and Department of Health and Human Services ("HHS") ("Defendants"), issued a series of directives and internal guidance restricting future NIH funding of "DEI studies" and other disfavored research topics. App. 66a–111a. Over just a few months, NIH terminated more than 1,700 grants for alleged connection to these forbidden subjects. *APHA v. NIH*, No. 25-cv-10787 (D. Mass.) (hereinafter "D. Ct. Dkt.") 103-3 ¶ 7.

Defendants' actions were a drastic departure from NIH's existing practices. Previously, NIH had operated predictably, consistently funding multi-year biomedical research projects after a rigorous, multi-stage peer review process. Those processes helped establish NIH as the world's leading innovator in the diagnosis and treatment of conditions like cancer, stroke, diabetes and Alzheimer's disease.

Researchers and organizations facing immediate disruption to multiyear, million-dollar research projects filed suit in the District of Massachusetts to set aside this unprecedented disruption to ongoing research. After a full trial on the merits, the district court issued detailed findings of fact and set aside and vacated two agency actions—(1) directives and guidance documents (the "Directives"), identifying the various forbidden research topics and restricting NIH's future grantmaking, App. 149a ¶ 1–2; and (2) the resulting terminations of Plaintiffs' grants, App. 150a. The district court concluded, based on its findings of fact, that both of these final agency actions were "arbitrary and capricious, and unlawful, in violation of

### 5 U.S.C. § 706(2)(A)."

While it is not clear from how they have styled their application, Defendants seek a stay only of the district court's order setting aside the termination of Plaintiffs' grants, and not the order setting aside the Directives. See Stay Appl. i (listing only arguments regarding grant decisions and terminations, excluding all mention of the vacated Directives). Defendants similarly did not seek to stay the order vacating the Directives in the First Circuit. App. 19a. Thus, the district court's order setting aside the Directives is not at issue here.

Regardless, the government is unlikely to succeed on the merits of either of the district court's set-aside orders, which are based on the same core finding of a "disconnect between the decision made and the explanation given." App. 125a (citing Dep't of Com. v. New York, 588 U.S. 752, 785 (2019)). Specifically, the court found no evidence in the administrative record that Defendants engaged in any analysis or reviewed any data to substantiate claims about the unscientific nature of supposed "DEI studies" and other newly-forbidden research, nor any explanation of how such terms applied to the wide range of terminated scientific research. App. 125a–26a.

The district court and the court of appeals denied the government's application for a stay of the district court's partial final judgment in favor of the Plaintiffs. The government has once again failed to meet the standard for a stay before this Court and its application should be denied.

First, the balance of equities is entirely in Plaintiffs' favor. The district court found that a stay would inflict irreparable harm, App. 146a, as the undisputed

evidence demonstrates the massive injury that will result from another disruption of hundreds of critical projects. Examples of purported "DEI studies" terminated by Defendants include: "Alzheimer's Disease and Related Dementia Neuropathologies and Exposures to Traffic Pollution Mixtures," A.R. 662–68; "A Multi-level Intervention to Reduce Kidney Health Disparities," A.R. 1626–30; "Understanding the Macrosocial Drivers of Cardiovascular Health in the Rural South," A.R. 4298–4303; "Understanding the Role of Coiled-Coil Domains in Regulating Liquid-Liquid Phase Separation of Protein Assemblies in Cell Division," A.R. 4271–77; "An Adaptive Framework to Synthesize and Reconfigure Bacterial Viruses (Phages) to Counter Antibiotic Resistance," A.R. 4304–11; and "Research Coordinating Center to Reduce Disparities in Multiple Chronic Diseases," A.R. 4683–89.

Even a brief stay would invalidate these and other multiyear projects, already paid for by Congress, in midstream, inflicting incalculable losses in public health and human life because of delays in bringing the fruits of Plaintiffs' research to Americans who desperately await clinical advancements. *See infra*, Section I. App. 146a. The government asserts only that the plaintiff States in the related case may have the resources to continue their research. Stay Appl. 37. This argument is unsupported by evidence and does not address the harms to the private Plaintiffs here. In comparison to irreparable non-monetary harm to public health, the government's assertion that it might not be fully reimbursed if it prevails on appeal carries far less weight. <sup>1</sup>

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<sup>&</sup>lt;sup>1</sup> Notably, Defendants have not sought to expedite their appeal to the First Circuit, even after Plaintiffs suggested expedition in their opposition to the stay application there. Br. for Pls.-Appellees, *APHA v. NIH*, No. 25-1611 (1st Cir. July 8, 2025), Dkt. 118310408.

Second, the government is incorrect in asserting that Plaintiffs' claims may only proceed in the Court of Federal Claims under the Tucker Act and this Court's recent stay order in Department of Education v. California, 145 S. Ct. 966 (2025) (per curiam). As this Court recognized in California, "a district court's jurisdiction 'is not barred by the possibility' that an order setting aside an agency's action may result in the disbursement of funds." Id. at 968 (citing Bowen v. Massachusetts, 487 U.S. 879, 910 (1988)).

This case is unlike California in several material respects: (1) Plaintiffs' irreparable harms, described above, are entirely different. Compare 145 S. Ct. at 968– 69 ("Respondents have represented in this litigation that they have the financial wherewithal to keep their programs running."). (2) Unlike in California, no contracts are at issue here. Plaintiffs did not seek contractual remedies, the district court granted only classic equitable relief under the APA, and the NIH itself explicitly distinguishes between "grants" and "contracts" in materials relating to its grants program. D. Ct. Dkt. 72-1. The *California* plaintiffs, in contrast, based claims on the terms and conditions of their grant agreements, and did not dispute that those agreements were contracts enforceable in the Court of Federal Claims. See App. 22a (citing Reply Br. for Pet'r at 7, U.S. Dep't of Ed. v. California, No. 24A910 (S. Ct. Mar. 31, 2025)). (3) The district court in *California* ordered the defendants "to pay out pastdue grant obligations and to continue paying obligations as they accrue," 145 S. Ct. at 968, while the district court here issued a judgment declaring the "Directives" and "Resulting Grant Terminations" are "of no effect, void, [and] illegal" and "set aside and vacated" those agency actions. App. 150a. Thus, Defendants' reliance on *California* is misplaced and the court of appeals was correct in holding that Plaintiffs' claims belong in the district court and not the Court of Federal Claims.

Third, Defendants are unlikely to prevail on their other legal arguments. Defendants forfeited the argument that NIH's grant terminations are "committed to agency discretion" and thus unreviewable under the APA. Regardless, myriad statutes circumscribe NIH's grantmaking discretion. Nor are Defendants likely to obtain reversal of the district court's order finding the grant terminations arbitrary and capricious. The problem identified by the district court was not, as Defendants assert, a disagreement with the NIH's policy judgment, but rather with a basic failure to engage in reasoning and explain that reasoning, as the APA requires. App. 125a–34a.

Fourth, the government fails to identify a certworthy issue. The government broadly asserts that the lower courts are flouting this Court's stay order in California. But the government has failed to satisfactorily explain how the district court's order conflicts with the guideposts in this Court's brief per curiam order in California, much less a specific split among lower courts applying those guideposts.

The government's stay application should be denied.

#### **STATEMENT**

### I. FACTUAL BACKGROUND

NIH is the primary source of federal funding for biomedical and public health research in the United States. App. 50a; D. Ct. Dkt. 38-2. Often referred to as the "crown jewel" of the federal government's scientific research apparatus, NIH-funded

research has led to over 100 Nobel Prizes and supported more than 99% of the drugs approved by federal regulators from 2010–2019.<sup>2</sup>

Congress has long supplied careful instructions for how the NIH should disburse its funding. App. 50a. The Public Health Service Act, 42 U.S.C. § 201 et seq., mandates research "relating to the causes, diagnosis, treatment, control and prevention of physical and mental diseases and impairments," including by offering "grants-in-aid to universities...other public and private institutions, and to individuals." App. 47a-48a; 42 U.S.C. § 241(a)(3). Within this mandate, Congress further directs the agency to prioritize certain training objectives and areas of research, such as establishing the National Institute on Minority Health and Health Disparities ("NIMHD") with the of "conduct[ing] purpose and support[ing] . . . research, training, dissemination of information, and other programs with respect to minority health conditions and other populations with health disparities." 42 U.S.C. § 285t(a); see also 42 U.S.C. §§ 285t(b), 282(h).

NIH funding flows through Institutes and Centers ("ICs"). And here too, Congress has prioritized certain aims, requiring ICs to "utilize diverse study populations, with special consideration to biological, social, and other determinants of health that contribute to health disparities[.]" 42 U.S.C. § 282(b)(8)(D)(ii).

Medical research takes time, so NIH grants generally span multiple years.

App. 51a. To ensure funding continuity and avoid wasting taxpayer money, Congress

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<sup>&</sup>lt;sup>2</sup> See Nobel Laureates, Nat'l Insts. of Health (Jan. 21, 2025), https://perma.cc/7EZC-8DAK; E. Galkina Cleary et al., Comparison of Research Spending on New Drug Approvals by the National Institutes of Health vs the Pharmaceutical Industry, 2010-2019 4 (JAMA Health Forum 2023, e230511), https://perma.cc/PDU2-FWSB.

requires that NIH operate predictably, through six-year strategic plans. App. 48a; 42 U.S.C. § 282(m)(1). This "framework of stability and predictability has proven itself ... over multiple administrations. It is one reason the United States... in partnership with the scientific research community, has been unsurpassed in its contributions to breakthroughs in science that have enhanced our lives." App. 51a.

NIH's funding decisions are further guided by regulations mandating a rigorous, multi-level analysis of the scientific merit of all grant applications, taking into account the competency of research personnel, the feasibility of the project, and the likelihood that it will produce meaningful results, among other factors. 42 C.F.R. § 52.5. Given this meticulous framework, grant terminations have historically been rare. D. Ct. Dkt. 38-26 ¶ 38. Here, too, regulations constrain the agency's discretion. NIH may unilaterally terminate a grant only for failure to comply with grant requirements or for cause. 45 C.F.R. § 75.372(a) (2020).

Despite these statutory and regulatory constraints, the new administration issued executive orders in January 2025 that directed agencies to "terminate, to the maximum extent allowed by law, all 'equity-related' grants or contracts" within 60 days (Exec. Order No. 14,151), "ensure grant funds do not promote gender ideology" (Exec. Order No. 14,168), and end "immoral race- and sex-based preferences under the guise of so-called [DEI] . . . ." (Exec. Order No. 14,173). App. 53a–55a.

The district court's 67-page findings of fact detail what happened next. App. 47a–114a. Defendants issued a series of Directives restricting NIH funding of "DEI studies," "research programs based on gender identity," and an expanding list of

other disfavored concepts, including through mandates to terminate grants, unpublish existing funding opportunities, and withhold awards. App. 69a–70a. NIH identified grants to terminate and explained its termination decisions by a series of boilerplate justifications set forth in the Directives and also pasted into each termination letter and revised "Notice of Award":

- **DEI**: Research programs based primarily on artificial and non-scientific categories, including 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. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.
- Transgender issues: 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. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.
- Vaccine Hesitancy: It is the policy of NIH not to prioritize research activities that focuses [sic] gaining scientific knowledge on why individuals are hesitant to be vaccinated and/or explore ways to improve vaccine interest and commitment. NIH is obligated to carefully steward grant awards to ensure taxpayer dollars are used in ways that benefit the American people and improve their quality of life. Your project does not satisfy these criteria.
- **COVID**: The end of the pandemic provides cause to terminate COVID-related grant funds. These grant funds were issued for a limited purpose: to ameliorate the effects of the pandemic. Now that the pandemic is over, the grant funds are no longer necessary.
- **Climate Change**: Not consistent with HHS/NIH priorities particularly in the area of health effects of climate change.
- **Influencing Public Opinion**: This project is terminated because it does not effectuate the NIH/HHS' priorities; specifically, research related to attempts to influence the public's opinion.

App. 87a-90a, 103a-11a. Each paragraph represents the sum total of Defendants'

reasoning for the restriction, review of future NIH funding, and the termination of thousands of grants. App. 126a (Counsel conceding: "That is the agency's reasoning."); see also D. Ct. Dkt. 66 at 30–31.

A cavalcade of grant terminations followed. On February 28, 2025, Acting NIH Director Matthew Memoli forwarded an initial spreadsheet to NIH staff, with directions to terminate all the grants listed therein by the end of the day. App. 75a–77a. The agency effectuated each termination through a template termination letter supplied by HHS, without any individualized assessment of particular grants. App. 78a–87a. Each termination letter cited 2 C.F.R. § 200.340(a)(4) (failure to effectuate agency priorities), as the legal basis for termination, even though that regulation does not currently apply to NIH. App. 136a–37a.

NIH went on to hastily cancel hundreds of research projects in this haphazard manner, with some spreadsheets listing as many as 530 grants for immediate, bulk termination. App. 102a. This included the termination of entire programs mandated by Congress to recruit individuals historically underrepresented in the biomedical research field. D. Ct. Dkt. 72-3 ¶ 9–10, see e.g., 42 U.S.C. § 288(a)(4).

The district court's review of the administrative record uncovered no working definition of "DEI," "gender identity," or the other forbidden topics, and no data or analysis to support the Directives' conclusions and resulting terminations. App. 125a. The Directives instruct that "DEI studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans," but nothing in the record explains, for example, how

research on "the role of homocysteine-floate-thymidylate synthase axis and uracil accumulation in African American prostate tumors" or "family language planning and language acquisition among deaf and hard of hearing children" (D. Ct. Dkt. 137-2, Row Nos. 275, 363) posed harm to anyone's health.

As a result of the terminations, Plaintiffs were unable to continue their research; some lost the ability to perform statistical analyses of data already collected. D. Ct. Dkt. 38-19 ¶ 56; 38-20 ¶¶ 23, 37; 38-30 ¶¶ 25–26; 38-31 ¶ 32; 38-33 ¶ 21. Research staff were fired and graduate students denied training opportunities. D. Ct. Dkt. 38-19 ¶ 51; 38-20 ¶ 41; 38-31 ¶¶ 24, 28; Dkt. 25 ¶ 10. Study participants had treatments or interventions interrupted. D. Ct. Dkt. 38-30 ¶¶ 27–28; 38-19 ¶ 20; 38-20 ¶ 37. As one physician-scientist explained, "there will be a dearth of important innovations designed to improve the lives of people experiencing [] horrible conditions. We cannot even know what lifechanging treatments will now go undiscovered without this funding." D. Ct. Dkt. 38-32 ¶ 23.

### II. PROCEDURAL BACKGROUND

### A. Plaintiffs Bring Suit to Stop Defendants' Unlawful Behavior.

On April 2, 2025, Plaintiffs sued to challenge the Directives and the resulting grant terminations under the APA and the U.S. Constitution. D. Ct. Dkt. 1. Plaintiffs filed a motion for preliminary injunction, D. Ct. Dkt. 37, which the district court collapsed into a trial on the merits, Fed. R. Civ. P. 65(a), construing Defendants' opposition as a motion to dismiss (Memorandum and Order (the "MTD Order")). App. 170a.

The MTD Order rejected Defendants' arguments that the court lacked subject matter jurisdiction based on the Tucker Act, agency discretion, and other grounds, adopting the reasoning of its holding in the related case, *Massachusetts v. Kennedy*, No. 25-10814, 2025 WL 1371785, at \*5 (D. Mass. May 12, 2025). App. 182a–83a.

The district court then held a consolidated bench trial for "Phase 1" of both cases, addressing Plaintiffs' APA claims based on thousands of pages in a certified administrative record produced by Defendants. App. 44a–45a. At the conclusion of the trial, the court issued an oral order that the Directives are "arbitrary and capricious," "void," and "illegal" and made the same findings with respect to the grant terminations resulting from the Directives. App. 159a–60a.

## B. The District Court Issues a Partial Final Judgment Holding that the Directives and Grant Terminations Are Unlawful.

On June 23, 2025, the district court issued a partial final judgment under Federal Rule of Civil Procedure 54(b), declaring the Directives "of no effect, void, illegal, set aside, and vacated" under the APA. App. 150a. The judgment also made the same declaration as to the resulting termination of grants. App. 150a (emphasis removed). The court issued a similar judgment in the related case. App. 152a. The next day, the court denied Defendants' motion for a stay. App. 144a.

The district court then issued findings of fact and rulings of law supporting the judgment and explaining why, *inter alia*, the Directives and resulting grant terminations were arbitrary and capricious and not in accordance with law. App. 41a. The district court noted that judicial review "under the arbitrary or capricious standard of Section 706(2)(A) is narrow," that it "may not substitute its judgment for

that of the agency," and that it cannot set aside agency action "solely because it might have been influenced by political considerations or prompted by an Administration's priorities." App. 121a–23a (citation modified).

The district court then determined that "even under this narrow scope of review," Defendants' actions were "breathtakingly arbitrary and capricious." App. 124a. First, it found that the Directives fail to define operative terms. This, the district court explained, "allows the [agency] to arrive at whatever conclusion it wishes without adequately explaining the standard on which its decision is based," App. 127a.

The district court further found that the Directives and corresponding termination letters consisted of "wholly unsupported statements"—there was no evidence that Defendants undertook any analysis, reviewed evidence, or engaged in any reasoning. App. 125a, 127a–28a, 131a–32a. Defendants failed to explain their reversal of prior agency decision making, App. 133a, and largely failed to consider "the reliance interests that naturally inure to NIH grant process." App. 133a. The court also held that Defendants' termination of grants pursuant to 2 C.F.R. § 200.340(a)(4), an "inapplicable regulation," was "contrary to law" under Section 706(2)(A). App. 138a.

# C. The First Circuit Denies Defendants' Motion to Stay the Judgment.

Defendants then filed what they styled as a "[t]ime sensitive" stay motion in the First Circuit. App. 35a. After briefing, a unanimous panel of the First Circuit denied Defendants' motion for a stay, finding that "under Supreme Court precedent, the Department has not met its burden of establishing the grounds for a stay." App. 14a. First, the court of appeals held that Defendants did not make, and thus waived, an argument that the district court lacked jurisdiction for its declaratory judgment vacating the Directives, but "[r]egardless, the district court clearly had jurisdiction to grant 'prospective relief'" under *Bowen*, 487 U.S. at 910. App. 19a.

With respect to the judgment vacating the grant terminations, the court of appeals held that under Bowen, California, and Great-West Life & Annuity Insurance Company v. Knudson, 534 U.S. 204 (2002), Defendants did not have a strong likelihood of success in their challenge to the court's jurisdiction, holding that "(1) the district court's orders here did not award 'past due sums,' but rather provided declaratory relief that is unavailable in the Court of Federal Claims; and (2) neither the plaintiffs' claims nor the court's orders depend on the terms or conditions of any contract." App. 19a–20a, Great-West, 534 U.S. at 204. Distinguishing California, the court of appeals held that the district court did not "enforce a contractual obligation to pay money" and instead "simply declared that [Defendants] unlawfully terminated certain grants." App. 21a–22a. Unlike in this case, the First Circuit explained, the California plaintiffs did not dispute their Department of Education grants are contracts and brought at least one claim based on contractual terms and conditions. App. 22a–23a.

The court of appeals also held that Defendants are unlikely to succeed in arguing that Plaintiffs challenged unreviewable lump-sum appropriations under Lincoln v. Vigil, 508 U.S. 182 (1993). App. 24a–26a. The court held that Defendants failed to include the argument in its motion to stay in the district court, forfeiting it, and regardless, statutes governing NIH grantmaking authority and HHS regulations governing terminations provide "judicially manageable standards' for evaluating the

Department's actions." App. 25a-26a.

The court of appeals also held that Defendants were unlikely to succeed in challenging the district court's orders vacating the terminations as arbitrary and capricious. Reviewing for clear error, the court of appeals held that the district court's "close review" of the administrative record and "comprehensive findings" in support of its conclusion gave rise to "no obvious error." App. 9a, 27a.

Finally, the court of appeals held that the balance of equities did not support a stay. App. 33a. While Defendants might "be unable to recover some funds disbursed during the pendency of this litigation," they failed to quantify the loss or provide evidence it was imminent. App. 31a, 34a. By contrast, Plaintiffs provided concrete, unrefuted evidence of substantial irreparable harm if the orders were stayed, including non-monetary harms that could not be remedied through later payment and serious consequences for public health. App. 31a–33a. Almost a week after the First Circuit denied the stay, Defendants filed this Application.

#### **ARGUMENT**

Defendants have not carried their heavy burden to justify a stay. First, and most fundamentally, the balance of equities counsels firmly against a stay, as Plaintiffs' undisputed evidence of irreparable harm strongly outweighs any potential monetary harm to Defendants. Second, the district court, not the Court of Federal Claims, had jurisdiction under the APA to resolve Plaintiffs' claims. This case is materially distinguishable from *California* in terms of both the asserted equities and the legal issues—the district court granted a quintessentially equitable remedy based

on statutory violations. Third, Defendants are unlikely to succeed on their other legal arguments. The district court's findings of fact amply illustrate the arbitrary and capricious nature of Defendants' actions, and there is no serious argument that NIH grantmaking decisions—which are cabined by numerous statutory requirements—fall within the narrow category of actions committed to agency discretion by law. Finally, this case is not a likely candidate for certiorari, as lower courts are applying the Court's stay order in *California* as well as longstanding precedents in *Bowen* and *Great-West* to various facts in the cases before them, and the government fails to identify any specific conflict in their decisions.

# I. THE IRREPARABLE INJURIES THE GOVERNMENT HAS INFLICTED ON PLAINTIFFS AND BIOMEDICAL RESEARCH STARKLY DISFAVOR A STAY.

The most obvious distinction between this case and *California* is also the most crucial of this Court's stay factors: Here, the balance of irreparable injuries decisively favors Plaintiffs, not the government. *Cf. Nken v. Holder*, 556 U.S. 418, 432 (2009) ("The authority to grant stays has historically been justified by the perceived need to prevent irreparable injury." (citation modified)); *see also, e.g., Graddick v. Newman*, 453 U.S. 928, 933 (1981). This is not a case about monetary harm that could be temporarily addressed through alternative funding sources, but rather about profound injury to public health that cannot be fully remedied at a later date. A stay would abruptly, and in many cases permanently, halt lifesaving biomedical research that Congress has directed the NIH to fund, with irreparable consequences for scientific progress. That, and the obvious harm to those who suffer from chronic or life-

threatening diseases and their loved ones, must be balanced against NIH's ill-defined monetary interests and any asserted incursion on its policymaking latitude.

Ample, unrebutted evidence demonstrates the significant, compounding harms Plaintiffs and the public would face from a stay. The Directives and terminations jeopardize—and in some cases eliminate—research that Congress funded for the benefit of public health. See, e.g., D. Ct. Dkt. 38-30 ¶¶ 25–26; 38-19 ¶ 56; 38-34 ¶ 30; 38-20 ¶¶ 23, 37; 38-22 ¶ 17. Most immediately, some study participants will have treatments or interventions interrupted. See, e.g., D. Ct. Dkt. 38-30 ¶¶ 27–28; 38-19 ¶ 20. Stopping and starting this research is not like flipping a light switch: Ending a study midway can completely ruin the data collected for the entire study, see, e.g., Dkt. 38-19 ¶ 20; 38-20 ¶¶ 23, 37; 38-31 ¶ 32; 38-34 ¶ 30, and restarting a study takes significant time due to participant recruitment and staff hiring, see, e.g., D. Ct. Dkt. 38-33 ¶ 21. At each stage, researchers must keep in mind how disruptions implicate their ethical obligations to study participants. See, e.g., D. Ct. Dkt. 38-20 ¶ 37. What's more, because shutting down research impedes Plaintiffs' career progression, the scientific research enterprise in the United States will be threatened for generations to come. D. Ct. Dkt. 38-21 ¶ 22; 38-39 ¶¶ 17–18; 38-41 ¶¶ 14–17; 38-25 ¶¶ 10, 16; 38- $31 \P 24, 25-27, 31; 38-20 \P 41-42; 38-30 \P 31; 38-32 \P 21; 38-34 \P 26, 27; Dkt. 38-34 \P 26, 27; Dkt. 38-34 \P 26, 27; Dkt. 38-34 <math>\P 38-34 \P 38-34$  $35 \P\P 20-21; 38-36 \P 15; 38-37 \P 24; 38-40 \P\P 19-22.$ 

Further distinguishing *California*, Plaintiffs have not represented and cannot "represent in this litigation that they have the financial wherewithal to keep their" research "running" absent a stay. *California*, 145 S. Ct. at 969. Rather, Plaintiffs

provided the district court with unrebutted evidence indicating the opposite. *See*, *e.g.*, D. Ct. Dkt. 38-31 ¶ 26; 38-33 ¶ 23; 38-20 ¶¶ 23, 37, 41; 38-34 ¶ 25; 38-31 ¶ 26. Whether the Plaintiff States in the related case have the ability to make up for NIH funding, as Defendants have argued, is unproven and in no event affects the private Plaintiffs' undisputed showing of irreparable harm. The possibility of NIH providing *phaseout* funds to wind down projects will also not keep Plaintiffs' lifesaving biomedical research going. App. 29a.

While the court of appeals also concluded that Defendants have shown irreparable harm to the extent "the Department may be unable to recover some funds disbursed during the pendency of the litigation," Defendants provided no basis on which to quantify that potential loss. App. 31a. And unlike in *California*, a situation where "the short-term nature of a TRO" could "incentivize plaintiffs to draw down nearly \$65 million in a matter of weeks," here the district court's order is "not time-limited, impos[ing] no such concentrated financial pressure." App. 31a, 34a.

As for Defendants' argument that the district court's order "improperly intrudes on a coordinate branch of the government and prevents the government from enforcing its policies," Stay Appl. 37 (citing *Trump v. CASA, Inc.*, 145 S. Ct. 2540, 2561 (2025)), it is not at all clear how a case about universal injunctions (a remedy the district court did not here issue) transforms the government's asserted pocketbook injury into something more sweeping. *See* 145 S. Ct. at 2561. *CASA* expressly did not affect the setting aside of arbitrary and capricious agency action under the APA. *See* 145 S. Ct. at 2555 n.10, 2567 (Kavanaugh, J., concurring). And if this Court "were to adopt the

government's assertion that the irreparable harm standard is satisfied by the fact of executive action alone, no act of the executive branch asserted to be inconsistent with a legislative enactment could be subject to" judicial relief. See Cmty. Legal Servs. in E. Palo Alto v. Dep't of Health & Hum. Servs., 137 F.4th 932, 943 (9th Cir. 2025).

In this Court's hands rests the ongoing viability of research to "help[] the public gain a more integral understanding of how alcohol use and alcohol use disorder could contribute to the development of Alzheimer's disease," D. Ct. Dkt. 38-21 ¶ 24, research presenting "our first opportunity to study how aging is affected by HIV, related medications, and other factors," D. Ct. Dkt. 38-33 ¶ 24, research "equip[ping] peers with the tools to respond effectively and compassionately to disclosures of sexual violence," D. Ct. Dkt. 38-34 ¶ 32, and studies like "Evaluating Centralizing Interventions to Address Low Adherence to Lung Cancer Screening Follow-up in Decentralized Settings," "Molecular understanding of maternal humoral responses to pregnancy," "Leveraging early-life microbes to prevent type 1 diabetes," D. Ct. Dkt. 138-1, and hundreds more. Measured against dollars, the balance of equities rests firmly with Plaintiffs.

# II. THE DISTRICT COURT HAS JURISDICTION OVER THIS CASE; THE COURT OF FEDERAL CLAIMS DOES NOT.

The government argues that *California* is "materially identical" and "should have conclusively resolved this case" simply because both matters challenge grant terminations under the APA and, in the government's telling, *California* holds the Court of Federal Claims has exclusive jurisdiction over grant cases under the Tucker Act. Stay Appl. 19, 22. These arguments are wrong. *California* is distinct from this

case, not only in the clear evidence of irreparable harm described above, but also on the operative facts and the legal issues upon which the Supreme Court based its order.

Even under the framework for deciding the applicability of the Tucker Act which Defendants put forward, jurisdiction is proper in the district court, not the Court of Federal Claims: Plaintiffs did not raise contract claims but rather sought to enforce the APA. Consistent with those claims, the district court did not order any remedies sounding in contract, such as damages or specific performance; rather, the court ordered equitable relief pursuant to the APA, setting aside and vacating arbitrary and capricious agency actions. Finally, the Court of Federal Claims would not consider Plaintiffs' grants to be "contracts" subject to its exclusive jurisdiction—indeed, NIH itself treats grants as distinct from "contracts." Thus, Defendants' argument would mean that no court has jurisdiction to determine the legality of Defendants' policy determinations. This runs afoul of Congress's intent to ensure the availability of judicial review of arbitrary and capricious agency action.

### A. This Case is Distinguishable from *California*.

Defendants' primary argument against jurisdiction in the district court is that this Court's order in *California* compels that result. That is incorrect and mischaracterizes both *California*'s facts and holding as well as the facts of this case.

Most fundamentally, *California* involved an order that "require[d] the government to pay out past-due grant obligations." *California*, 145 S. Ct. at 968. This Court held that the district court likely lacked jurisdiction because the APA's "waiver of sovereign immunity" does not apply "if any other statute that grants consent to suit

expressly or impliedly forbids the relief which is sought" or if the claim seeks "money damages." *Id.* (citing 5 U.S.C. § 702). Since this Court determined that the district court had issued an order "to enforce a contractual obligation to pay money," and the Tucker Act provides the Court of Federal Claims with jurisdiction over contract suits against the United States, this Court held the APA's limited waiver of sovereign immunity did not apply. 145 S. Ct. at 968 (citing *Great-West*, 534 U.S. at 212).

Not so here. The district court granted only equitable relief under the APA, setting aside and vacating agency actions—the Directives and grant terminations. See App. 149a ¶¶ 1, 2 (The Directives "taken as a whole are declared to be final agency action, arbitrary and capricious, and unlawful . . . . [They are] set aside and vacated."); App. 150a ¶ 4 ("[T]he Resulting Grant Terminations are hereby of no effect, void, illegal, set aside and vacated."). This relief is specifically authorized by the APA. 5 U.S.C. § 706(2)(a) ((district court may "hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."). In contrast, in California, the district court ordered the government to "immediately restore Plaintiff States to the pre-existing status quo prior to the termination"—language that sounds in contractual damages and specific performance. Mem. and Order on Pl. States' Mot. for TRO at 9, California

<sup>&</sup>lt;sup>3</sup> Defendants argue that the district court's orders with respect to the Directives and the terminations "merge" because "[o]rdering the government not to apply the guidance to respondents' grants and ordering the government to reinstate those grants are [] effectively the same remedy." Stay Appl. 25–26. This is plainly incorrect and does not justify expanding Defendants' stay application to the judgment setting aside the Directives. Vacatur of the terminations flowed from and was necessitated by vacatur of the Directives; The inverse is not true. The Directives do not merely compel the termination of grants; they instruct NIH staff regarding support of biomedical research, including, inter alia, withdrawing funding opportunities and new applications. See Appl. 68a–69a (staff must review "existing applications," "notice of funding opportunities," and "other transactions").

v. United States Dep't of Educ., No. 25-10548 (D. Mass. Mar. 10, 2025), Dkt. 41.

Put differently, unlike in *California*, the district court here did not order payment of "specific sums already calculated, past due, and designed to compensate for completed labors," relief appropriate for the Court of Federal Claims, *Maine Cmty*. *Health Options v. United States*, 590 U.S. 296, 298 (2020). Rather, as in *Bowen*, the district court "t[old] the United States that it may not [act] on the grounds given." App. 21a (citing *Bowen*, 487 U.S. at 910). In other words, the district court simply ordered the agency to follow the law. *Cf. Ferreiro v. United States*, 501 F.3d 1349, 1353 n.3 (Fed. Cir. 2007) ("An order compelling the government to follow its regulations is equitable in nature and is beyond the jurisdiction" of the Court of Federal Claims.).

Defendants' repeated assertion that the district court here did order payments as a remedy (see e.g., Stay Appl. 3, stating the government was ordered to "pay[] out over \$783 million in grants") is simply false. The district court never ordered such payments, and the government's \$783 million figure appears to be invented out of whole cloth—it is nowhere in the proceedings below. App. 150a, 159a–60a. The district court did express an expectation that grant funding would flow as a consequence of its order, and stated "if" its order vacating the Directives and terminations "does not result" in disbursement of funds, the court could exercise "continuing jurisdiction." App. 160a–61a. But expressing an expectation that the government will act in accordance with a declaratory judgment is not the same as ordering money to be paid for purposes of the Tucker Act—as this Court recognized in Bowen. 487 U.S. at 910 ("[T]o the extent that the district court's judgment [results in a reimbursement] this

outcome is a mere by-product of that court's primary function of reviewing the Secretary's interpretation of federal law.").

California therefore does not "squarely control" this case, Trump v. Boyle, No. 25A11, slip op. at 1 (S. Ct. July 23, 2025).

### B. Plaintiffs' Claims Are Not Contractual Under Megapulse.

Defendants' argument that Plaintiffs' claims are "contractual" and thus belong in the Court of Federal Claims also fails. Defendants rely on the D.C. Circuit's *Megapulse* "rights"-and-"remedies" framework, which inquires into "the type of relief sought" and "the source of the rights upon which the plaintiff bases its claims." Stay Appl. 21 (citing *Megapulse, Inc. v. Lewis*, 672 F.2d 959, 968 (D.C. Cir. 1982)). Under that approach, "[i]f rights and remedies are statutorily or constitutionally based, then district courts have jurisdiction; if rights and remedies are contractually based then only the Court of Federal Claims does." *Cmty. Legal Servs.*, 137 F.4th at 938 (citation modified). Under this widely adopted framework, asserted by Defendants themselves, Plaintiffs' claims are not contractual in nature and belonged in the district court.

### 1. The type of relief sought is not contractual.

The district court did not order money damages, specific performance of contractual terms, or any other relief that sounds in contract. Instead, Plaintiffs sought, and the district court ordered, quintessentially equitable relief under the APA. App. 20a (the district court "provide[d] declaratory relief that is well within the scope of the APA.") (citing *U.S. Bancorp Mortg. Co. v. Bonner Mall P'ship*, 513 U.S. 18, 25 (1994) (describing the "equitable remedy of vacatur")). As in *Bowen*, and unlike in

California, the district court's order of declaratory and prospective equitable relief is expressly authorized by the APA. 5 U.S.C. § 702; see also Bowen, 487 U.S. at 898 ("Congress understood that § 702, as amended, would authorize judicial review of the 'administration of Federal grant-in-aid programs.") (citing H. R. Rep. No. 94-1656, at 8 (1976); S. Rep. No. 94-996, at 9 (1976)).

Moreover, unlike in *California*, where the only final agency action that was challenged was grant terminations, here Plaintiffs sought relief based primarily on the illegality of the Directives, and the district court vacated the downstream terminations as unlawful precisely *because* the Directives that led to them were unlawful. The district court's set-aside of the grant terminations is therefore no more a contractual remedy than its set-aside of the Directives. Neither is "the prototypical contract remedy of damages, nor the classic contractual remedy of specific performance." *See Crowley Gov't Servs., Inc. v. General Servs. Admin*, 38 F.4th 1099, 1110 (D.C. Cir. 2022) (citation modified).

Put simply, this is not a case where certain grantees had their funding cut and are attempting to recoup those funds, as in *California*. Rather, it is a broader challenge to an agency's action in violation of the APA. The court of appeals recognized that "plaintiffs argued that the Challenged Directives are unlawful agency-wide policies because they violate various federal statutes" and "the [grant] terminations flowed directly from those unlawful policies," and correctly concluded that these are "classic examples of claims that belong in federal district court" and not the Court of Federal Claims. App. 23a. Indeed, the kind of relief sought and ordered here is unavailable in

the Court of Federal Claims. See *Bowen*, 487 U. S. at 905 ("The Claims Court does not have the general equitable powers of a district court to grant prospective relief," whereas the district court has jurisdiction under the APA to grant "prospective relief" that governs "a complex ongoing relationship between the parties"). "It seems highly unlikely that Congress intended to designate an Article I court as the primary forum for judicial review of agency action that may involve questions of policy that can arise in cases such as these." *Id.* at 908 n.46.4

# 2. Plaintiffs' claims do not turn on the terms and conditions of any contract, but rather on statutory requirements.

Plaintiffs' claims are also not contractual because Plaintiffs do not seek to enforce the terms and conditions of any agreement with NIH, but rather seek to hold Defendants accountable to their obligations under relevant statutes and regulations. In contrast, the plaintiff States in *California* asserted at least one claim that depended on the terms and conditions of their education grant agreements. Appl. to Vacate at 16, *United States Dep't of Ed. v. California*, No. 24A910 (S. Ct. Mar. 26, 2025).

Plaintiffs' claims did not require the district court to parse Defendants' obligations to the Plaintiffs under any agreement. As the court of appeals' order explains, "the district court neither examined any of the plaintiffs' grant terms nor interpreted them in reaching its ruling that the grant terminations must be set aside. App. 22a. The source of Plaintiffs' rights is the APA's prohibition on arbitrary and

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<sup>&</sup>lt;sup>4</sup> Notably, Defendants do not attempt to argue that the Court of Federal Claims can provide a sufficient alternative remedy such that the district court lacks jurisdiction under 5 U.S.C. § 704's requirement that "there is no other adequate remedy in a court," implicitly acknowledging that this Court's holding in *Bowen* would squarely refute such an argument. 487 U.S. at 904 ("The remedy available to the State in the Claims Court is plainly not the kind of 'special and adequate review procedure' that will oust a district court of its normal jurisdiction under the APA.").

capricious agency action.

Defendants argue that "[w]ithout a grant agreement, the respondents would have had no right to payment in the first place," Stay Appl. 22, but the mere fact that a case requires making "some reference to or incorporation of a contract" does not necessarily bring it "within the Tucker Act." Crowley, 38 F.4th at 1108-09 (citing Megapulse, 672 F.2d at 967–98). Rather, the touchstone is whether the court must look to contract terms in order to determine the parties' rights. Cf. Maine Cmty. Health Options, 590 U.S. at 327 (claim falls under the Tucker Act, not the APA, where plaintiffs seek to recover "specific sums already calculated" under the terms of a federal agreement to "compensate for completed labors"). Plaintiffs' claims here required the district court to analyze Defendants' reasons for issuing the Directives and terminating Plaintiffs' grants. For this reason, the district court's orders "hinge entirely on intragovernmental communications—the type of administrative record at the heart of the APA." App. 23a. No analysis of any contractual term was required to adjudicate the claims. This case is not one where the plaintiff's "source of right" is a contract. See Crowley, 38 F.4th at 1108–09 (plaintiffs' claims "require[d] primarily an examination of the statutes"); Cmty. Legal Servs., 137 F.4th at 938 ("plaintiffs seek to enforce compliance with statutes and regulations, not any government contract").

# C. The Court of Federal Claims Would Not Have Exercised Jurisdiction Over Plaintiffs' Claims.

Setting aside Defendants' erroneous assertions regarding *California* and *Megapulse*, if Plaintiffs *had* sought relief in the Court of Federal Claims, that court's existing precedent would likely have made those efforts futile. The only relevant

documents here—the "Notice of Award," which sets forth each grant's terms and conditions—are not "contracts" under that court's established caselaw. See, e.g., St. Bernard Par. Gov't v. United States, 134 Fed. Cl. 730, 735 (2017), aff'd on other grounds, 916 F.3d 987 (Fed. Cir. 2019) (cooperative agreement is not a contract).

To start, the Court of Federal Claims looks to the agency's custom or practice to determine whether the agency intended to enter into a contract. See generally Hanlin v. United States, 316 F.3d 1325, 1329 (Fed. Cir. 2003). But NIH practice expressly distinguishes between the grants at issue here and the agency's contracts. Congress has separately addressed NIH's authority to award grants and its authority to enter into contracts. See, e.g., 42 U.S.C. §§ 241(a)(3), 241(a)(7) (distinguishing the Secretary's authority to "make grants-in-aid to universities . . . and other public or private institutions... for general support of their research" from the authority to "enter into contracts"); 42 U.S.C. § 284(b)(2) (differentiating between IC Directors' authority to enter into grants versus contracts). And nowhere has Congress expressed any intent for grant awards to be binding on the government, as a contract would be. See Adia Holdings, Inc. v. United States, 170 Fed. Cl. 296, 301–02 (2024) ("absent some clear indication that the legislature intends to bind itself contractually, the presumption is that a law is not intended to create private contractual or vested rights"); Imaginarium, LLC v. United States, 166 Fed. Cl. 234, 242 (2023) (same).

Agency regulations and NIH's implementation of its grants program also maintain this distinction between grants and contracts. See 45 C.F.R. § 75.2 ("grant agreement" is an "instrument of financial assistance," designed to "carry out a public

purpose authorized by a law of the United States . . . and not to acquire property or services for the Federal awarding agency[.]"). Indeed, in public-facing materials describing funding categories, NIH *explicitly* distinguishes a grant (an "assistance mechanism to support research for the public good") from a contract (a "legally binding agreement" NIH uses "to acquire goods or services for the direct use or benefit of the government"):

Grants vs. Contracts	
Grant	Contract
<ul> <li>Assistance mechanism to support research for the public good</li> </ul>	<ul> <li>Legally binding agreement to acquire goods or services for the direct use or benefit of the government.</li> </ul>
<ul> <li>Peer review of broad criteria</li> <li>Limited government oversight and control</li> </ul>	<ul> <li>Award based on stated evaluation factors</li> <li>More government oversight and control</li> <li>Deliverables</li> </ul>
<ul> <li>Reports</li> </ul>	

D. Ct. Dkt. 72-1 at 2–3. NIH's grant policy similarly describes the Notice of Award for grants as "the legal document issued to notify the recipient that an award has been made and that funds may be requested" rather than a contractually binding agreement (emphasis added). See A.R. 3982. While NIH's grant policy explains that the Notice of Award imposes a legal obligation on the recipient to abide by certain terms and conditions (see A.R. 3984), nowhere does the Notice of Award impose a binding obligation on Defendants. See A.R. 3982–86. Such a one-sided arrangement lacks the mutuality of obligation that defines a contract. See, e.g., Adia Holdings, 170 Fed. Cl. at 304 ("mere fact that [grantees] must comply with certain requirements as a condition of a grant does not mean that the United States has somehow manifested its intent to contract") (citing Imaginarium, 166 Fed. Cl. at 244; Harlem Globetrotters

Int'l, Inc. v. United States, 168 Fed. Cl. 31, 38 (2023)).

The Notices of Award also do not constitute contracts because "consideration must render a benefit to the government, and not merely a detriment to the contractor," St. Bernard Par. Gov't, 134 Fed. Cl. at 735, and there is no such consideration given here. The benefit to the government must be "direct" and "tangible," not "generalized" or "incidental." Id. at 736. The Federal Circuit has therefore made clear that any "indirect[] benefit" to an agency that results from funding a project to "advance the agency's overall mission" is insufficient to establish consideration. See Hymas v. United States, 810 F.3d 1312, 1328 (Fed. Cir. 2016); Adia Holdings, 170 Fed. Cl. at 304 (grant awards were not contracts because they did not require grant recipients "to provide anything to the government in exchange for the grant monies they receive"). Public benefits from the research funded by a federal grant do not qualify as "the kind of direct benefit . . . that would support the finding" of consideration. St. Bernard Par. Gov't, 134 Fed. Cl. at 735–36. Cf Am. Near E. Refugee Aid v. United States Agency for Int'l Dev., 703 F. Supp. 3d 126, 133 (D.D.C. 2023) (agreement under which agency, pursuant to its mission, provided funds for external projects to improve water and sanitation in the West Bank lacked consideration for Court of Federal Claims jurisdiction).

Here, NIH awarded grants to Plaintiffs for the general support of Plaintiffs' research and to achieve statutory goals. See 42 U.S.C. §§ 241(a)(3), 284(b)(2)(B), 288(a)(1)(B). While Plaintiffs' research advances the general health and welfare of the public, in accord with Congress's purposes, Defendants point to no "direct" or

"tangible" benefit to them within the meaning of the court of federal claims' precedents defining a contract. See Stay Appl. 24.5

Thus, if Plaintiffs were not bringing classic APA claims for classic APA relief, and instead were pursuing contractual damages and specific performance, without contracts to sue on, the Court of Federal Claims would deny jurisdiction. This means that if Defendants prevail on their argument that the district court here lacked jurisdiction, no court will have jurisdiction to hear Plaintiffs' claims. Indeed, if NIH announced a new policy to only award grants to male researchers, or researchers whose names begin with the letter "M," and terminated all non-compliant grants midstream, on the government's argument those agency actions would be unreviewable. Not only is this result contrary to common sense, it conflicts with the basic principle that a federal district court cannot "be deprived of jurisdiction by the Tucker Act when no jurisdiction lies in the Court of Federal Claims." See Tootle v. Sec'y of Navy, 446 F.3d 167, 176–77 (D.C. Cir. 2006); cf. Axon Enter., Inc. v. Fed. Trade Comm'n, 598 U.S. 175, 190 (2023) (district court should not be deprived of jurisdiction where doing so "could foreclose all meaningful judicial review."). And the government's argument is at odds with this Court's specific instruction that "the Administrative

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<sup>&</sup>lt;sup>5</sup> It is true that recipients must give NIH a royalty-free, nonexclusive, and irrevocable license to recipient data (recipients otherwise retain intellectual property rights). A.R. 4045. But this is not a "direct" and "tangible" benefit that could constitute consideration. See Am. Ctr. for Int'l Lab. Solidarity, 2025 WL 1795090, at \*17 ("As to the 'royalty-free rights to media created by the grantee[s],' defendants offer no evidence that these rights have any, much less significant, value—easily distinguishing them from defendants' citation to Thermalon" (internal citations omitted)); cf. Thermalon Indus., Ltd. v. United States, 34 Fed. Cl. 411, 415 (1995) (finding consideration where an agreement between the National Science Foundation ("NSF") and grant recipients for high-technology research into thermal insulation granted NSF the right to publish plaintiff's research results, title to equipment purchased with grant funds, and a royalty-free license, which "had significant economic value").

Procedure Act's 'generous review provisions' must be given a 'hospitable' interpretation." *Bowen*, 487 U.S. at 904 (citing *Abbott Lab'ys v. Gardner*, 387 U.S. 136, 140–41), *see also id.* at 903 (APA's "central purpose" is to "provid[e] a broad spectrum of judicial review of agency action"), H. R. Rep. No. 79-1980 (1946) ("To preclude judicial review under this bill a statute, if not specific in withholding such review, must upon its face give clear and convincing evidence of an intent to withhold it.")

# III. THE GOVERNMENT IS UNLIKELY TO SUCCEED ON ITS REMAINING LEGAL ARGUMENTS.

Defendants further argue the district court erred in finding their actions arbitrary and capricious, and in allowing review under the APA. They are unlikely to succeed on either point.

# A. The Directives and Grant Terminations Were Manifestly Arbitrary and Capricious.

On the merits: An agency action is arbitrary and capricious "if it is not reasonable and reasonably explained." *Ohio v. EPA*, 603 U.S. 279, 292 (2024) (quotation omitted). After a careful review of the administrative record and a trial on the merits, the district court issued a 103-page ruling, thoroughly laying out Defendants' decisionmaking process and explaining in detail why the Directives and resulting grant terminations were "breathtakingly arbitrary and capricious." App. 124a. In light of these findings, Defendants cannot show that they are likely to succeed on appeal on this issue.

Indeed, Defendants largely ignore the court's factual findings, instead asserting that, "[a]t bottom, the district court disagreed with the Administration's view that federal science funding should not support DEI or gender ideology." Stay Appl. 34. But

seeking to implement a policy judgment does not absolve Defendants of their statutory duty to act reasonably. When changing a policy, the APA demands the agency "show that there are good reasons for the new policy," particularly when it "rests upon factual findings that contradict those which underlay its prior policy." FCC v. Fox Television Stations, Inc., 556 U.S. 502, 515 (2009). Nothing in the record shows any acknowledgment of—much less engagement with—the information underlying Defendants' prior policy, see App. 133a, or the conclusions of NIH and external scientists who reviewed and approved terminated projects through a rigorous process, see D. Ct. Dkt. 41 at 30 n.26; 38-26 ¶ 25–37. This is especially egregious in light of the years-long efforts by Plaintiffs and Members to apply for, refine, implement, and report on their research projects. See D. Ct. Dkt. 41 at 15–17, 24 nn.25–26, 29–30.

Nor have Defendants pointed to any record evidence of any actual analysis, reasoning, or data to support the policy shift described in the Directives. App. 126a, 130a–32a. There is nothing, for example, to support Defendants' conclusory assertions that so-called DEI and gender-identity studies "do nothing to expand our knowledge of living systems" and "can be 'artificial and non-scientific." See App. 130a–31a; see also Dep't of Homeland Sec. v. Regents of the Univ. of California, 591 U.S. 1, 30 (2020) (DACA "rescission memorandum contains no discussion" of issue and therefore was arbitrary and capricious.). That such unreasoned statements were parroted across boilerplate termination letters does not resolve this problem or demonstrate evenhandedness, as Defendants would have it, Stay Appl. 33—instead, it shows the sweeping scope of NIH's failure to make any individualized findings, or engage with

any data or information. See, e.g., Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 48 (1983) (citing with approval court of appeals' statement that "[t]here are no findings and no analysis here to justify the choice made, no indication of the basis on which the [agency] exercised its expert discretion.").

The lack of definitions for key terms in the Directives strengthens the district court's findings, as researchers were left without "an identifiable metric" "to assess whether their [research] falls within the" agency's categories of forbidden topics, App. 126a–27a (quotation omitted); cf. Dep't of Com., 588 U.S. at 785 ("The reasoned explanation requirement... is meant to ensure that agencies offer genuine justifications for important decisions, reasons that can be scrutinized by courts and the interested public."). The district court found that the chaotic implementation of the Directives was a direct consequence of this definitional absence, App. 126a–33a, allowing Defendants "to arrive at whatever conclusion [they] wishe[d] without adequately explaining the standard on which its decision is based." App. 127a (internal quotation omitted).

Contrary to Defendants' assertion that the Directives stemmed from the Acting Director's expertise, and described general priorities that allowed NIH staff to "use[] their scientific background and knowledge of their programs to review grants" on a grant-by-grant basis, Stay Appl. 30, 32, the district court found that much, if not all, of the language in the Directives and template termination letters was in fact provided to NIH by officials outside the agency. See App. 71a, 84a–87a. The district court also found there were no individualized assessments of the grants that were terminated.

See App. 125a. Indeed, the district court found that lists of grant terminations were compiled in bulk fashion—again, often by individuals outside of NIH. See App. 79a, 83a, 92a, 99a–103a, 114a, 124a–25a; see also A.R. 2488; A.R. 2562; A.R. 3122; A.R. 3452; A.R. 3511. NIH implemented these terminations with lightning speed, with officials often spending mere minutes bulk-terminating grants. App. 99a; A.R. 3452; A.R. 3511.

Finally, Defendants failed to consider the reliance interests at stake—namely, the impact to researchers' career progression, the risk to human life, and the damage to the overall scientific endeavor and the body of public health. Having changed their policy, Defendants were "required to assess whether there were reliance interests, determine whether they were significant, and weigh any such interests against competing policy concerns." *Regents*, 591 U.S. at 33. In their stay application to the First Circuit, Defendants pointed to a single sentence in one of the termination letters mentioning the possibility of some phaseout funds, A.R. 106, but the court of appeals correctly concluded that did "not account for the broad scope of financial and non-financial interests staked on grant awards, including years of research and millions of hours of work. Nor does it have any bearing on whether the Department considered those myriad interests before issuing and implementing its Directives[.]" App. 29a; see also 133a (district court findings on reliance interests).

Despite claiming below that NIH "plainly considered and understood" obvious reliance interests, D. Ct. Dkt. 111 at 15, Defendants now assert there were *no* reliance interests at stake because "[g]rantees can hardly claim unfair surprise when the new

Administration took a different view of the NIH's priorities." Stay Appl. 34 (citing 2 C.F.R. 200.340(a)(4)). That logic would have applied with equal force to the recission of the DACA Memorandum at issue in *Regents*. 591 U.S. at 33–34 (noting that document states "that the program 'conferred no substantive rights' and provided benefits only in two-year increments). This Court nevertheless held that DACA recipients had reliance interests that the agency failed to consider. *See id.* at 34.

Thus, the district court correctly reached the conclusion that Defendants' actions were neither reasoned nor reasonable.

### B. NIH Grantmaking Is Not Committed to Agency Discretion.

Nor are Defendants likely to succeed on the basis that their actions are committed to agency discretion within the meaning of § 701(a)(2) of the APA, and thus unreviewable. Congress has provided numerous guideposts for how the NIH should award grants, including mandates to prioritize research into health disparities and broaden the biomedical workforce. By supplying those guideposts, Congress has constrained NIH's grantmaking discretion in a manner that is very much susceptible to judicial review.

# 1. Defendants forfeited this argument by failing to raise it before the district court.

As an initial matter, the court of appeals correctly held that Defendants forfeited this argument by failing to raise it before the district court. App. 25a; see Fed. R. App. P. 8(a)(1). Defendants assert that their argument was "incorporated by reference" in their initial stay motion, Stay Appl. 29, because they stated they were likely to prevail on the merits "[f]or these and the other reasons argued by Defendants

throughout the various briefs filed in these two cases." D. Ct. Dkt. 141 at 6 (emphasis added). Such "vague appeal[s]" to general principles do not suffice to preserve arguments. See Bankers Life & Cas. Ins. Co. v. Crenshaw, 486 U.S. 71, 77 (1988). As the First Circuit recognized, to hold otherwise would invite parties to make an endrun around Federal Rule of Appellate Procedure 8(a)(1) and leave appellate courts to grapple with stay arguments in the first instance. App. 25a.

# 2. The grant terminations are not committed to agency discretion.

Regardless, the argument fails on its own terms because Congress has set priorities and guided and cabined agency discretion. To determine reviewability, courts look for statutory limits on an agency's discretion. See Lincoln, 508 U.S. at 193; Heckler v. Chaney, 470 U.S. 821, 832–33 (1985). This Court reads the APA's "§ 701(a)(2) exception quite narrowly, restricting it to those rare circumstances where the relevant statute is drawn so that a court would have no meaningful standard against which to judge the agency's exercise of discretion." Dep't of Com., 588 U.S. at 772 (citing Weyerhaeuser Co. v. U.S. Fish & Wildlife Serv., 586 U.S. 9, 23 (2018)). Only where there is "no law to apply" does § 701(a)(2) bar judicial review; thus, the APA contemplates judicial review even where a statutory scheme confers broad agency authority. Id. at 771–72, 773 (citing Overton Park, 401 U.S. 402, 410 (1971)).

Defendants essentially argue that the NIH has untrammeled discretion to make and terminate grants out of Congress's lump-sum appropriation. But while "the allocation of funds from a lump-sum appropriation" may be, as a general matter, "traditionally regarded as committed to agency discretion," it does not follow that *all* 

grantmaking decisions for lump-sum appropriations are categorically unreviewable under the APA. *Lincoln*, 508 U.S. at 192. This is because "Congress may always circumscribe agency discretion to allocate resources by putting restrictions in the operative statutes." *Id.* at 193.

Congress has provided "judicially manageable standards" here, *Chaney*, 470 U.S. at 830–31, and NIH "is not free simply to disregard statutory responsibilities." *Id.* Congress has enacted statutes governing NIH grantmaking that, among other things, "authorize[] . . . moneys expressly for the" grants and research at issue, and "statutorily restrict[] what can be done with [NIH's] funds," *Lincoln*, 508 U.S at 192.6

First, numerous statutory provisions mandate that NIH fund research into health disparities and guide NIH's discretion in how that research should be conducted. For example, Congress mandates that certain NIH subdivisions "shall in expending amounts appropriated . . . give priority to conducting and supporting minority health disparities research," 42 U.S.C. § 283p; created NIMHD to conduct and support research regarding populations with health disparities and minority health conditions, 42 U.S.C. §§ 285t(a)—(b); requires NIMHD to prioritize minority health disparity research, 42 U.S.C. § 285t(f)(1)(D); and requires the NIH Director to pay special consideration to "determinants of health that contribute to health disparities," 42 U.S.C. § 282(b)(8)(D)(ii).

Second, Defendants are also subject to explicit statutory mandates to broaden

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<sup>&</sup>lt;sup>6</sup> Defendants imply that this Court should limit its review to appropriations statutes and ignore all other statutory frameworks governing the agency's grantmaking authority, Stay Appl. 27–28, but *Lincoln* squarely foreclosed such a cramped review, 508 U.S. at 193–94 (analyzing appropriations statutes *and* Snyder and Indian Improvement Acts).

the biomedical workforce. Congress has mandated that the HHS Secretary, acting through the NIH Director and IC directors, "shall, in conducting and supporting programs for research, research training, recruitment, and other activities, provide for an increase in the number of women and individuals from disadvantaged backgrounds (including racial and ethnic minorities) in the fields of biomedical and behavior." 42 U.S.C. § 282(h). Congress also mandates that the NIHMD director "shall" make grant awards to support research training for "members of minority health disparity populations or other health disparity populations." 42 U.S.C §§ 285t—l(a), (b). And Congress has set out recruitment goals for certain training awards by statute. 42 U.S.C. § 288(a)(4).

These detailed statutory requirements are nothing like the scheme this Court confronted in *Lincoln*, which "[spoke] about Indian health only in general terms." 508 U.S at 193–94. Instead, it is akin to the facts in *Department of Commerce*, where statutory provisions provided sufficient meaningful standards even though they "conferred broad authority on the Secretary" and "[left] much to the Secretary's discretion." 588 U.S. at 771; see also Shawnee Tribe v. Mnuchin, 984 F.3d 94, 100–01 (D.C. Cir. 2021) (collecting cases).

Relevant regulations also inform reviewability. See Physicians for Soc. Resp. v. Wheeler, 956 F.3d 634, 643 (D.C. Cir. 2020). And "HHS's regulations expressly address—and limit—the agency's discretion," restricting when and how NIH may unilaterally terminate funding. Pol'y & Rsch., LLC v. United States Dep't of Health & Human Servs., 313 F. Supp. 3d 62, 76 (D.D.C. 2018) (Jackson, J.) (concluding that 45

C.F.R. § 75.372—the relevant regulation here—confers reviewability).

Finally, Defendants argue that because the district court "did not find" that Defendants acted in excess of statutory authority, this somehow precludes APA review. Stay Appl. 29. This is a mischaracterization. The court found it unnecessary to rule on Plaintiffs' 706(2)(C) claim, having already set aside the offending Directives under 706(2)(A); no finding was made as to whether or not Defendants' actions violate Congressional mandates. App. 139a. Moreover, this "conflate[s] reviewability with a particular outcome" as to whether the agency acted contrary to statute. Trout Unlimited v. Pirzadeh, 1 F.4th 738, 759 (9th Cir. 2021). Courts "need not conclusively decide the proper interpretation [of a statute] to determine whether the exception to review contained in APA § 701(a)(2) applies . . . . That would put the cart before the horse." Raymond Proffitt Found. v. U.S. Army Corps of Eng'rs, 343 F.3d 199, 208 (3d Cir. 2003). "Rather, in determining whether judicial review is available," courts look for "clear and convincing evidence of a contrary legislative intent' before [they] 'will restrict access to judicial review." Id. (citing Abbott Lab'ys., 387 U.S. at 141); see also Regents, 591 U.S. at 19 (first assessing reviewability and then determining whether there was abuse of discretion); Dep't of Com., 588 U.S. at 773 (same). And in any event, the district court did conclude that Defendants' actions were not in accordance with the regulatory framework at issue. App. 136a-37a. At bottom, "[b]ecause this is not a case in which there is no law to apply," Defendants' actions are subject to judicial review. See Dep't of Com., 588 U.S. at 773.

# III. DEFENDANTS HAVE NOT DEMONSTRATED THAT CERTIORARI IS LIKELY.

Lastly, Defendants have not demonstrated that certiorari is likely. This Court has longstanding precedent on the interplay between the Tucker Act and reviewability under the APA. See Bowen, 487 U.S. at 909–10. California was not a departure from or reversal of Bowen, but an interpretation of Bowen and its progeny. See California, 145 S. Ct. at 968.

Pointing to different outcomes in different recent grant cases, Defendants attempt to concoct a circuit split, but in fact the cases cited by Defendants just reflect lower courts' careful consideration of *California* alongside *Bowen* and *Great-West*, taking into consideration the specific facts and procedural history of each case. *See*, *e.g.*, Mot. Order, *New York v. United States Dep't of Educ.*, No. 25-1424 (2d Cir. June 20, 2025), Dkt. 40.1 at 3 ("[W]e find this case more analogous to *Bowen* than *California.*"); *Widakuswara v. Lake*, No. 25-5144, 2025 WL 1521355, at \*1 (D.C. Cir. May 28, 2025) (holding relief sought differed from that in *California*); *Cmty. Legal Servs.*, 137 F.4th at 939 (distinguishing *California* where claims were rooted in statute rather than contract). Not only is it permissible that different courts will come to different conclusions when applying *California* to different facts, it should be expected. *See Beame v. Friends of the Earth*, 434 U.S. 1310, 1314 (1977) (Court unlikely to grant certiorari when "[t]he Court of Appeals gave alternative rationales for its result, and its opinion as to each appears facially correct.").

#### CONCLUSION

This Court should deny Defendants' application for a stay.

Respectfully Submitted,

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Dated: August 1, 2025