UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

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

Plaintiffs,

v.

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

Defendants.

Case No. 1:25-cv-10787

[PROPOSED] BRIEF OF *AMICI CURIAE*
THE ASSOCIATION OF AMERICAN MEDICAL COLLEGES, THE AMERICAN ASSOCIATION OF STATE COLLEGES AND UNIVERSITIES, THE AMERICAN COUNCIL ON EDUCATION, THE ASSOCIATION OF AMERICAN UNIVERSITIES, THE ASSOCIATION OF GOVERNING BOARDS OF UNIVERSITIES AND COLLEGES, THE ASSOCIATION OF PUBLIC AND LAND-GRANT UNIVERSITIES, COGR, AND THE NATIONAL ASSOCIATION OF INDEPENDENT COLLEGES AND UNIVERSITIES

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I. STATEMENT OF INTEREST

The Association of American Medical Colleges (AAMC) is a nonprofit association of 160 accredited U.S. medical schools, nearly 500 academic health systems (AMCs) and teaching hospitals, and more than 70 academic societies dedicated to improving the health of people everywhere through medical education, research, care, and community collaboration. The American Association of State Colleges and Universities (AASCU) is a higher education association that represents over 500 regional public colleges, universities, and systems. The American Council on Education (ACE) is the major coordinating body for more than 1,600 colleges and universities, related associations, and other organizations worldwide. The Association of American Universities (AAU) is composed of sixty-nine of America's leading public and private research universities that earn the majority of competitively awarded federal funding for research. The Association of Governing Boards of Universities and Colleges (AGB) serves more than 1,200 member boards, 1,900 institutions, and almost 40,000 board members. The Association of Public and Land-grant Universities (APLU) consists of more than 230 public and private institutions that conduct $64 billion in research. COGR, an association of over 225 public and private research universities, affiliated medical centers, and independent research institutes, is a national authority on federal policies and regulations affecting U.S. research institutions. The National Association of Independent Colleges and Universities (NAICU) is the unified national voice of private, nonprofit higher education in the United States, which includes more than 5 million students attending 1,700 independent colleges and universities.

Institutions represented by *Amici* conduct the vast majority of all research sponsored by the National Institutes of Health (NIH). Breakthroughs and discoveries resulting from that research transform health care and improve the quality of life for millions of Americans. Our nation's biomedical research enterprise "has led to transformative scientific and societal

breakthroughs, establishing the United States as a global leader in research and acting as a vital engine of the nation's economy" while providing "advanced biomedical training to countless talented global scholars every year." E.A. Reece et al., *Four Opportunities to Revitalize the US Biomedical Research Enterprise*, Health Affairs (Jan. 22, 2025), at 140. *Amici* have a significant interest in the federal support of biomedical research through NIH reliably and predictably implementing the well-developed funding system established by Congress.

Moreover, to further the specific grants that they have secured through NIH's competitive funding process, *Amici* member institutions make significant investments in their own infrastructure, researchers, and staff as required to execute these groundbreaking studies—again in reliance on assurances made by NIH regarding the amount, duration, and terms of grant funding. Institutions that have enrolled individuals in NIH-funded clinical trials have done so in reliance on the stability of that funding over the years it takes to complete a clinical trial. The terminations at issue in this case destroy these reliance interests at every level of the research enterprise. Here, there is no evidence that NIH considered *any* reliance interests—of research institutions, scientists, students, research subjects, patients, or their families. Accordingly, AAMC, AASCU, ACE, AAU, AGB, APLU, COGR, and NAICU—who together represent every level of the American biomedical research enterprise—have a significant interest in this case.

II. INTRODUCTION AND SUMMARY

Federal biomedical research grants are not gifts. Rather, they represent a decision by the government to find partners who can best combine resources with federal agencies to advance science and improve human health. To facilitate this partnership between the government and research institutions, Congress directed NIH to fund research in a manner that is transparent, stable, predictable, and reliable, in accordance with publicly announced multi-year strategic plans. Research institutions and other key stakeholders depend on this stability, including the critical

understanding developed over decades that ongoing research grants will not be terminated except in rare circumstances related to the conduct of the research, with advance notice and an opportunity to remedy the issue of concern. The sudden and unexpected termination of existing grants based on purported changes to previously established and announced NIH priorities—as well as the unexplained series of slowdowns and cancellations in what had traditionally been a predictable process of awarding new grants—fundamentally undermines the whole research enterprise. *Amici* support Plaintiffs' arguments in favor of a preliminary injunction to reverse the dismantling of congressionally directed grantmaking processes and write separately to address the specific harms attributable to the abrupt and unlawful grant terminations.

Defendants clearly lacked authority to terminate the grants at issue here. As supposed support for the terminations, NIH invoked Office of Management and Budget (OMB) guidance, but the text and history of the guidance make plain that termination is only authorized in very limited circumstances when the grantee can no longer meet the original objectives of the grant. Defendants' overly broad reading of this guidance as permitting terminations based on claimed policy changes is contrary to its plain text, drafting history, law, and congressional mandate.

NIH's *en masse* grant terminations are also arbitrary and capricious. The agency purportedly reversed its publicly announced research priorities in internal agency directives void of any reasoned explanation. NIH does not endeavor to explain—let alone rationally explain—how particular awards violated the priorities it previously announced. Moreover, NIH failed to weigh the enormous reliance interests of institutions, researchers, study participants, and the public in the stability, predictability, and reliability of NIH-launched research endeavors. Thus, the terminations should be set aside under the Administrative Procedure Act ("APA").

III. BACKGROUND

A. Statutory and Regulatory Requirements for Funding Outside Research in a Manner that is Transparent, Stable, Predictable, and Reliable

Congressional Funding Mandate. In 1930, Congress established the "National Institute of Health" (singular) for the purpose of "ascertaining the cause, prevention, and cure of disease affecting human beings." *See* Ransdell Act, Pub. L. No. 71–251, 46 Stat. 379 (May 26, 1930). Today, NIH has grown to 27 individual institutes and centers ("ICs," plural), most of which have their own statutorily established research missions. *See* 42 U.S.C. §§ 285-285t (establishing twenty-one institutes with separate research missions); *NIH Organization*, NIH (June 14, 2018). The director of each IC must "encourage and support research, investigations, experiments, demonstrations, and studies in the health sciences." 42 U.S.C. § 284(b)(1)(A).

Congress directed NIH and its ICs to fulfill their research missions by: (1) conducting research internally (intramural research); and (2) awarding institutional grants to non-NIH researchers (extramural research). 42 U.S.C. §§ 241, 282, 284. Approximately 80 percent of NIH's annual budget is dedicated to extramural funding, supporting more than 300,000 research personnel at over 2,500 institutions. NIH, *Budget*, (Oct. 3, 2024). NIH is the largest funder of health and medical research in the world. Cong. Rsch. Serv., CRS R41705 (Jan. 13, 2025).

The grantmaking process typically begins with a notice of funding opportunity ("NOFO") that outlines NIH's or IC's program goals and objectives. *See* U.S. Dep't of Health & Hum. Servs., *NIH Grants Policy Statement*, §§ 2.3.5, 2.4.3 (Apr. 2024) (hereinafter "GPS"). In response, researchers across the nation and their home institutions develop and submit project proposals that must include details such as the project's objectives, methodology, significance, and proposed budget. 45 C.F.R., Part 75. The applications undergo two layers of evaluation: (1) of the project's scientific merit and potential impact on the field of study; and (2) of its alignment with NIH or IC

strategic plans and overall research and funding priorities. *See* 42 U.S.C. §§ 284a, 289a; GPS § 2.4. This process results in a recommendation to the individual IC director, who makes the final decision of whether to issue a notice of award ("NOA") to a grantee.

Although both involve the transfer of money, grants are legally distinct from contracts.[1] *See* 31 U.S.C. § 6304 (explaining that the principal purpose of a grant is "to transfer a thing of value to the … recipient to carry out a public purpose of support or stimulation authorized by a law of the United States" rather than the acquisition of "property or services for the direct benefit or use of the United States Government"); GPS § 2.3.3 (citing this statute to note this distinction).

Congressionally Mandated Strategic Plans. Congress expressly requires the Director of NIH to develop a strategic plan at least every six years. 42 U.S.C. §§ 282(b)(5), (m)(1). NIH must submit that plan to Congress and post the plan on its website. *Id.* One goal of the strategic planning requirement is "encouraging long-term planning." *See* Press Release, Susan Collins, Senator, United States Senate, *Senators Introduce Bipartisan Bill to Advance Strategic Planning and*

[1] Amici endorse Plaintiffs' arguments that the Tucker Act does not divest this court of jurisdiction in this case. Plaintiffs seek injunctive and declaratory relief from agency actions unlawful under the Constitution and the APA—claims that are properly before Article III courts. *See* 28 U.S.C. § 1331; 5 U.S.C. § 702. The claims in this case do not allege breaches of contracts, base any allegations on the terms of any contract, or seek money damages, and therefore are clearly outside the scope of the Tucker Act. *See Am. Sci. & Eng'g, Inc. v. Califano*, 571 F.2d 58, 61 (1st Cir. 1978) (holding that the Tucker Act's implied divesture of Article III jurisdiction applies only when a plaintiff's claim is "essentially a contract dispute"). In addition, the Supreme Court has made clear that Article III jurisdiction is proper for claims seeking injunctive or declaratory relief from unlawful agency action even if such relief might ultimately result in "the payment of money" by the federal government. *Bowen v. Massachusetts*, 487 U.S. 879, 900-01, 910 (1988). Finally, this court properly has jurisdiction in this case because the "limited relief available in the [Federal Court of Claims] is not an adequate substitute for review in the District Court." *Bowen*, 487 U.S. at 901. NIH has terminated hundreds of NIH-funded research grants and effectively cancelled the review process for other new and continuing awards. It would be senseless for institutions to file separate Tucker Act claims for damages suffered by Defendants' actions. Such litigation not only would be wasteful and inefficient but also would fail to remedy Plaintiffs' injuries from NIH's unlawful across-the-board policies that are wreaking havoc on institutions, researchers, and patients right now.

Representation in Medical Research at NIH (Apr. 6, 2016) (describing bill ultimately incorporated into the 21st Century Cures Act, Pub. L. No. 114-255, 130 Stat. 1033 (Dec. 13, 2016)).

The NIH Strategic Plan must adhere to specific congressional requirements. The plan must "provide direction to the biomedical research investments made by the National Institutes of Health, to facilitate collaboration across the institutes and centers, to leverage scientific opportunity, and to advance biomedicine." 42 U.S.C. § 282(m)(1)-(2). The plan must specifically "identify strategic research priorities and objectives across biomedical research," including "priorities and objectives to advance the treatment, cure, and prevention of health conditions," "emerging scientific opportunities," and "the identification of near-, mid-, and long-term scientific needs." 42 U.S.C. § 282(m)(2)(A). Finally, the plan must "address the [NIH's] proposed and ongoing activities related to training and the biomedical workforce." 42 U.S.C. § 282(m)(2)(E). In developing the strategic plan, the Director must consult with not only the individual ICs but also "researchers, patient advocacy groups, and industry leaders." 42 U.S.C. § 282(m)(4). The Director must also specifically consider "biological, social, and other determinants of health that contribute to health disparities" and "disease burden in the United States and the potential for return on investment to the United States." 42 U.S.C. § 282(m)(2)(B).

Congress also requires individual NIH ICs to prepare their own strategic plans "in such a manner that such plans will be informed by [the broader agency-wide NIH Strategic Plan]." *See* 42 U.S.C. §282(m)(3). The ICs are expressly required to include details in their strategic plans "to ensure that future activities by such institutes and centers take into account women and minorities and are focused on reducing health disparities." 42 U.S.C. § 289a-2(a)(3)(A).

Congress has made clear that NIH and IC strategic plans are not mere formalities but rather critical documents that guide how NIH will allocate and award extramural research funds. The

NIH Director must "ensure that the resources of the National Institutes of Health are sufficiently allocated for research projects identified in [NIH and IC] strategic plans." 42 U.S.C. § 282(b)(6). In addition, individual ICs must consider "the mission of the [IC] and . . . [its] strategic plan" when "review[ing] and mak[ing] the final decision with respect to making [a grant] award." 42 U.S.C. § 284(b)(3)(A)–(B). Congress intended that NIH and IC strategic plans be reliable indicators to the broader research community of the types of research that NIH will fund.

Other Statutory Mandates for NIH Funding. Congress has also issued other statutory directives to NIH. For example, Congress has expressly required NIH to "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 behavioral research," "encourage efforts to improve research related to the health of sexual and gender minority populations," and support research and training "with respect to minority health conditions and other populations with health disparities." Compl. ¶ 229 (collecting relevant statutes). Congress has also directed NIH 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). For example, it has required the National Heart, Lung, and Blood Institute to conduct research into certain heart conditions in women, "including African-American women and other women who are members of racial or ethnic minority groups." 42 U.S.C. 285b-7a(c)(1).

Latest Strategic Plans Reflecting Congressionally Mandated Priorities. NIH developed and issued its current strategic plan, for FY 2021-2025, after extensive consideration and feedback from stakeholders, including some of the *Amici*. NIH, *NIH-Wide Strategic Plan for Fiscal Years 2021–2025* (July 30, 2021) (hereinafter "FY21-25 NIH-wide Strategic Plan") at 44. The NIH-wide Strategic Plan identifies three objectives: (1) "advancing biomedical and behavioral

sciences," (2) "developing, maintaining, and renewing scientific research capacity," and (3) "exemplifying and promoting the highest level of scientific integrity, public accountability, and social responsibility in the conduct of science." *Id*. at 3-30. The plan also identifies "crosscutting themes" to be prioritized across all objectives, including "enhancing women's health," "improving minority health," and "reducing health disparities." *Id*. at 32-33.

As an example of an IC strategic plan, the National Center for Complementary and Integrative Health (NCCIH) established a strategic plan for 2021-2025 that prioritizes efforts to "fund research with diverse populations" to improve "minority health and eliminat[e] health disparities." *See* NCCIH, *NCCIH Strategic Plan FY 2021-2025*. To implement this plan, NCCIH issued a NOFO entitled "Research With Activities Related to Diversity" to "support research that is well aligned with the NCCIH Strategic Plan." Dep't of Health & Hum. Services, PAR-23-122 (Mar. 17, 2023), https://grants.nih.gov/grants/guide/pa-files/PAR-23-122.html.

B. Award Recipients and Key Stakeholders Depend on a Stable, Predictable, and Reliable NIH Awards Process

NIH's funding of extramural research in a stable, predictable, and reliable manner is not only statutorily required but also necessary to secure sufficient participation in research and the achievement of meaningful outcomes.

Grants Rarely Terminated. Terminations of ongoing NIH awards have historically been exceedingly rare, regardless of changes in presidential administrations. HHS regulations currently in effect provide that an HHS award may be terminated only in three circumstances: (1) by the HHS agency "if the [awardee] fails to comply with the terms and conditions of the award"; (2) by the HHS agency "for cause"; or (3) "with the consent" of the awardee. 45 C.F.R. § 75.372(a).[2]

[2] As discussed in Section IV-A below, since 2020, the Office of Management and Budget's Uniform Guidance for federal awards, 2 C.F.R., Part 200, has also included a provision allowing termination "to the greatest extent authorized by law, if an award no longer effectuates the program

NIH's GPS also provides that:

> "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision. . . . NIH may immediately terminate a grant when necessary, such as to protect the public health and welfare from the effects of a serious deficiency."

GPS § 8.5.2.

The understanding that an award will not be terminated while a research project is ongoing—except in rare circumstances—is what encourages and enables grantees, researchers, research participants, and other key stakeholders to commit to, invest in, and conduct the research activities necessary to accomplish NIH's research mission. As described below, these reliance interests are present at every level of the research enterprise.

Researchers. Abrupt and widespread termination of ongoing awards has a devastating impact on researchers. First, such instability discourages individuals from starting or continuing the grueling academic journey to become high-level scientific researchers. Due to the uncertainty created by NIH's actions at issue in this case, some research institutions have already rescinded offers of admissions to highly-qualified graduate students or otherwise reduced the number of graduate program slots, and other institutions are considering similar actions. *See* AAMC Survey, Understanding the Impact of Federal Funding Cuts on U.S. Medical Schools (Apr. 2025) (hereinafter AAMC Survey) (reporting reduction in graduate student slots, slowing rate of acceptance, and withdrawing offers) Second, uncertainty regarding funding would prevent universities and research institutions from recruiting and supporting high-quality scientists to partner with the government in its research objectives. *Id.* (reporting hiring freezes, reducing and

goals or agency priorities." 2 C.F.R. § 200.340(a)(2) (2020). However, HHS regulations did not adopt this termination provision until October 2024, and such adoption is not effective until October 2025. 89 Fed. Reg. 80,055, 80,056 (Oct. 2, 2024).

pausing recruitment of PhD candidates and post-doc appointments, and deferring start dates for new hires). Third, the ever-present threat of layoffs for ongoing projects based on abruptly shifting NIH priorities would make it difficult to attract and retain high-quality research staff. *Id.* (indicating most institutions may have or may soon reduce staff "due to federal research funding uncertainty or cuts").

Research and Related Clinical Infrastructure. The reliability of funding gives research institutions the confidence to invest in and build, expand, and equip research and related clinical infrastructure. Such upfront costs are often unrecoverable, and therefore institutions cannot make such investments without assurance that the government will uphold its end of the bargain to fund the project through completion absent some misconduct. For example, building a cancer center requires an enormous and sustained commitment of resources to secure the advanced equipment and facilities needed for diagnosis, treatment, and research. Due to the recent funding uncertainties, some AAMC medical schools have begun suspending or changing the scope of capital planning projects. *See* AAMC Survey. Less reliable NIH awards will also interfere with institutions' abilities to obtain a line or letter of credit for the procurement of resources and increase the expense of bond financing for future investments in research and related clinical facilities.

Clinical Trial Participation and Ethics. The risk of abrupt termination of funding for NIH-supported clinical research would also disrupt ongoing trials and discourage participant enrollment.[3] As an example, the Adolescent Medicine Trials Network for HIV/AIDS Intervention, a multi-year program designed to improve the diagnosis, treatment, and prevention of HIV infections in adolescents and young adults, received notice of grant termination because it was

[3] *See* Katherine J. Wu, *The NIH's Most Reckless Cuts Yet: Ending Clinical Trials with N Warning Can Put Patients at Risk*, THE ATLANTIC (Mar. 27, 2025).

"based on . . . amorphous equity objectives." Anil Oza, *NIH Cuts Halt 24-year Program to Prevent HIV/AIDS in Adolescents and Young Adults*, StatNews (Mar. 25, 2025). As a result of this grant termination, neither individual participants nor the nation as a whole will benefit from the interventions and research that are the cornerstones of this impactful, long-standing collaborative program. *Id.* If individuals became aware that any clinical trial could be halted suddenly, with no advanced notice, based on the whims of a new administration and that there might be insufficient funding to guarantee that the trial will continue through the end of the study, they might be unwilling to enroll at all. *See e.g.* AAMC, *What's At Stake When Clinical Trials Research Gets Cut* (April 24, 2025), https://www.aamc.org/news/whats-stake-when-clinical-trials-research-gets-cut. Doctors may also be less willing to refer and enroll individuals in clinical trials seeking breakthrough cures. The abrupt termination of research also compromises the ability of researchers to meet ethical imperatives to protect research subjects from unnecessary harm. Research with human subjects cannot be initiated without the approval of an Institutional Review Board, which must determine that the "risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result." 45 C.F.R. § 46.111(a)(2). If the research results in no generalizable knowledge because a grant is prematurely terminated, the risks that those people faced would be unreasonable.

Multi-Year Data Collection and Analysis. Multi-year research projects are designed to collect and analyze scientific data throughout the course of the research. Many studies cannot be restarted once interrupted. The unexpected termination of a grant wastes years of research, squanders taxpayer dollars, and risks rendering the contributions of human subjects and animal models unusable.

IV. ARGUMENT

A. NIH Lacks Authority to Terminate Existing Grants Based on the Abrupt Rejection of Established Agency Priorities

Defendants' terminations are ultra vires. As the purported basis for their grant terminations, Defendants invoke a provision of the OMB's Uniform Guidance for federal awards that allows an agency to terminate an award "to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities." 2 C.F.R. § 200.340(a)(2) (2020).[4].

This termination provision is not controlling here. Although published in the Code of Federal Regulations, the Uniform Guidance is only a guidance document and lacks force unless adopted by an agency by regulation. 2 C.F. R. § 1.105(b) ("Publication of the OMB guidance in the CFR does not change its nature—it is guidance, not regulation."); *see also* Mem. of Law in Supp. of Pls.' Mot. for Prelim. Inj. at 35-36, ECF No. 78. HHS did not specifically adopt this termination provision in HHS regulations until October 2024, and such adoption is not effective until October 2025. 89 Fed. Reg. 80,055, 80,056 (Oct. 2, 2024).

Regardless, the text and history of Section 200.340(a)(2) (2020), as well as NIH's specific statutory mandates, make clear that the guidance does not authorize Defendants to terminate NIH awards at will, based solely on the assertion of a shift in agency priorities. Instead, at most, it authorizes termination by NIH only under very limited circumstances, which are not present here.

Text and History Support Narrow Reading. Section 200.340(a)(2) (2020) states that a Federal award may be terminated "if an award no longer *effectuates* the program goals or agency priorities." 2 C.F.R. § 200.340(a)(2) (2020) (emphasis added). The most natural reading of the word "effectuates" indicates that any termination must relate to the grantee's ability to meet the

[4] In 2024, OMB moved the provision from (a)(2) to (a)(4) and slightly amended its language. 89 Fed. Reg. 30,046, 30,169 (Apr. 22, 2024). The arguments below apply equally to (a)(4).

program's existing goals or agency priorities *set at the time of the award*, not new priorities. Supporting this conclusion OMB commentary provides as examples of terminations under this provision instances in which the agency obtained "additional evidence reveal[ing] that a specific award objective is ineffective at achieving program goals" or "additional evidence [that causes] the Federal awarding agency to significantly question the feasibility of the intended objective of the award." See 85 Fed. Reg. 49,506, 49,507-08 (Aug. 13, 2020). OMB did not intend for the regulation to empower agencies to terminate awards based on a post hoc replacement of the goals and objectives themselves.[5]

Moreover, the next paragraph of the guidance, 2 C.F.R. § 200.340(b), requires the agency to "clearly and unambiguously specify [the] termination provisions applicable to each Federal award." 2 C.F.R. § 200.340(b). NIH's reading of 2 C.F.R. § 200.340 (a)(2) conflicts with 2 C.F.R. § 200.340(b) because allowing terminations based on an abrupt shift in an agency's priorities would not give "clear and unambiguous" notice to award participants of when their ongoing funding is at risk. Indeed, OMB added Sections 200.340(a) and 200.340(b) at the same time and confirmed in its commentary that "agencies are not able to terminate grants arbitrarily." See 85 Fed. Reg. at 49,509.

Defendants' Reading Contradicts Statutes. Even worse, Defendants' interpretation of Section 200.340(a)(2) (2020)—as allowing NIH to terminate funding simply by asserting new agency priorities—is inconsistent with statutory requirements and objectives. *See Dixon v. United States*, 381 U.S. 68, 74 (1965) ("A regulation which . . . operates to create a rule out of harmony with the statute, is a mere nullity."); *see also McCuin v. Sec'y of Health & Hum. Servs.*, 817 F.2d

[5] NIH's new interpretation is not due deference under *Auer v. Robbins*, 519 U.S. 452 (1997), because it (1) "runs counter to" the regulation's original intent, *Gonzales v. Oregon*, 546 U.S. 243, 258 (2006), and (2) creates "unfair surprise," *Kisor v. Wilkie*, 588 U.S. 558, 579 (2019).

161, 168 (1st Cir. 1987) ("In interpreting statutes and regulations, courts must try to give them a harmonious, comprehensive meaning, giving effect, when possible, to all provisions.").

As described in Section III-A above, Congress has mandated that NIH implement its extramural research program in a manner that is stable, predictable, reliable, and in accordance with the publicly announced multi-year prioritizations set forth in the strategic plans submitted to Congress. Defendants' reading of Section 200.340(a)(2) (2020) would not only create substantial *instability* in the NIH award process, but also directly undermine the congressionally mandated NIH and IC strategic plans. The plans would no longer be reliable indicators to the research community and the public at large of the "direction" of "biomedical research investments made by [NIH]," including NIH's "priorities and objectives to advance the treatment, cure, and prevention of health conditions," "emerging scientific opportunities," and "near-, mid-, and long-term scientific needs" as required by 42 U.S.C. §§ 282(m)(1)-(2). Rather, they would be mere formalities always threatened by abrupt shifts in NIH priorities. Congress expressly rejected such an ad hoc approach by requiring both the NIH Director and ICs to allocate resources, including for extramural research, according to strategic plans. 42 U.S.C. §§ 282(b)(6), 284(b)(3)(A)–(B).

In addition, such a reading would frustrate the very purpose of Congress authorizing NIH to make extramural awards in the first place—namely, to "encourage and support" research that improves human health. 42 U.S.C. § 284(b)(1)-(2). As explained in Section III-B above, abrupt terminations of ongoing awards would undermine the prerequisite predictability that enables sufficient research community participation in the NIH extramural research enterprise. Simply put, NIH's actions will discourage grantees and other required stakeholders from investing their tremendous time, resources, and personal risk into projects if the agency can decide, at any moment, that it will not see a project through because of an abrupt shift in priorities.

Furthermore, NIH's interpretation of Section 200.340(a)(2) (2020) conflicts with Title VI of the 1964 Civil Rights Act, which mandates concrete procedural steps for "terminating . . . financial assistance" based on alleged violations of civil rights laws. 42 U.S.C. §§ 2000d-1, 2000d-2. Section 200.30(a)(2) (2020) cannot authorize the agency to immediately terminate a grant based on a sudden change in agency priorities because that sweeping power would enable the agency to evade Title VI's mandated procedural steps where, as here, the agency is alleging violations of federal civil rights laws.

Finally, in areas where Congress expressly directed NIH to develop plans for or prioritize certain areas of research, *see supra* Section III-A, the agency cannot use 2 C.F.R. § 200.340(a)(2) to terminate awards. Such terminations would not only halt current research in those areas but also disincentivize the research community's future participation in such research—the exact opposite of Congress's direction.

B. The Agency's En Masse Grant Terminations Based on a Purported Shift in Agency Priorities Were Arbitrary and Capricious

The terminations at issue violate the cardinal rule of administrative law: all agency action must be the product of "reasoned decisionmaking." *Dep't of Homeland Sec. v. Regents of the Univ. of California*, 591 U.S. 1, 16 (2020) (citation omitted). Defendants' boilerplate terminations are anything but reasoned. As explained below, NIH failed to provide sufficient explanation for its purported change in research priorities; failed to provide a specific rationale for the terminations themselves; failed to weigh the substantial reliance interests based on those grants; and failed to consider reasonable alternatives to wholesale termination. Such arbitrary and irrational action is exactly what the APA prohibits. 5 U.S.C. § 706(2)(a).

No Reasoned Explanation for Priority Changes or Terminations. The APA requires a reasoned explanation whenever an agency changes its position or policy. *Encino Motorcars, LLC*

v. Navarro, 579 U.S. 211, 221 (2016) ("Agencies are free to change their existing policies as long as they provide a reasoned explanation for the change."). The agency must also examine relevant data and articulate "a rational connection between the facts found and the choice made." *See Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

NIH and its ICs publicly articulated their research priorities in their strategic plans. For example, the NIH-wide Strategic Plan—which is applicable through Fiscal Year 2025—declares that across all of its objectives, NIH will consider how to "improve[] minority health," "reduce[] health disparities," and "enhance[] women's health." FY21-25 NIH-wide Strategic Plan at 32-33. The strategic plan further states that it will "promote health equity" through its commitment to minority health, which involves a focus on the "distinctive health characteristics and attributes of minority racial and/or ethnic groups." *Id.* IC strategic plans similarly prioritize funding research to increase workforce "diversity," promote health "equity," and ensure "inclusion" of minorities in federally funded research. NIH, *Minority Health and Health Disparities Strategic Plan 2021–2025*, at 3, 24, 26 (Mar. 31, 2021); *see also* Nat'l Inst. of Arth. and Musc. and Skin Dis., *NIAMS Strategic Plan Fiscal Years 2025-2029* (Apr. 3, 2025), https://www.niams.nih.gov/about/strategic-plan-fiscal-years-2025-2029 (including an entire section on "Priority 6: Conducting Research to Address Health Disparities" even after the plan was "revised on April 03, 2025 to reflect the current administration's priorities"). Likewise, IC strategic plans expressly prioritize research into vaccine "uptake." *See, e.g.*, *NIH Strategic Plan for Herpes Simplex Virus Research*, Nat'l Inst. of All. and Infect. Dis., at 17, 19, (Sept. 19, 2023).

These plans were not informal policy statements, but rather formal, congressionally-mandated declarations of agency priorities. Unlike non-binding guidance, NIH must also allocate resources and award extramural research grants in accordance with these plans. *See supra* Section

III-A. As in *Regents*, priorities in the strategic plans were implemented through a formal process in which the agency "solicited applications" via NOAs, "instituted a standardized review process" of those applications, and "sent formal notices" of awards. *Regents*, 591 U.S. at 18; *see also FDA v. Wages and White Lions Invs., L.L.C.*, 604 U.S. ___ 23 n.5 (2025) (indicating that policy statements implemented in a manner similar to *Regents* would be subject to the change-in-position doctrine). Thus, the change-in-position doctrine would apply if NIH shifted away from funding priorities identified in its plans. *Id.*

Here, NIH did just that. In a series of internal Directives that resulted in the Termination Notices, NIH leadership (1) declared that the agency would "*no longer* prioritize research and research training programs that focus on Diversity, Equity, and Inclusion" and (2) directed staff to claim in the Termination Notices that it was "the policy of NIH *not to further* prioritize" research programs" related to "equity objectives," "gender identity," and "ways to improve vaccine interest and commitment." Management Staff Guidance—Award Assessments for Alignment with Agency Priorities—March 2025 (Mar. 25, 2025), *see also* Compl. ¶ 98. This was a clear shift away from NIH and IC strategic plans, which, as described above, established these topics as *priorities*.

A conclusory statement is not a reasoned explanation. *Massachusetts v. NIH*, No. 25-CV-10338, 2025 WL 702163, at *17 (D. Mass. Mar. 5, 2025). Instead, the agency must explain why it is making the change and provide "good reasons" for doing so. *Encino*, 579 U.S. at 221. Here, the Directives that purportedly reversed NIH's priorities did not explain the change. For example, in the March 25th Directive—NIH's most detailed articulation—simply declared that "[i]t is the policy of NIH not to prioritize research" into vaccine hesitancy or "ways to improve vaccine interest and commitment" because federal funds must be used to "benefit the American people and

improve their quality of life." Decl. Supp. Pl.'s Mot. Prelim. Inj., Ex. 10. But NIH did not explain why research into increasing the uptake of vaccines does not benefit the American people.

Moreover, NIH sent boilerplate letters to recipients. Compl. ¶ 105, 202. These letters did not indicate or explain *why* a particular project implicated one of the priorities that NIH was purportedly eliminating.

No Regard for Reliance Interests. The APA also demands that an agency changing its position "assess whether there were reliance interests" in its prior position, "determine whether they were significant, and weigh any such interests against competing policy concerns." *Regents*, 591 U.S. at 33.

NIH fostered significant reliance interests among institutions, researchers, study participants, and the public when it awarded grants in accordance with the priorities in its publicly announced strategic plans. *See generally supra* Section III-B. Relying on the understanding that grants would continue through their terms, institutions planned their budgets years in advance, invested in costly infrastructure, and recruited and hired talent. *Id.* Researchers and students rely on that stability to fund their training and in planning their careers and study designs. *Id.* Study participants rely on the foundational understanding that they are protected by the determinations made by IRBs that the risks they are taking are reasonable given the likelihood that the research will result in generalizable knowledge, cures, or treatments. *Id*.

When NIH terminated its grants *en masse*, it failed to consider these reliance interests. For instance, the agency gives no consideration to the reliance interests embedded in the multi-year design of the grant-supported research projects. A clinical trial stopped in the middle of a multi-year project period, likely, means that no usable findings will result from the project. Disrupting a non-clinical, lab-based study could result in lost personnel, the euthanasia of animal models, and

the opportunity cost associated with what is now a dead-end project except in the unlikely event of alternative funding. NIH also did not consider how such abrupt terminations would impact study participants. Compl. ¶ 204.

NIH also failed to consider the impact of the terminations on the scientific workforce. As stated by an NIH Advisory Committee in 2023, "Science, technology, engineering, and mathematics (STEM) doctorate holders are critical to the health of the national and global scientific ecosystem. Within the U.S. research enterprise, postdoctoral scholars, predominantly based in academic research labs, are a bellwether of its sustainability." NIH, *NIH Advisory Committee to the Director Working Group on Re-envisioning NIH-Supported Postdoctoral Training* (Dec. 15, 2023) at 4. Even before the terminations at issue here, NIH had reported a "marked decline in the number of postdoctoral scientists nationally, threatening the full expanse of the American research enterprise." *Id.* at 6. These abrupt grant terminations could be a death knell to the academic careers of many promising scientists—a possibility that NIH failed to consider in issuing the terminations. Indeed, the ill-advised actions by NIH are likely to result in U.S.-based researchers pursuing academic opportunities in other countries or abandoning science altogether. Catherine Offord, *Overseas Universities See Opportunity in U.S. 'Brain Drain*,' Science (Mar. 21, 2025), at 1,244.

No Consideration of Reasonable Alternatives. NIH failed to consider alternatives within the ambit of its prior policy before changing that policy, *Regents*, 591 U.S. at 30, and to consider reasonable alternatives within the ambit of the policy it was applying in the Termination Notices, *State Farm*, 463 U.S. at 51. It did neither. At a policy level, NIH did not consider alternatives to the wholesale reversal of its priorities. For example, NIH did not consider tailoring, rather than eliminating, its health equity priority by requiring equal research into all demographic groups. That alternative could have potentially addressed any concern that this research was

discriminatory. At the level of implementation, NIH did not consider the reasonable alternative of modifying the project. *See* GPS § 8.5.2 ("NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision."). NIH's conclusory statements that modification was not possible "do not suffice." *See Encino*, 579 U.S. at 224 (citation omitted).

V. CONCLUSION

For the reasons above and in Plaintiffs' brief, the Court should enter the requested preliminary injunction against Defendants to protect the nation's research infrastructure.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that this document will be served on all registered parties through the court's CM/ECF system.

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