No. 25A103

IN THE
Supreme Court of the United States

NATIONAL INSTITUTES OF HEALTH, ET AL., *APPLICANTS*,

v.

AMERICAN PUBLIC HEALTH ASS'N, ET AL., *RESPONDENTS*.

ROBERT F. KENNEDY, JR., ET AL., *APPLICANTS*,

v.

COMMONWEALTH OF MASSACHUSETTS, ET AL., *RESPONDENTS*.

Application to Stay the Judgments of the United States District Court for the District of Massachusetts and Request for an Immediate Administrative Stay

BRIEF OF THE ASSOCIATION OF AMERICAN MEDICAL COLLEGES; THE ASSOCIATION OF AMERICAN UNIVERSITIES; THE ASSOCIATION OF PUBLIC AND LAND-GRANT UNIVERSITIES; THE AMERICAN COUNCIL ON EDUCATION; THE NATIONAL ASSOCIATION OF INDEPENDENT COLLEGES AND UNIVERSITIES; COGR; THE AMERICAN ASSOCIATION OF STATE COLLEGES AND UNIVERSITIES; AND THE ASSOCIATION OF GOVERNING BOARDS OF UNIVERSITIES AND COLLEGES AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS

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INTEREST OF *AMICI CURIAE*[1]

Amici curiae's member institutions are collectively responsible for the vast majority of all scientific research sponsored by the National Institutes of Health (NIH). The Association of American Medical Colleges (AAMC) is a nonprofit association of 160 accredited U.S. medical schools, nearly 500 academic health systems 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 Association of American Universities (AAU) is composed of sixty-nine leading public and private U.S. research universities, which collectively earn the majority of competitively awarded federal funding for research. The Association of Public and Land-grant Universities (APLU) consists of more than 240 public research universities and systems that conduct $64 billion in research. The American Council on Education (ACE) serves as the major coordinating body for the nation's colleges and universities, with a diverse membership of nearly 1,600 colleges and universities, related associations, and other organizations. 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 five million students attending 1,700 independent colleges and universities. COGR, an association of over 225 public and private research universities, affiliated medical centers, and independent research

[1] Pursuant to Rule 37.6, counsel for *Amici Curiae* state that no counsel for a party authored this brief in whole or in part, and no person or entity other than *Amici* or their counsel has made a monetary contribution to the preparation or submission of this brief.

institutes, is a national authority on federal policies and regulations affecting U.S. research institutions. 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 Association of Governing Boards of Universities and Colleges (AGB) has, for nearly 100 years, remained the premier organization centered on governance in higher education, serving more than 1,200 member boards, 1,900 institutions, and almost 40,000 board members.

The research conducted by the members of *Amici*—with NIH's longstanding support—has yielded discoveries that have transformed health care and improved the lives of millions of Americans. It "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*, 44 Health Affs. 140 (2025). This success is possible only because of NIH's longstanding and reliable commitment to funding scientific research according to scientific principles and peer-review process.

Amici submit this brief to provide the research community's perspective on the critical importance of NIH's continued adherence to scientific principles in grantmaking and the dire consequences if this Court were to reinstate NIH's recent *en masse* termination of grants based on non-scientific considerations. To fulfill their missions of pursuing groundbreaking scientific research, *Amici*'s member institutions have made significant investments in infrastructure, equipment, researchers, and staff—relying in

large part on grants secured through NIH's competitive funding process and the stability NIH's science-based process provides. Based on NIH's longstanding adherence to science-based processes, as well as its express commitments, institutions have enrolled individuals—at significant investment by participants and organizations—in multi-year clinical trials designed to create and test life-saving treatments, and they have built laboratories designed to conduct long-term experiments to develop novel therapies. By terminating grants midstream—and without any consideration of these kinds of reliance interests—NIH has destabilized every aspect of biomedical research.

INTRODUCTION AND SUMMARY OF ARGUMENT

This case is about the Executive Branch's recent, unprecedented efforts to undermine the congressionally mandated scientific mission of NIH, the largest funder of scientific research in the world.[2] NIH awards billions of dollars each year to support the scientists, studies, and institutions that drive American innovation. These grants, in the words of Senator Todd Young, are not "gift[s]" or "handouts."[3] They fund science that the government has determined will further the national interest, leveraging what has aptly been described as the symbiotic relationship between the government and the research community—which has built the physical and human capital to carry out this work, and has played a key role in assessing the quality and promise of proposed research.

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[2] Kavya Sekar, Cong. Rsch. Serv., R41705, *The National Institutes of Health (NIH): Background and Congressional Issues* (updated Jan. 13, 2025), https://sgp.fas.org/crs/misc/R41705.pdf [https://perma.cc/5KQ3-A433].

[3] Sen. Todd Young & Matthew Pottinger, Opinion, *Funding for R&D Isn't a Gift to Academia*, Wash. Post (Mar. 24, 2025), https://www.washingtonpost.com/opinions/2025/03/24/research-development-china-national-security/ [https://perma.cc/ZB3D-LRCK].

At the foundation of this relationship is the principle that decisions about what scientific research is funded and supported to its conclusion should be based on the scientific and health needs of the nation.

In recent months, however, the Executive Branch has jettisoned NIH's scientific decisionmaking via agencywide directives that mandated the termination *en masse* of NIH grants deemed related to disfavored political topics. The district court correctly recognized these actions are unlawful and arbitrary and capricious. *Amici* agree with respondents that the government has met none of the requirements for a stay of that decision. Rather than repeat those arguments, *Amici* wish to provide the research community's perspectives on two important issues.

First, the blanket termination of NIH grants flouts longstanding principles of science-based decisionmaking. NIH's decades-old adherence to scientific principles has helped ensure that NIH awards fund only methodologically sound research projects that move their scientific disciplines forward, and that these projects will proceed to conclusion unless the same scientific principles support termination. And this approach has allowed researchers to plan long-term projects without fear that their work will be upended midstream based on a transition in Executive Branch leadership, forcing them to halt their research and waste taxpayer dollars. The government's action here is utterly inconsistent with these principles: it issued top-down directives mandating the termination of grants without individualized inquiry, citing no scientific justifications.

Second, there will be dire consequences if the blanket termination's shockwaves through the research landscape are allowed to continue during the appeal of these cases—

consequences that will be exceedingly difficult to reverse. NIH's mass termination has disrupted research into diseases like breast and cervical cancer, diabetes, Alzheimer's disease, and cardiovascular disease, and it has forced clinical trials testing potentially life-saving treatments to halt, resulting in significant harm to participants that could not be remedied in the Court of Federal Claims. Granting a stay would only exacerbate these devastating effects on researchers, patients, and public health more broadly.

Amici do not doubt the Executive Branch's prerogative to set and implement policy objectives that differ from those of previous administrations. But changes in priorities must be implemented via lawful processes and must account for the scientific principles that have long governed NIH decisionmaking—and that, indeed, both statute and regulation obligate NIH to follow. If allowed to proceed, the government's contrary approach would inflict irreparable harm on this nation's scientific-research enterprise. The Court should deny the government's stay request.

ARGUMENT

I. The Administration's Blanket Cancellation of NIH Grants Flouts Longstanding Principles of Science-Based Decisionmaking.

A. NIH Has Long Been Guided by Scientific Principles in Its Grant Process.

NIH is the world's preeminent funder of scientific research. Nearly a century ago, Congress established the agency to "ascertain[] the cause, prevention, and cure of disease affecting human beings." Ransdell Act, ch. 320, 46 Stat. 379 (1930). Since 1944, NIH has advanced that goal through "extramural" funding for external research at universities and other institutions. *See* Public Health Service Act, ch. 373, § 301, 58 Stat. 682, 691-92

(1944). Today, more than 80 percent of NIH's annual budget is dedicated to extramural funding, supporting more than 300,000 research personnel at over 2,500 institutions.[4] In fiscal year 2024, NIH spent over $36 billion on over 60,000 research grants.

Consistent with its congressional mandate, NIH's efforts are driven by science. That includes the processes by which NIH awards, administers, and, if necessary, terminates grants. The governing regulations require a competitive process for grant applications, with multiple stages of scientific review. At the outset, the agency issues a notice of funding opportunity outlining 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); 45 C.F.R. pt. 75, app. I(A). Researchers across the nation submit detailed project proposals in response to such notices, with information about their project's objectives, methodology, significance, and budget. Preparing these applications consumes substantial institutional resources and often takes months to complete.

Grant applications undergo three layers of scientific evaluation. First, a "scientific review group" (also known as a "study section") composed of peer reviewers evaluates a proposed project's scientific and technical merit and potential impact on its field of study. *See* 42 U.S.C. § 289a (imposing "[p]eer review requirements" on grant applications); 42 C.F.R. pt. 52h.7. Peer reviewers are career scientists who participate in this process as volunteers to advance progress in their fields of scientific study. The scientific review group must consider factors, including "[t]he adequacy of the approach and methodology

[4] *Budget*, NIH, https://www.nih.gov/about-nih/organization/budget [https://perma.cc/F7YY-48E7] (last reviewed June 13, 2025).

proposed"; "[t]he significance of the goals of the proposed research, from a scientific or technical standpoint"; and "[t]he qualifications and experience of the principal investigator and proposed staff." 42 C.F.R. pt. 52h.8. Congress codified this peer-review requirement to "prevent[] funding [for] 'questionable projects'" without "scientific merit." *Reauthorization of Health Legislation: Hearing Before the S. Comm. on Labor and Human Resources on S.2311*, 97th Cong. 70 (1982) (written responses by Assistant Secretary of HHS Edward Brandt).

Next, grant applications proceed to a second stage of review by an external "advisory council"—made up of, again, scientists. Congress tasked this group with "recommend[ing] for approval applications for projects which show promise of making valuable contributions to human knowledge." 42 U.S.C. §§ 284a, 289a. Advisory councils largely comprise external experts in the field of study. *See* 42 U.S.C. § 284a(b)(3)(A) (requiring the Secretary to appoint "leading representatives of the health and scientific disciplines . . . relevant to" the Institute's field). For example, the National Advisory Council for Human Genome Research consists of six genetics professors (in addition to the National Human Genome Research Institute's Acting Director, who is chair).[5]

If a grant application has made it this far, the next step is review by an individual Institute or Center (IC) director, who makes the final decision as to whether a notice of award should issue. IC directors, again, are typically scientists or physicians who are

[5] National Human Genome Research Institute, National Advisory Council for Human Genome Research, Roster, https://internet.csr.nih.gov/Committees/Members/100681/HGRAC [https://perma.cc/5YNT-TJKY] (last visited July 31, 2025).

experts in their Institute's area of focus. For example, the director of the National Eye Institute is a pediatric ophthalmologist board-certified in clinical informatics with a research background in biomedical informatics and clinical ophthalmology; and the National Institute of Alcohol Abuse and Alcoholism's director is an internationally recognized "expert on alcohol and stress" and "the neurobiology of alcohol and drug addiction," and the author of more than 800 peer-reviewed scientific papers and an authoritative textbook.[6] IC directors bring their extensive scientific experience and expertise to bear on award decisions.

In the rare circumstances in which it is necessary to terminate a grant, that process, too, follows scientific principles and promotes stability and reliance. The applicable regulations provide that NIH may unilaterally terminate an award only (1) "if the [awardee] fails to comply with the terms and conditions of the award" or (2) "for cause." 45 C.F.R. § 75.372(a). NIH's Grants Policy Statement makes clear that unless immediate termination is "necessary, such as to protect the public health and welfare from the effects of a serious deficiency," NIH "generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action." GPS § 8.5.2.

[6] *See, e.g.*, Michael F. Chiang, M.D., NIH National Eye Institute (last updated Dec. 4, 2024), https://www.nei.nih.gov/about/nei-leadership/michael-f-chiang-md [https://perma.cc/Z8L9-5Z2U]; NIAA Director's Page: NIAA Director George F. Koob, Ph.D., NIH National Institute on Alcohol Abuse and Alcoholism, https://www.niaaa.nih.gov/about-niaaa/directors-page [https://perma.cc/9TDZ-W4X7] (last visited July 31, 2025).

Prior to the events at issue here, NIH hewed closely to these regulations, and terminations were rare. Before 2025, NIH typically terminated grants only with the recipient's consent or where the recipient failed to comply with the terms and conditions of the award and NIH was unable to identify corrective action. *See Am. Pub. Health Ass'n ("APHA") v. NIH*, No. CV 25-10787, __ F. Supp. 3d __, 2025 WL 1822487, at *11 (D. Mass. July 2, 2025) (citing deposition testimony of NIH Chief Grants Management Officer). Since 2012, NIH has terminated "probably less than five" grants for noncompliance with the terms and conditions of the original award. *Id.* This science-based, stability-promoting approach has helped to ensure that NIH-funded research is of high scientific and technical quality and genuinely represents progress in its field of study. And it has created stability and continuity for research that—by definition—NIH has already decided will contribute to scientific progress. *See supra* at 6-7.

B. The Government's *En Masse* Grant Termination Deviates from This Longstanding System of Scientific Decisionmaking.

NIH's recent actions mark a 180-degree reversal from the agency's longstanding adherence to the scientific principles just described. In the words of current and former NIH officials, these directives and resulting blanket termination are "unprecedented in the history of the agency": until now, NIH "was not in the business of canceling its grants," and especially not "in the middle of a project."[7] The agency has justified its

[7] *See, e.g.*, AAMC, *Impact of NIH Grant Terminations* (May 6, 2025), https://www.aamc.org/media/83356/download [https://perma.cc/2HMD-63UW]; Katherine J. Wu, *The NIH's Grant Terminations Are "Utter and Complete Chaos,"* Atlantic (Mar. 14, 2025), https://www.theatlantic.com/health/archive/2025/03/nih-grant-terminations/682039/ [https://perma.cc/RTF5-XUJR]; Ex. 28 ¶ 20, *APHA*, No. 25-cv-10787 (D. Mass. Apr. 25, 2025), ECF No. 38-28 (declaration of anonymous epidemiology professor) ("In my

blanket termination on a regulation that it claims authorizes unilateral termination where grants "no longer effectuate[] the program goals or agency priorities." 2 C.F.R. § 200.340(a)(4); *see APHA*, 2025 WL 1822487, at *9. But even if that regulation applied here, it provides no logical or legal grounds for jettisoning the science-based approach that Congress has required NIH to follow for decades. One could imagine a science-based approach that (for example) assesses grants against the goals they originally hoped to achieve and weighs whether changed circumstances call into question the original, science-based approval.[8] But it is quite clear that no such science-based process happened here. The Administration instead simply compared language in project descriptions to a list of proscribed topics. *See APHA*, 2025 WL 1822487 at *10-11. The agency did not evaluate the quality of study designs or compare projects to other existing research to determine whether the projects were likely to progress understanding in a particular research discipline. *See id.*; *cf.* 42 C.F.R. pt. 52h.7. The agency did not evaluate whether a particular research project had made sufficient progress toward pre-approved aims to contribute to scientific understanding. Nor did the agency solicit the views of scientific experts, despite having access to thousands of internal and external scientists in every field related to the grants at issue, as evidenced by the many who, at three distinct stages of rigorous scientific review, had already evaluated the grants and determined that they

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decades-long career, I have never personally experienced a grant being discontinued in the middle of a project—until now."); *see also* Annie Waldman et al., *Science Shattered*, ProPublica (June 12, 2025), https://projects.propublica.org/nih-cuts-research-lost-trump/ [https://perma.cc/B8HY-ZHT9].

[8] Consistent with the focus of this brief, *Amici* do not address whether this regulation applies or, if so, what restrictions it imposes.

advance scientific understanding. The obvious disconnect between the blanket mandate to terminate these grants, on one hand, and the well-defined and consistent scientific process for awarding them, on the other, underscores NIH's improper departure from scientific principles and procedural fairness.

The government purported to invoke scientific justifications for its actions—terminating, for example, awards supposedly connected with the nebulous and undefined topic of "DEI" based on a boilerplate statement that DEI is "antithetical to scientific inquiry." *APHA*, 2025 WL 1822487, at *5, *10. But intoning a conclusory sentence that invokes science is no substitute for the genuine *scientific process* that has for decades been the hallmark of NIH decisionmaking. And it is no surprise that NIH could not provide a genuinely science-based rationale—because it did not allow for the individualized consideration, nor did it involve the scientific experts, that such a rationale would require. That is a stark departure from longstanding practice, in which agency officials much closer to the research projects have made termination decisions. *Compare* Ex. 8 at 46:10-11, *APHA*, No. 25-cv-10787 (D. Mass. Apr. 25, 2025), ECF No. 38-8 (deposition testimony by NIH grants manager Michelle Bulls explaining that, in the normal course, she "work[s] with the Institutes and Centers to help them determine how to develop corrective actions" before resorting to termination), *with APHA*, 2025 WL 1822487, at *9 (Bulls' testimony that the Acting NIH Director ordered the terminations).

Congressional mandates and binding agency regulations also foreclose the government's sweeping new directives and rationale for blanket termination. Agency regulations require, for example, scientific review groups evaluating grant applications

to consider "[t]he adequacy of plans to include both genders, minorities, children and special populations as appropriate for the scientific goals of the research," 42 C.F.R. pt. 52h.8(f), because building a representative sample is a hallmark of sound science. Congress, too, instructed NIH to conduct research within now-prohibited areas of study, recognizing that they have scientific merit and that the public interest warrants such study. *See, e.g.*, 42 U.S.C. § 285t(b) (establishing National Institute on Minority Health and Health Disparities and directing Institute's director to "give priority to conducting and supporting minority health disparities research"); *id.* § 287d(d)(4)(A) (similar with respect to Office of Research on Women's Health, requiring "research on gender differences" in "clinical drug trials" and "disease etiology"); *id.* § 283p (instructing NIH director to "encourage efforts to improve research related to the health of sexual and gender minority populations"); *id.* § 282(b) (similar). At a minimum, then, the government would have had to engage in individualized inquiry to determine whether a particular research project engaged in genuine scientific inquiry. That did not happen here.

The Executive Branch has leeway to determine its policy priorities, including ones that depart from prior administrations' priorities, *see Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42 (1983), but it must do so in accordance with law, including the Administrative Procedure Act. Consistent with its congressional mandate, NIH's priorities must be—and always have been—guided by and consistent with science. This mandate touches every level of NIH's operation—from the "*scientifically based* strategic planning" it is required to "implement[] in support of research priorities" to the rigorous technical and scientific lens that peer reviewers and

two additional sets of scientific experts must apply to individual grant applications. 42 U.S.C. § 282(b)(5) (emphasis added); *see supra* at 6-7. Any departure by NIH from the status quo requires strict adherence to proper procedures. *See supra* Part I.A. That is especially so here: the relationship between NIH and its research community rests on certainty and stability in grantmaking, guided by the scientific principles that have made NIH the world's preeminent funder of life-saving research.

II. The Mass Termination of NIH Grants Has Destabilized the Scientific Research Landscape, Decimated Reliance Interests, and Wasted Government Resources.

A. NIH's Actions Are Unprecedented and Disastrous for Science.

The magnitude of NIH's recent actions is unprecedented, and the agency's abrupt shift from its longstanding commitments to scientific advancement has thrown the research community into disarray.[9] This seismic shock to the NIH research landscape has had immediate and devastating effects, and granting a stay here will ensure that the reverberations will be felt for years to come.

Begin with the sheer number of grant terminations mandated by the agencywide directives. In these cases, the district court ruled that the termination of grants pursuant to these directives was unlawful, including roughly 1,200 grants identified by plaintiffs (nearly 850 in *Massachusetts* and 367 in *APHA*). Partial Final Judgment, *Massachusetts v. Kennedy*, No. 1:25-cv-10814 (D. Mass. June 23, 2025), ECF No. 151; Appendix at 1086-

[9] *See, e.g.*, Wu, *The NIH's Grant Terminations*, *supra*; Annie Waldman et al., *Science Shattered*, *supra* ("The mass cancellation of grants in response to political policy shifts has no precedent, former and current NIH officials told ProPublica. It threatens the stability of the institution and the scientific enterprise of the nation at large.").

1102, *APHA*, No. 25-1611 (1st Cir. July 8, 2025) (APHA App.). That figure is underinclusive—for one, it does not include any grants to researchers or institutions other than the plaintiffs or members of the associational plaintiffs in *APHA* and *Massachusetts*, including many of *Amici*'s member institutions, who have had myriad grants terminated on the grounds challenged in those cases.[10]

As explained above, this *en masse* termination is unparalleled in the agency's history.[11] Recall that since 2002, the agency has terminated "probably less than five" grants for failure to comply with the relevant terms and conditions. *See supra* at 9. And NIH's longstanding practice in cases of serious noncompliance has been to suspend grants and work with researchers to achieve compliance. *See* GPS § 8.5.2. That practice, and the resulting rarity of terminations in recent decades, has allowed grant recipients and other key stakeholders to invest in, commit to, and conduct their research. *See supra* at 8-9.

These terminations have devastated projects critical to our understanding of human health and disease. The out-of-the-blue terminations have put recipients in untenable positions, often requiring immediate action to shut down research activities (including ongoing trials with human participants and animal test subjects) and cut staff. NIH has cut funding for projects geared toward improving our scientific understanding of human health and disease prevention, including studies focusing on minority and underserved populations. NIH's recent terminations have affected grants for research

[10] *See also* Grant Witness, https://grant-witness.us/nih-data.html (last accessed July 31, 2025) (tracking over 4,500 NIH grants canceled in 2025, over $14 billion).

[11] *See supra* at 9-10 & n.7.

into breast and cervical cancer,[12] cardiovascular disease,[13] Alzheimer's disease,[14] diabetes,[15] HIV and sexually transmitted infections,[16] suicide risk and prevention,[17] alcohol-use disorder,[18] smoking,[19] opioid addiction,[20] COVID-19,[21] and many other conditions of vital concern to the nation's public health.[22]

Of course, a study's focus on the impact of a disease or treatment on a specific minority or underserved population does not render it non-scientific. Quite the contrary, scientific experts have long recognized the many and important reasons to study specific populations. That is precisely why Congress has mandated for many years that NIH fund health-disparities research. *See supra* at 11-12. Failure to study minority and underserved populations can, for instance, compound existing health disparities,

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[12] *See, e.g.*, APHA App. 1097.

[13] *See, e.g.*, APHA App. 1080.

[14] *See, e.g.*, APHA App. 1089, 1099.

[15] *See, e.g.*, APHA App. 1077, 1079, 1092, 1102.

[16] *See, e.g.*, APHA App. 1088, 1090.

[17] *See, e.g.*, APHA App. 1080, 1090, 1091, 1101.

[18] *See, e.g.*, APHA App. 1071, 1088.

[19] *See, e.g.*, APHA App. 1102.

[20] *See, e.g.*, APHA App. 1071.

[21] *See, e.g.*, APHA App. 1093.

[22] *See* Opening Br. at 11, *APHA*, No. 25-cv-10787 (D. Mass. June 9, 2025), ECF No. 103; *see also* Irena Hwang et al., *The Disappearing Funds for Global Health*, N.Y. Times (June 4, 2025), https://www.nytimes.com/interactive/2025/06/04/health/trump-cuts-nih-grants-research.html [https://perma.cc/WYX5-SJUW] (documenting breadth of topics subjected to grant cancellations and delayed funding); Kathryn Palmer, *As NIH Pulls Funding, Scientist Worries About "Frightening Implications,"* Inside Higher Ed (Mar. 28, 2025), https://www.insidehighered.com/news/government/science-research-policy/2025/03/28/nih-grant-terminations-have-frightening [https://perma.cc/YJ3N-F8BU].

especially when certain conditions occur more frequently in certain populations, as well as reduce access to effective medical treatments or interventions for those groups.[23] Additionally, research seeking to understand why certain populations have different treatment outcomes or suffer disparate rates of disease can help scientists and doctors understand the scientific basis for those diseases in new ways, resulting in information that improves care and treatments for every population and individual. Indeed, NIH has touted its findings from such studies in the past, across administrations.[24]

B. The Grant Terminations Have Shattered Reasonable Reliance Interests Across the Research Enterprise and Squandered Government Resources.

1. The Blanket Termination Violated Long-Held Reliance Interests and Trust, Triggering Widespread Uncertainty.

Recipients and stakeholders at all levels of the research enterprise have substantial reliance interests in NIH funding—which have been severely undermined by the abrupt and widespread terminations in the underlying cases.[25] Because funding

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[23] *See, e.g.*, *Why Diverse Representation in Clinical Research Matters and the Current State of Representation Within the Clinical Research Ecosystem*, *in* Improving Representation in Clinical Trials and Research: Building Research Equity for Women and Underrepresented Groups 23–35 (Kirsten Bibbins-Domingo & Alex Helman eds., 2022), https://www.ncbi.nlm.nih.gov/books/NBK584403/pdf/Bookshelf_NBK584403.pdf [https://perma.cc/MW88-GSX2].

[24] *See, e.g.*, NIH, *2018 Research Highlights – Clinical Advances* (Dec. 18, 2018), https://www.nih.gov/news-events/nih-research-matters/2018-research-highlights-clinical-advances [https://perma.cc/E2TA-V52X] (highlighting study on factors contributing to a higher incidence of diabetes for African Americans); NIH, *2019 Research Highlights – Human Health Advances* (Dec. 18, 2019), https://www.nih.gov/news-events/nih-research-matters/2019-research-highlights-human-health-advances [https://perma.cc/5Y24-74AT] (highlighting study on asthma treatments for African-American children).

[25] *See, e.g.*, Rinad S. Beidas et al., *Implementation Science Grant Terminations in the United States*, Implementation Sci. (May 6, 2025) ("Terminations affected all ranks of

recipients understand that grantmaking and terminations have been governed by scientific principles, rather than a top-down policy directive, they can confidently plan long-term research projects without fear that their research will be prematurely canceled based on changes in Executive Branch leadership. This certainty in grantmaking enables grantees, researchers, research participants, and other stakeholders to commit to, invest in, and conduct the research activities necessary to accomplish NIH's research mission.

The benefits of this stability go both ways, contributing to what funding agencies like NIH and their research communities have described as a "symbiotic" relationship. *See, e.g.*, *Ass'n of Am. Univs. v. Dep't of Energy*, No. 25-cv-10912, __ F. Supp. 3d __, 2025 WL 1414135, at *19 (D. Mass. May 15, 2025). The public, through the federal government, invests in the training and research carried out in universities and their hospitals. In return, the university trains future researchers and physicians, provides health care to the community, and improves that care through medical and scientific advances. Universities, in particular, play a critical role in the government-funded-research ecosystem because, unlike private companies, their research "is often driven by curiosity, not profit."[26] The government thus relies on universities for critical innovation that may not be obviously or immediately marketable commercially.

The government's actions in these cases threaten every aspect of this research ecosystem. And the ripple effects of NIH's directives and resulting *en masse* termination

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scientists but included many at vulnerable stages of career development. The nature and magnitude of the terminations will diminish current implementation research and may impede progress.").

[26] Young & Pottinger, *supra*.

extend to researchers, staff, graduate and doctoral students, and postdoctoral fellows; institutions; the future research workforce; and patients, trial participants, test subjects, and their families.[27] The district court's decision halts further damage to the research and people responsible for protecting U.S. health and security. Granting the government's stay application would resurrect and exacerbate the damage described below.

Researchers, Staff Members, Students, and Fellows. The blanket termination has had a devastating impact on individual recipients engaged in research and their teams, including research staff, graduate students, and postdoctoral fellows. Following termination, many researchers have had to abandon their projects midstream.[28] Some have had to pause their research, jeopardizing or eliminating their ability to perform analysis on any data that may have been collected or causing their studies to lose validity.[29] Many grant recipients have been forced to lay off staff and student-employees,

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[27] *See, e.g.*, Columbia Mailman School of Public Health, *Grant Terminations Undermine Relationships Between Researchers and the Communities They Serve* (May 7, 2025), https://www.publichealth.columbia.edu/news/grant-terminations-undermine-relationships-between-researchers-communities-they-serve [https://perma.cc/AM3F-VWKQ] ("[G]rant terminations . . . affect the investigator, their research team, and the larger funding of the school and university. But they also have a negative impact on community partners, and on study participants who often volunteer their time and share medical and environmental samples with researchers. These relationships take trust.").

[28] *See, e.g.*, APHA App. 111 (researcher did "not anticipate being able to secure sufficient funding to allow us to resume" study); APHA App. 555 (project was ended "about halfway through" a 15-month intervention period, resulting in "unusable" data and "biospecimen samples" that had to be discarded).

[29] *See, e.g.*, APHA App. 111 ([B]ecause the termination forced us to prematurely begin the intervention for the control group, we can no longer use any of the data from this cohort for our analysis. . . ."); APHA App. 108 (loss of funds resulting in inability to "pay for an individual with the pertinent statistical background and expertise to analyze data" already collected, which was already limited because "participants [had] yet to complete the entire course of the study").

and many researchers with project-specific knowledge and experience have left their positions.[30] Many recipients are unable to secure replacement funding or cannot raise nearly enough to allow their projects to continue.[31]

To highlight two examples, one associate professor—who has secured over fifteen NIH grants over the course of her career—lost her entire current portfolio of multiple grants, her salary, and the funds to pay roughly 18 people who supported her research, upending the lives of her team members, including multiple graduate and doctoral students and postdoctoral fellows. APHA App. 017. Another professor, whose "life's work" has been the study of Alzheimer's disease, was forced to lay off staff members following the terminations of millions in funding, and has scrambled to find alternative funds to pay five graduate students.[32] These are just two examples among the hundreds

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[30] *See, e.g.*, Supplemental Appendix at 454, *Massachusetts v. Kennedy*, No. 25-1612 (1st Cir. July 8, 2025) (Massachusetts Supp. App.) ("Our grant supports the salaries of three highly trained research staff, all of whom were to be terminated without any warning and without cause. This termination renders them immediately unemployed, resulting in their loss of benefits accrued over years of service in the State University of New York (SUNY) system. Furthermore, loss of these three staff members impedes our ability to conduct activities in coordination with our staff to close out the grant as per NIH requirements, as instructed in the termination notice . . . .").

[31] *See, e.g.*, APHA App. 113 ("[A]lthough my co-investigators and I are scrambling to secure replacement funding, that endeavor is taking away time from our current research, and I do not anticipate being able to secure nearly enough . . . [the] (millions of dollars) that we would have had with those terminated grants.").

[32] Marcelo Jauregui-Volpe, *New Brief Finds NIH Has Canceled $ 1.9 Billion in Grants*, AAU (May 9, 2025), https://www.aau.edu/newsroom/leading-research-universities-report/new-brief-finds-nih-has-canceled-19-billion-grants [https://perma.cc/G8W3-LEBH].

of terminations that have thrown people's lives into chaos, jeopardized their research, and delayed or derailed their careers.[33]

The government's actions here have outsized effects on young researchers at the outset of their careers.[34] By ending pipeline training grants, NIH has removed critical opportunities for developing scientists to advance and gain research experience. Facing gaps in funding resulting from the terminations, institutions have also rescinded offers of admission to highly qualified graduate students and have reduced graduate program slots.[35] These lost opportunities do not merely impede the progress of early-career scientists—they could halt them altogether. Without the early experiences, mentorship, and research-skill development these opportunities provide, young scientists' future employment and career prospects suffer, perhaps irrevocably. NIH's actions have eroded

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[33] *See* APHA App. 952–53 & nn.43-48; *see, e.g.*, APHA App. 016 ("This grant's termination has effectively derailed the career trajectory of a talented postdoctoral fellow[.]"); APHA App. 112 ("These terminations have and will continue to negatively impact our staff").

[34] *See, e.g.*, Beidas et al., *supra* at 2 ("The fact that . . . the grant terminations affected trainees via individual and institutional training awards . . . [is] a setback for investments in the next generation of researchers. Training and career development awards support emerging scientists at a vulnerable moment in scientific development before their areas of expertise and institutional roles are firmly set.").

[35] *See, e.g.*, APHA App. 684 ("The grant termination means I can no longer take on new graduate students, undermining my ability to fulfill my role as a mentor and educator in training the next generation of scientists at my institution."); Massachusetts Supp. App. 535-36 (university forced to "reduce graduate admissions via rescission of funding offers"; has reduced "graduate offers of admission to doctoral programs by 27%"; and has "rescinded funding offers from 100 accepted applicants"); *see also, e.g.*, Massachusetts Supp. App. 87 ("The cuts to the NIH funding have a profound and often underappreciated impact on graduate students. Cuts to NIH funding, especially cuts without warning, have immediate and consequential impacts on our graduate students, who often live paycheck to paycheck, putting their housing and basic needs at risk. Graduate students . . . rely heavily on NIH grants not only for resources to support research, but also for their own stipends, tuition support, and training programs.").

the trust and stability researchers require to start and persevere through arduous academic training and lengthy and demanding research agendas.[36]

Institutions. NIH's actions have also undercut the ability of institutions such as universities and research centers to plan, build, and equip critical research and clinical infrastructure.[37] Upfront costs for such capital expenditures are often unrecoverable, so institutions rely on government assurances and the historical availability of funding to plan and fund such projects. For instance, building a cancer research center requires significant upfront and sustained investments to secure state-of-the-art equipment and the facilities needed for diagnosis, treatment, and research. But the recent funding terminations have made such investments riskier and thus less likely to occur. That is especially true for novel or ambitious projects, or those with longer time horizons—the very sorts of projects that NIH has long made possible. The atmosphere of uncertainty and precarity has similarly made it difficult for universities and research institutions to recruit and support high-quality scientists for existing facilities.

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[36] *See, e.g.*, APHA App. 324 ("I have . . . heard from numerous APHA members expressing concerns about being able to continue research in their chosen area of study based on the termination notices they have received from NIH.").

[37] *See, e.g.*, AAMC, *The Impact of Federal Actions on Academic Medicine and the U.S. Health Care System* (June 11, 2025), https://www.aamc.org/about-us/aamc-leads/impact-federal-actions-academic-medicine-and-us-health-care-system [https://perma.cc/5BHY-D8XP]; *see also, e.g.*, Massachusetts Supp. App. 114-15 (after grant terminations, university must "grapple with maintaining essential research infrastructure, facing financial strain" and has been forced into "an immediate state of review and analysis of non-cancellable financial obligations and mitigation efforts for each project," requiring programs "to stop activities, reduce project personnel, and shutdown programs").

Clinical Trials. The abrupt termination of funding for clinical trials harms the people in those trials. Patients enrolled in clinical trials stalled or terminated due to grant terminations can face delayed treatments; or in some cases, they may never receive treatments at all, despite their reasonable expectations to continue the clinical trials to which they committed their time and health. For instance, one terminated grant funded a study involving more than 1,000 human subjects who underwent diagnostic tests on the understanding they would be provided with those important health results, but the funding to provide those results is now gone. Massachusetts Supp. App. 327. Many of these interrupted treatments and interventions could be life-saving.[38] Further, human participants are often put in vulnerable positions that demand trust in the researchers conducting the study.[39] For some patients, opting to participate in a trial required them to forgo other treatment options. The risk of abrupt termination also vitiates patient

[38] *See, e.g.*, Massachusetts Supp. App. 101 (study on suicide risk and prevention involving over 85 active participants was terminated midway, forcing the cessation of "essential suicide prevention care and regular suicide risk assessments, putting every active participant at very high risk for death or injury due to suicide"); Massachusetts Supp. App. 327 ("Some of the studies for which [the university] has suffered delays[] . . . involve clinical trials for life-saving medications or procedures. These delays harm lives of patients. For example, one is a trial involving assisted living residents with Alzheimer's disease and related dementias. Another relates to prescribing the best antidiabetic drug for each person (i.e. using genetics to determine who will respond best to different classes of drugs.").

[39] *See, e.g.*, APHA App. 555 ("The termination of this grant additionally raises serious ethical concerns due to the lack of a clear process for participants actively involved in the trial. Without the ability to bill or invoice, and with no plan for study close-out activities, participants—who were receiving an intervention as part of the study—are left in an uncertain and unsupported position. As a highly marginalized and at-risk population with mistrust of healthcare and research settings, the abrupt termination of the project may not only cause immediate harm and distress, but may also have long-term consequences.").

autonomy and discourages participant enrollment in the first place.[40] For animal test subjects, the consequences are especially profound: abrupt grant terminations will likely result in euthanasia due to the loss of funding for those studies.[41]

2. The Mass Termination Has Squandered Valuable Government Resources.

Rather than save government resources for more "scientific" projects, NIH's actions have wasted vast government resources by requiring projects to end midstream. Some halted projects cannot easily be resumed once stopped (*e.g.*, many clinical trials that operate on prescribed timelines and testing parameters) and even those that could restart in theory simply will not due to lack of funding.[42] Midstream cancellation also very often means the wholesale loss of all of the funding expended on a project up to the point of termination due to the research lifecycle, which places many "payoff" activities at the end of a grant—*e.g.*, final result gathering, data analysis, and publication. If granted, the

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[40] *See, e.g.*, Katherine J. Wu, *The NIH's Most Reckless Cuts Yet*, Atlantic (Mar. 27, 2025), https://www.theatlantic.com/health/archive/2025/03/trump-nih-clinical-trials-patient-safey/682217/ [https://perma.cc/QF9Q-YTHG] ("By design, clinical trials ask their participants to take on risk. To develop new vaccines, drugs, or therapies, scientists first have to ask volunteers to try out those interventions, with no guarantee that they'll work or be free of side effects. To minimize harm, researchers promise to care for and monitor participants through a trial's end, long enough to collect the data necessary to determine if a therapy is effective and at what cost. End a trial too early, and researchers might not be able to figure out if it worked—or participants may be left worse off than when they started."); *see also* APHA App. 729 ("The abrupt termination of the project harmed the trust we built with community partner organizations and members of the community who participated").

[41] Massachusetts Supp. App. 238 ("Some of these studies involve the use of animal test subjects, all of which would need to be terminated due to loss of funding."); Massachusetts Supp. App. 517 (similar).

[42] *See, e.g.*, APHA App. 017-18, 108, 111-12, 555, 684, 729, 785.

government's request for a stay would seal the fate of these grants, ensuring that many are never restarted and cannot achieve the aims for which they were approved.

For instance, one researcher's grant was canceled four years into a five-year grant, meaning that "[c]ritical findings" already obtained through the research may "never be published—a waste of the taxpayer dollars that funded years of prior research." APHA App. 014. Another researcher conducted a two-year study with over 3,100 participants, many of whom completed their participation period. *Id.* at 105. Nonetheless, with data collection ongoing, the grant was terminated about halfway through. *Id.* at 107. That termination will "severely hinder and may well completely preclude [the researchers'] ability to draw conclusions and develop recommendations" from the study. *Id.* at 108.[43]

The full losses resulting from the grant terminations—and extent of waste of taxpayer dollars—have yet to be seen. But there is no doubt they will only increase if grants are again terminated and chaos in the research enterprise continues to compound.

3. The Government Failed to Consider Harm to Reliance Interests or Waste to Government Resources.

The government did not consider *any* of the above-described reliance interests or the harms to the government's interests before issuing the directives that led to the mass termination at issue here. Indeed, the agency did not consider even the risk to human participants in clinical trials. This lack of consideration is especially striking given

[43] *See also, e.g.*, APHA App. 555 ("At the time of termination, we were only about halfway through the 15-month intervention period for our participants. The data we have collected will now be unusable for analysis to achieve the project aims, and the biospecimen samples collected have been discarded."); Massachusetts Supp. App. 397 (termination of funding would have "significant and immediate consequences for the 1020 study participants" and would also require the "waste of biospecimens").

researchers' decades of reliance on NIH's prior practices and policies. *Dep't of Homeland Security v. Regents of the Univ. of Cal.*, 591 U.S. 1 (2020) (agency action arbitrary and capricious for failure to address "legitimate reliance" interests by regulated parties).

The government downplays the reliance interests at stake, contending that NIH's "invit[ation] [to] grantees to request transition funds 'to support an orderly phaseout of the project'" is sufficient to dispel "any reliance concerns" related to their project funding. Stay App. 33-34. But "transition funds," or closeout costs, are simply those expenses incurred before termination that may nevertheless be recoverable. So they do not come close to accounting for grantees'—or institutions'—reliance interests in the ongoing progress and completion of their work, which has informed their decisionmaking, planning, and investments throughout the course of a funded project (and for many, their careers). These funds do nothing to help stranded clinical trial participants.

Further, just because the government *can* cancel grants—within the constraints under the governing statutes and regulations—does not mean that recipients cannot reasonably expect their funding to be safe from sudden termination with little or no explanation, in manifest disregard of the scientific principles that NIH has followed. *Cf.* Stay App. 34. Researchers' reliance interests are not diminished by what—until this point—was a scant possibility of termination, especially in light of NIH's longstanding practice of working with researchers to address legitimate noncompliance issues.

CONCLUSION

For the foregoing reasons, *Amici Curiae* respectfully request that this Court deny the stay application.

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Respectfully submitted,

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