**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-WGY

**PLAINTIFFS' OPENING BRIEF FOR PHASE 1 PROCEEDING**

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## INTRODUCTION

This case challenges an ideological assault on science. Beginning in February 2025, Defendants created and implemented a series of Directives leading to the termination of hundreds of grants—totaling billions of dollars—funded by the National Institutes of Health ("NIH"). Terminated research includes projects essential to two fundamental, Congressionally-mandated goals: understanding and addressing health disparities among Americans and diversifying the biomedical workforce for the betterment of public health. Defendants have also refused to consider hundreds of funding applications, disrupting scientific progress for years to come.

As a result of this purge, funding for research in critical areas like cancer, heart disease, and Alzheimer's disease have been gutted or remain at risk, and programs designed to diversify the biomedical workforce have been eliminated wholesale. Plaintiffs Ibis Reproductive Health ("Ibis"), Brittany Charlton, Katie Edwards, Peter Lurie, Nicole Maphis, and members[1] of Plaintiffs APHA and UAW (collectively, "Plaintiffs and Members") are among the researchers caught in the crosshairs.

While Plaintiffs respectfully challenge the completeness of Defendants' administrative record by separate motion, the current record still shows that Defendants failed to develop—much less apply—any working definitions for the forbidden research topics; did not rely on any data or science when purging awards; did not consider the disruption that would ensue for researchers, study participants, and public health; and violated Congressionally-imposed requirements to research health disparities and diversify the workforce. Instead, the record shows that bare

[1] "Members" refers to all current members of the associational Plaintiffs, American Public Health Association ("APHA") and United Automobile, Aerospace, and Agricultural Implement Workers ("UAW"), including Pre-Members of UAW (individuals for whom UAW is their exclusive bargaining representative in ongoing negotiations with their employer, and who intend to become dues-paying members once a collective bargaining unit is in place).

termination lists were circulated with same-day deadlines, and actors *outside of NIH* provided lists of grants to be terminated through senior NIH officials' rubber-stamps, obliterating without any meaningful review research that had undergone years of rigorous peer review.

The Directives and their implementation violate the Administrative Procedure Act on three independent grounds, each of which is sufficient to require they be set aside: they are arbitrary and capricious, contravene statutory mandates, and violate HHS's own regulations governing grant terminations. To stop this sweeping assault on public health, Plaintiffs respectfully request that this Court declare the Directives unlawful, vacate them and their current implementation in their entirety, and permanently enjoin their further implementation. *See* Ex. A, Proposed Order.

## FACTUAL BACKGROUND

### I. NIH OVERVIEW

Operated by HHS, NIH is the country's primary source of federal funding for biomedical and public health research. ECF Nos. 38-2, 38-3. It is comprised of 27 institutes and centers ("ICs") and provides almost 50,000 competitive grants, totaling billions of dollars, to more than 300,000 researchers outside the agency ("extramural research"). ECF Nos. 38-1, 38-2, 38-26 ¶ 15. NIH's extramural research awards include project-based grants for scientific and biomedical research projects, ECF No. 38-26 ¶ 15, and pipeline grants to institutions and individuals for career development or training, including congressionally mandated programs, 42 U.S.C. § 288(a)(1)(A), awarded through a rigorous two stage peer-review process that is likewise statutorily mandated. ECF Nos. 38-26 ¶¶ 19, 26; 38-32 ¶ 6; 38-27 ¶¶ 17–21; 38-23 ¶¶ 21, 31–46, 50–51, Ex. A, C; 38-42 ¶ 5; 38-5 at 2.4; 42 U.S.C. § 289(a); 42 C.F.R. § 52.5.

The Public Health Service Act ("PHSA") authorizes NIH to promote research into physical and mental diseases and impairments, including studies conducted by NIH and through extramural research. 42 U.S.C. § 241(a), (a)(3). Statutes require NIH and ICs to (1) conduct research that

promotes health equity and reduces health disparities; and (2) recruit underrepresented groups into the biomedical research field, including racial minorities, women, and those from economically disadvantaged backgrounds. 42 U.S.C. § 282 (b)(4), (b)(8)(d)(ii), (h), (m)(2)(b)(iii); 42 U.S.C. § 283(p); 42 U.S.C. § 283*o*(b)(2); 42 U.S.C. § 285(t); 42 U.S.C. § 285t-1(a), (b); 42 U.S.C § 288(a)(4); 42 U.S.C. § 289a-2. NIH must also, by statute, develop a five-year strategic plan that identifies research priorities and facilitates collaboration across the ICs, and must ensure its resources "are sufficiently allocated for" these priorities. 42 U.S.C. § 282(b)(6), (m).

Given the scientific rigor with which grants are awarded and the governing HHS regulations that allow for unilateral termination of grants only for non-compliance, terminations at NIH have historically been rare. *See, e.g.*, ECF Nos. 38-6, 38-26 ¶ 38; 45 C.F.R. § 75.372(a) (2024). Instead, NIH would generally pursue corrective action in response to concerns about performance of the grant and, even in instances of scientific misconduct, would take steps to preserve the results of research where possible. ECF Nos. 38-26 ¶¶ 39–40.

## II. PURSUANT TO THE DIRECTIVES, DEFENDANTS TERMINATE GRANTS AND WITHDRAW OR REFUSE TO CONSIDER APPLICATIONS.

### A. Overview of the Directives

In recent months, HHS and NIH have issued a series of directives ("the Directives") that suspended NIH funding and have resulted in the termination of billions of dollars in scientific research support for grants and granting programs, and the removal of previously published funding opportunities and applications submitted for the opportunities, all because they allegedly "no longer effectuate[] agency priorities." *See* AR3192-3203.[2] Over the course of all of these

[2] References to the administrative record produced by Defendants on June 2, 2025 will match the page numbers in the record (*e.g.*, "AR0004" corresponds to "NIH_GRANTS_000004").

Directives, the universe of topics to be defunded expanded, but the substance of the boilerplate termination justifications remained the same, and came to include the following:

- **DEI**: Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

- **Transgender issues**: Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.

- **Vaccine Hesitancy**: It is the policy of NIH not to prioritize research activities that focuses [sic] gaining scientific knowledge on why individuals are hesitant to be vaccinated and/or explore ways to improve vaccine interest and commitment. NIH is obligated to carefully steward grant awards to ensure taxpayer dollars are used in ways that benefit the American people and improve their quality of life. Your project does not satisfy these criteria.

- **COVID**: The end of the pandemic provides cause to terminate COVID-related grant funds. These grant funds were issued for a limited purpose: to ameliorate the effects of the pandemic. Now that the pandemic is over, the grant funds are no longer necessary.

- **Climate Change**: Not consistent with HHS/NIH priorities particularly in the area of health effects of climate change.

- **China**: Bolstering Chinese universities does not enhance the American people's quality of life or improve America's position in the world. On the contrary, funding research in China contravenes American national security interests and hinders America's foreign-policy objectives.

- **Influencing Public Opinion**: This project is terminated because it does not effectuate the NIH/HHS' priorities; specifically, research related to attempts to influence the public's opinion.

AR3536. Other defunded grant categories for which boilerplate termination language does not appear in the Directives include South Africa and any subawards to foreign entities. AR3523.

Despite the massive disruption caused by these Directives, the record is devoid of *any* reasoning, analysis, or evidence to support the remarkable assertion that NIH research projects subject to rigorous review were actually "antithetical to the scientific inquiry" and "unscientific" or any other of the Directives' bald assertions. The record thus confirms that the Directives set forth categories of newly forbidden research and programs without any definition of what belongs in those categories, provide only boilerplate and conclusory justifications for why these are forbidden, and point to no research, data, or any other support to back up their justifications and their about-face from prior NIH priorities and determinations.

**B. Development and Implementation of the Directives**

Pursuant to these Directives, Defendants swiftly terminated hundreds of grants previously subjected to a rigorous selection process and found to align with NIH priorities, ECF No. 41 at 15-17, 39-43, including grants addressing research areas essential for public health and diversifying the workforce, *id.*; Ex. 55[3] (Ex. A).[4] The record—even with its limitations—shows that the purges occurred without any scientific or individualized review.

The Directives followed Executive Orders from President Trump requiring, among other things, that agency heads "terminate, to the maximum extent allowed by law, all … 'equity related' grants or contracts" within 60 days."[5] On February 10, 2025, the "Secretarial Directive on DEI-related Funding" ("Secretarial Directive") instructed agencies to "briefly pause" payments made to grantees "related to DEI and similar programs" and stated that "grants may be terminated in accordance with federal law." AR0004.

[3] Citations to "Ex. []" refer to the numbered exhibits attached to the Declaration of Jessie J. Rossman dated June 9, 2025.

[4] In prior filings and supporting declarations, Plaintiffs have recounted just some of the chaos that ensued because of Defendants' actions. *See, e.g.*, ECF No. 71 at 11–18, 39–43. But in light of the focus of the phase 1 proceeding on *the Directives* themselves, Plaintiffs respectfully reserve the right to fully address in any pre-hearing filings how the terminations and failure to consider applications unfolded, in the event there are subsequent phases for this case.

[5] *Ending Radical and Wasteful Government DEI Programs and Preferencing,* 90 Fed. Reg. 8339 (Jan. 20, 2025).

On February 12, 2025, the Directive titled "NIH Review of Agency Priorities Based on the New Administration's Goals" ("Lauer Memorandum") informed grants-management officers that NIH was reevaluating the agency's priorities based on the new administration's goals, but court injunctions must limit immediate implementation. AR0009. However, that same day the Acting General Counsel "clarif[ied]" that agencies could "exercise their own lawful authorities to withhold funding," AR0010, and "Supplemental Guidance" issued the next day directed grants-management officers to "fully restrict[]" grants where the "sole purpose" is to support "DEI activities." AR0016. The Supplemental Guidance provided neither a definition of "DEI activities" nor discussion of how to discern whether a grant supports the same. *Id.*

On February 21, 2025, NIH issued a "Directive on NIH Priorities" requiring the agency to cease its support of "low-value and off-mission research programs," including studies based on "DEI" and "gender identity" (the "February 21 Directive"), neither of which were defined. AR2930, AR3821. The record reflects that the Directive stated, without citation or backing from any evidence, that "[r]esearch programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness." AR3821. A cover email from Matt Memoli—the Acting NIH Director—forwarding the Directive to a number of NIH staff indicated that NIH could "set priorities at an NIH level, which now allows us to proceed with the process of making sure programs are meeting these goals." AR3823. That same afternoon, Liza Bundesen—the former Deputy Director of NIH Office of Policy for Extramural Research Administration ("OPERA")—forwarded the Directive to NIH colleagues, stating that "**today**, we have to pull down all of the

NOFOs[6] that we previously pulled down and put back up (DEI, gender ideology, environmental justice, etc.)." AR3823.

The next day, Brad Smith—an official at the so-called Department of Government Efficiency ("DOGE")—emailed Memoli with a list of 18 NOFOs, stating "[p]er our conversation, below are a number of NOFOs that it may be worth your team reviewing to make sure they align with your directive and priorities." AR3752–53. NIH's review of these NOFOs lasted at most 25 minutes, at which point Memoli emailed the entire list to NIH officials with the subject line "NOFOs that need to come down," stating "I was sent a list of NOFOs to review that are still up. After my review I have determined these NOFOs in their current form have issues that cause to not be properly directed at current NIH priorities. Please take these NOFOs down." AR3810.

The first wave of grant terminations soon followed. On February 28, 2025, Memoli emailed Bundesen (copying DOGE and HHS officials), attaching a spreadsheet of grants and instructing NIH to "[p]lease terminate the grants on the attached spreadsheet by COB today. Attached is an OGC cleared termination letter." AR2295, AR2296, AR2469.[7] That evening, Rachel Riley—described in the record as an HHS official—sent multiple emails in a thread with the subject line, "Grants for immediate termination today." AR2296. These and the hundreds of subsequent terminations used the template termination (or similar) language from HHS described above. *See* AR3192-3203.

On March 4, 2025, NIH issued the first iteration of what would become an ever-expanding memo describing "Award Assessments for Alignment with Agency Priorities" (the "Priorities

[6] A "NOFO" refers to a Notice of Funding Opportunity, which ICs post to identify the criteria that will be used to assess each application. *See* ECF Nos. 41 at 11; 38-26 ¶ 27; 38-5 at 2.4.1.3.

[7] When Defendants produced excel versions of the spreadsheets, a different termination list was labeled "AR2296," leading to confusion in the record that Defendants must clarify on reply.

Directive"). AR2136. This Directive repeats that NIH would "no longer prioritize research and research training programs that focus on Diversity, Equity and Inclusion (DEI)" and creates a taxonomy of four categories to classify projects and determine actions "to completely excise all DEI activities." AR2136-37. The first category consists of projects for which "the sole purpose . . . is DEI related" and the award "must not issue," and the second category consists of projects that "partially support[] DEI activities" and requires that such activities be "negotiated out" or else the award must be terminated. AR2136-37. This Directive also includes three appendices, the third of which provides specific scripts for staff to use when terminating grants allegedly connected to China, "[t]ransgender issues," or DEI, the latter parroting the unsupported statements from the February 21 Directive. AR2138-41; *compare* AR2141 *with* AR3821.

That same day, Michelle Bulls—the Director of OPERA—instructed staff to move forward with "the process for terminating awards based in DEI *as provided to [NIH] by HHS*." AR3453 (emphasis added). Bulls also directed the NIH chief grant management officers who had "issued termination letters yesterday (and Friday[])" to "review Appendix 2 – Guidance for staff to use when terminating awards identified by HHS or the IC related to DEI," and revise their previous terminations using the new guidance. AR3453. Bulk terminations followed. *See, e.g.*, AR2352; AR2353 (March 10 email attaching list of 43 grants and NOFOs "that need to be terminated/taken down, preferably by COB today if possible"); AR3512 (March 11 list of grants for potential termination); AR3820 (March 11 approval of terminations); AR3631–35 (email attaching March 12 list of grants to terminate).

On March 13, 2025, NIH issued another Directive (the "Awarded Revision Guidance"), which adds vaccine hesitancy to the list of deprioritized topics and provided the following termination boilerplate: "It is the policy of NIH not to prioritize [insert termination category

language]. Therefore, this project is terminated." AR1957 (bracketed placeholder in original). When sending this Directive to other NIH officials, Bulls attached a spreadsheet of termination letters sent on March 12 and provided "updated categories" that should be "use[d] when issuing NOAs to officially terminate the awards where letters were issued," and noted that her email constituted "[g]uidance" for NIH officials "to use when terminating awards identified by HHS or the IC due to DEI or other agency priorities." *Id.*; AR1968; AR1959. Resulting grant terminations parroted the boilerplate language from the Directives. *Compare* AR0709 *with* AR2136.

More terminations followed shortly after. On March 13, 2025, Memoli emailed NIH officials with a list of 450 grants to terminate over the following week. AR3122, AR3123. And on March 24, 2025, he sent another email stating "We have been asked to terminate the list of approximately 120 grants by COB today. The memo from HHS OGC defines the reason for the terminations so our letter should mirror this memo," AR2562 (referencing memorandum from HHS titled "Termination of COVID-19 Grants," AR2591).

On March 25, 2025, NIH issued the second iteration of the "NIH Grants Management Staff Guidance—Award Assessments for Alignment with Agency Priorities—March 2025" (the "Revised Priorities Directive"). AR3216. The Revised Priorities Directive expanded the categories of relevant projects, including by creating a category of terminations—"HHS Department Authority Terminations"—that consisted of any list of grants the "Director, NIH, or designee" sent to ICs to terminate.[8] AR3220. This Directive also expanded the topics of disfavored research to include climate change and added South Africa to a general topic of "countries of concern." AR3218. The Directive provides approved boilerplate termination language for nearly all the research topics. *See* AR3218.

[8] The Directive also created a subcategory for "Subprojects terminated by HHS," for which OPERA was to "restrict funds associated with the project" and "[n]o action [is] required from the IC." AR3220.

The day after issuing this Directive, on March 26, Memoli sent an email identifying more grants to be terminated "ASAP." AR2563. On March 28, after speaking with the OGC, Memoli emailed again with another list of 34 grants to terminate. AR2488, AR2489–2561.

By May 7, 2025, NIH had further institutionalized these practices. Bulls circulated another iteration of the Directive (the "May 7 Directive"), which sought "to expand the scope of categories within to include other agency priorities that will be defined by the Director, NIH." AR3548. Among other changes, the May 7 Directive stated that awards could not be issued both for unpublished NOFOs and also for NOFOs that "expired naturally, if the sole purpose was DEI or another category that does not effectuate the NIH/HHS priorities;" created a new category of "Directed Terminations" that encompasses the termination of entire programs, listing examples of COMPASS, FIRST, and MOSAIC K99/R00,[9] and stated there would "not be any other announcement" of program terminations except that "the NOFO will be unpublished"; and added several new appendices. AR3547–3548, AR3568–3577. A nascent "definitions" section appears in the Directive, still containing no definition of "gender identity/transgender issues," "DEI," or "COVID-related," and includes a placeholder for "Health Disparities," stating that a definition was "pending." AR3562–63. Appendix 3—providing the boilerplate explanation for each disfavored topic—replaced the phrase "Transgender Issues" with "Gender-Affirming Care." *Compare* AR3226 *with* AR3567.[10]

[9] "ComPASS" stands for "Community Partnerships to Advance Science for Society" and "FIRST" for "Faculty Institutional Recruitment for Sustainable Transformation." *See* https://commonfund.nih.gov/compass; https://commonfund.nih.gov/FIRST.

[10] The Gender-Affirming Care language includes a "reminder" not to "terminate any grants related to gender identity / transgender without clearance from OER." AR3567. Yet the boilerplate language for the terminations continues to state "research programs based on gender identity are often unscientific," and the May 7 Directive's definition of "Gender-Affirming Care" has no relevance to the research activities described in the boilerplate language. *Compare* AR3567 *with* AR3562. Nor does the definition of Gender-Affirming Care meaningfully relate to scores of grants previously terminated on the basis of "gender identity." *See, e.g.,* AR0155–0168 (appeal letter for grant terminated on the basis of "gender identity" where grant was studying biological changes in men and women associated with substance use exposure).

Just two days later, on May 9, 2025, Jon Lorsch—Acting Deputy Director for Extramural Research—emailed "several additional grants" for potential termination to Memoli. AR3452. No more than 2 minutes later, Memoli responded, "Please terminate those grants for being inconsistent with agency priorities." *Id.* On May 15, 2025, NIH issued a slightly altered version of the May 7 document, but it does not change the forbidden research topics. *See* AR3517.[11]

## III. THE DIRECTIVES DECIMATE GRANTS AND FUNDING OPPORTUNITIES CRITICAL TO PUBLIC HEALTH AND DIVERSIFYING THE BIOMEDICAL WORKFORCE.

This sweeping purge of NIH grants quickly reverberated through the field of biomedical research. As painstakingly documented by grant-watch.us, a website and series of databases that track terminated NIH grants, a total of 1,737 grants have been terminated based on vague "policy" assertions as of June 4, 2025. Ex. 55 ¶ 7; *see also* ECF Nos. 38-27 ¶¶ 5–12, Ex. A; 72-3 (Ex. A). The total budget allocated across these grants was approximately $7.2 billion. Ex. 55 ¶ 9. Approximately $3.8 billion has already been spent, leaving an estimated $3.4 billion in unspent value. *Id*. These terminations have touched every corner of the country, with institutions in 50 states and territories abruptly losing NIH funding.[12]

Terminated projects span a dizzying array of health issues, including breast cancer, uterine cancer, anal cancer, stroke risk, cardiac health, Alzheimer's Disease, HIV prevention, suicide prevention, alcohol use disorder, smoking cessation, eating disorders, sexually transmitted infections, COVID-19, depression, psychopathology, pain, and many other conditions that very often disproportionally burden minority communities. ECF No. 38-27 ¶ 13. Terminated grants tackled topics such as "Mitigating the Effects of Structural Racism on Chronic Kidney Disease

[11] Three additional spreadsheets of grants appear in the Administrative Record, without corresponding cover emails that would allow Plaintiffs to understand when or if they were terminated. *See* AR2311; AR2497; AR2564.
[12] *See* Association of American Medical Colleges (AAMC), *Impact of NIH Grant Terminations* (May 27, 2025), *available at* https://perma.cc/YF4W-GWKN.

Disparities Among African Americans"; "Assessing Cervical Cancer Healthcare Inequities in Diverse Populations"; "Elucidating the High and Heterogeneous Risk of Gestational Diabetes Among Asian Americans"; and "The Epidemiology of Alzheimer's Disease and Related Dementias in Sexual and Gender Minority Older Adults: Identifying Risk and Protective Factors." ECF Nos. 38-27 (Ex. A), 72-3 (Ex. A). Scores of terminated grants involved clinical trials.[13]

Among these hundreds of terminations are Pipeline Grants to support, train, and recruit a diverse group of scientists into biomedical research.[14] *See*, *e.g.*, ECF No. 38-27 (Ex. A) (listing terminated grants including Pipeline Grants such as FIRST, MARC, and U-RISE), ¶¶ 18–19, 22–25; *see also* ECF Nos. 38-35, 38-36, 38-41 (MOSAIC terminations); 38-38, 38-39 (IRACDA terminations); 38-42 (IMSD termination); 38-23 (MARC termination); Ex. 55 ¶¶ 10–14 (describing terminated grants that have no apparent connection to forbidden topics). Defendants have systematically eliminated entire granting programs designed for this purpose,[15] and have administratively withdrawn or refused to review applications that had been submitted for such programs. *See*, *e.g.*, ECF No. 72-10.

[13] *Id.* at 2; *see also* Irena Hwang et al., *The Gutting of America's Medical Research: Here Are the 2,500 Medical Research Grants Canceled or Delayed by Trump*, N.Y. TIMES (June 4, 2025), https://www.nytimes.com/interactive/2025/06/04/health/trump-cuts-nih-grants-research.html (documenting breadth of research topics subjected to grant cancellations and delayed funding).

[14] As demonstrated in Plaintiffs' Reply in Support of Plaintiffs' Motion for a Preliminary Injunction, and discussed further *infra*, Defendants' efforts in prior filings to show that they continue to preserve grants addressing health disparities and the recruitment of researchers from disadvantaged backgrounds are either distorted or flatly belied by the record. *See* ECF 71 at 8–10. *See also infra*, Background Section IV.

[15] *See*, *e.g.*, AR3701 (F31-Diversity); AR3705 (IRACDA); AR3713 (MOSAIC); AR3717 (ReWARD); AR3721 (R01); AR3726 (PREP); AR3729 (Bridges to the Doctorate Program); AR3730 (G-RISE); AR3734 (LEAD MSTP); AR3735 (MARC); AR3747 (ARC); AR3749 (Short-Term Research Education Experiences to Attract Talented Students to Biomedical Informatics/Data Science Careers and Enhance Diversity); AR3787 (Bridges to the Baccalaureate); *see also* ECF 72-3 ¶¶ 9-10 (all five National Research Service Awards ("NRSA") training programs that specifically recruit from underrepresented communities have been terminated).

## IV. THE DIRECTIVES HAVE RESULTED IN DISCRETE, ONGOING, AND WIDESPREAD HARM.

The terminations stemming from the Directives have caused widespread and ever-compounding harm. First, and most fundamentally, Plaintiffs' and Members' research addresses critical public health issues for the population at large. *See*, *e.g.*, ECF Nos. 38-22 ¶¶ 4–6, 11–15; 38-24 ¶¶ 3–4; 38-26 ¶ 11, 38-30 ¶ 4; 38-34 ¶ 33. The rapid, haphazard and sweeping implementation of the Directives has undermined these goals, as well as the transparency, stability, and reliability of biomedical research writ large. *See*, *e.g.*, ECF No. 47-1.

So too have the sudden terminations harmed grant recipients, those they employ, and their patients. Plaintiffs and Members rely on NIH funding for their salary, and have had their livelihoods upended, their lives destabilized, and their research jeopardized. *See, e.g.*, ECF Nos. 38-19 ¶ 51; 38-20 ¶¶ 17, 23; 38-21 ¶ 20; 38-24 ¶¶ 9–10, 17; 38-26 ¶ 45; 38-41 ¶ 14, 38-42 ¶ 13; Ex. 56 ¶¶ 6–7. Grant recipients have been forced to abruptly fire students and staffers and will likely have to continue to do so. *See, e.g.*, ECF Nos. 38-28 ¶ 22; 38-31 ¶¶ 24–26; 72-12 ¶¶ 3–5.

The Directives also upended the critical trust and rapport Plaintiffs and Members have carefully built with their research subjects, likely making it difficult or impossible to rebuild subject groups and continue their research in the future. *See*, *e.g.*, ECF Nos. 38-19 ¶¶ 53–55; 38-28 ¶ 22; 38-30 ¶¶ 24–29; 38-31 ¶¶ 30–33; 38-33 ¶ 22. At the same time, researchers previously funded by programs designed to diversify the scientific workforce worry that their grant terminations will tar them as unqualified "DEI hires," notwithstanding that they underwent the same rigorous peer review process to obtain their awards, and make it more difficult for them to secure future positions or more likely to be fired from current positions. *See*, *e.g.*, ECF No. 38-35 ¶¶ 23–26. The sudden interruptions in their academic progress have made students less competitive job candidates, undermining their professional development and careers. ECF Nos. 38-40 ¶ 22,

38-41 ¶ 14. Some fear being blacklisted from future grant applications or from employment consideration from universities seeking to avoid retaliation by the federal government. ECF Nos. 38-37 ¶¶ 28–31; 38-39 ¶¶ 19–22.

## ARGUMENT

## I. JURISDICTION

### A. The Court Has Jurisdiction Over Plaintiffs' Suit.

This Court has already ruled that it has subject matter jurisdiction over this lawsuit, rejecting Defendants' challenges to Plaintiffs' suit "relating to the Tucker Act, sovereign immunity, programmatic attack, jurisdiction over individual actions, and agency discretion." ECF No. 84 at 14 (adopting reasoning set forth in *Massachusetts v. Kennedy*, No. CV 25-10814-WGY, 2025 WL 1371785 at *5). Plaintiffs have comprehensively addressed each of these issues in prior briefing, ECF No. 41 at 19–23; ECF No. 71 at 5–11, and the Court has ruled in their favor, ECF No. 84 at 14; *see also Bowen v. Massachusetts*, 487 U.S. 879, 910 (1988); *see Kennedy*, 2025 WL 1371785 at *8–11. This Court's analysis should remain unchanged, and its jurisdiction is clear.

### B. Plaintiffs Have Standing.

By having their grants terminated and application withdrawn by Defendants, the individual plaintiffs and Ibis have (1) suffered an "injury in fact" that is "concrete and particularized"; (2) "fairly traceable" to the actions of defendants; and (3) "likely" redressable by a favorable decision. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560-61 (1992) (cleaned up). *See supra*, Background Section IV; ECF No. 41 at 18-19.

In addition, this Court already ruled that plaintiffs APHA and UAW adequately pled associational standing, and it has now been sufficiently proven. *See* ECF No. 84 at 21; ECF No. 41 at 19; ECF No. 71 at 11–12; ECF No. 79 at 2. The missions of both APHA and UAW are core to the interests they seek to protect here and each easily satisfies the 'undemanding' germaneness

test. *See* ECF No. 84 at 21; *see also* ECF Nos. 38-23 ¶ 2; 38-25 ¶¶ 10, 11, 13, 15; 79 at 3 n.1. Neither the claims asserted nor the relief requested require any individual member's participation in the action. As a result, "both the APHA and UAW have associational standing to sue on their members' behalf." ECF No. 84 at 21.

**C. The Directives Constitute Final Agency Actions.**

This Court has previously found at the pleading stage that the Directives constitute final agency action. *See Kennedy*, 2025 WL 1371785 at *10. The record now confirms that the Directives "mark the consummation of the agency's decisionmaking process" and determined "rights or obligations . . . from which legal consequences [flowed]." *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997) (internal quotes omitted). The Directives articulated NIH's settled position to not fund research on certain topics and resulted in direct legal consequences in the form of, among other things, grant terminations and withdrawal of funding opportunities and applications for those opportunities.[16] These Directives reflect NIH's decision to no longer prioritize research on certain prohibited topics, which has the "actual or immediately threatened effect" of hundreds of grants being terminated and applications withdrawn and are clearly reviewable under the APA. *See New York v. Trump,* 133 F.4th 51 (1st Cir. 2025) (implementation of "categorical funding freezes" constitutes "discrete final agency action").

The record bears out that the Directives are not "interlocutory": "if they were, defendants would not be implementing them by terminating hundreds of grants around the country." *Kennedy*, 2025 WL 1371785, at *10; *see also Supplemental Guidance*, AR0016 (noting that this Directive

[16] *See, e.g.*, *February 21 Directive*, AR2930–31 ("Such review shall be aimed at ensuring NIH grants . . . do not fund or support low-value and off-mission research activities or projects – including DEI and gender identity research activities and programs."); *March 25 Guidance*, AR3351 ("Prior to issuing all awards (competing and non-competing) or approving requests for carryover, ICs must review the specific aims/major goals of the project to assess whether the proposed project contains any DEI, gender identity or other research activities that are not an NIH/HHS priority/authority . . . ICs must take care to completely excise all non-priority activities using the following categories.")

was being issued to "supplement[]" guidance provided in the Lauer Memorandum, and directing grants-management officers to "fully restrict[]" grants where the "sole purpose" is to support "DEI activities."). As described above, the Directives were not simply to review grants but provided concretized instructions requiring bulk terminations and pre-determined actions for certain categories of topics. *See supra*, Background Section II.

## II. THE DIRECTIVES ARE ARBITRARY AND CAPRICIOUS.

The record proves that the Directives are arbitrary and capricious in violation of the APA in three ways: (1) there is *no* evidence that Defendants undertook any reasoned analysis to support the policies in the Directives; (2) Defendants failed to provide sufficient reasoning for the reversal of prior policy and prior agency decision making; and (3) Defendants failed to consider serious reliance interests. *See* also ECF No. 41 at 28–32; ECF No. 71 at 16–19.

### A. There is No Evidence of Reasoned Analysis for Issuance of the Directives.

First, the record shows that Defendants failed to "examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choices made." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (cleaned up). As this Court has explained, "[a]n agency action qualifies as 'arbitrary' or capricious' if it is not 'reasonable and reasonably explained.'" ECF No. 84 at 24 (quoting *Ohio v. Env't Prot. Agency*, 603 U.S. 279, 292 (2024)). "Statements of aspirational goals . . . are not the same as reasoned explanations for why an action is chosen or how the chosen action will effectuate the stated goals." *Ass'n of Am. Universities v. Dep't of Energy*, No. 25-CV-10912-ADB, 2025 WL 1414135 at *12 (D. Mass. May 15, 2025). And "conclusory and vague" "explanations" by the agency are neither reasonable nor reasoned decision-making. ECF No. 84 at 24, 31. At the motion-to-dismiss stage, this Court explained that the language across the Directives and terminations described "undefined gender identity issues" and "DEI language"

"untethered to the specific terminated grants, with what looks more like a political statement than reasoning about the grants, and without any explanation as to why no corrective action is possible." ECF No. 84 at 31–33.

That alone would render the Directives arbitrary and capricious, and the record proves the allegations to be true. *See* ECF No. 84 at 31–35. The record is devoid of "a working definition of Diversity, Equity, and Inclusion," "gender identity" or any of the other forbidden topics. *See* ECF No. 84 at 35 n.4; *cf. Schiff v. U.S. Office of Pers. Mgmt.*, No. CV 25-10595-LTS, 2025 WL 1481997 at *10 (D. Mass. May 23, 2025) ("Wholly absent from this process, it seems, was any consideration or reasoned explanation of what language 'promotes' or 'inculcates' gender identity[.]"). Indeed, the record shows that, *months* after this funding purge began, Defendants created a "Definition(s)" list that only lists two terms, "Health Disparities," for which a definition is "Pending" and "gender affirming care," which contains a definition with no obvious relationship to the grants that Defendants previously terminated under the name "gender identity" or "transgender issues." yet continues to use the same boilerplate justification. AR3562, 3567. Of course, Defendants cannot provide a *post hoc* definition or justification for their actions, so that definition cannot support Defendants' reasoning on cuts that preceded the May 7 Directive. *See Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1909–10 (2020). It is especially damning that Defendants have still provided "no satisfactory answer" on definitions despite "[t]he Court press[ing] this issue." ECF No. 84 at 35 n.4.

Further, there is no evidence in the record that Defendants undertook *any* kind of reasoned analysis to support the conclusory statements in each of the Directives. The record shows no data, study, or analysis to justify any aspect of the Directives, let alone specific assertions such as that "[r]esearch programs based on gender identity are often unscientific, have little identifiable return

on investment, and do nothing to enhance the health of many Americans," *see, e.g.*, AR2930; AR2141; AR 3567; *see also* ECF No. 84 at 31–32, or that "DEI studies" are "based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness," *see, e.g.*, AR2930; AR2141; AR3567; *see also* ECF No. 84 at 31–34.

Instead of providing any reasoned analysis, Defendants made the Directives out of whole cloth, and parroted the conclusory statements across iterations of the Directives and in termination letters for individual grants and programs. *See, e.g.*, AR2930, AR2141, AR3567 (same "DEI" language); AR2930, AR2141, AR3567 (same "gender identity" language). That use of boilerplate language evinces Defendants' failure to "consider individual, or any, data or information." *Am. Ass'n of Colls. for Tchr. Educ. v. McMahon*, No. 1:25-CV-00702-JRR, 2025 WL 833917, at *21 (D. Md. Mar. 17, 2025). And when NIH officials put these Directives into practice, they *at most* tried to invoke the same talismanic words: grants or programs are "unaligned with current NIH/HHS priorities." AR3820; *see also* AR2352, AR3631, AR3810.

Further, "the time and manner in which the Defendants implemented the [Directives] belies any plausible claim that [Defendants] acted in anything but an arbitrary and capricious way." *Schiff*, 2025 WL 1481997 at *10. For example, on February 22, it took Memoli no more than *25 minutes* to purportedly review and conclude that 18 NOFOs "need[ed] to come down." *See* AR3752, AR3810 ("After my review I have determined these NOFOs in their current form have issues that cause them to not be properly directed at current NIH priorities."). In another instance, on March 11, it took Memoli no more than *6 minutes* after receiving an email with 6 grants identified by Riley, to respond, "All of these grants can be terminated for being unaligned with

current NIH/HHS priorities." AR3511, AR3820. And in another case, on May 9, it took Memoli just *2 minutes* to review a list of "several additional grants" and direct that all should be terminated "for being inconsistent with agency priorities." *See* AR3452.

In several other instances, NIH officials were instructed to pull down NOFOs, terminate grants, and/or revise NOAs pursuant to the Directives *the same day* they were identified. AR2295, AR2469, AR2562–63, AR3631. Indeed, that deadline was often imposed even when the NIH officials received a list late in the evening. AR2296, AR3511, AR3820. *See Schiff*, 2025 WL 1481997 at *10 ("HHS relayed that directive internally on the day compliance was due, and by the end of that day, [the subagency] had searched [the database] and identified the content it would remove.").

The record also reflects that, at least in some instances, NIH program officers were "not consulted about" how the Directives were actually implemented. AR0125. At least for some ICs, "scientific program staff" "ha[d] no information about how awards are being identified for potential termination, what criteria are being used, or who is involved in making these decisions." *Id.*; *see Schiff*, 2025 WL 1481997, at *10 (noting that terminations were "apparently done without consulting any of [the website's] editors, and without advance notice to the authors.").

And in many instances, the record shows that individuals *outside of NIH* were involved in drafting and implementing the Directives.[17] Individuals outside of NIH also identified grants to terminate or NOFOs to take down.[18] Indeed, the Directives themselves explicitly spell out the

[17] *See* AR2296, (Riley—purportedly from HHS—writes "DRAFT LETTER ATTACHED" next to some grants and "I WILL DO NOW" next to others), AR2562 ("The memo from HHS OGC defines the reason for the termination so our letter should mirror this memo."); *May 7 Directive*, AR3573 ("For HHS directed terminations, the template letter and appeals language were provided by HHS, and must be used as is.").

[18] *See* AR2296 (Riley provides lists of grants to be terminated), AR2562 ("We *have been asked* to terminate the list of approximately 120 grants by COB today." (emphasis added); AR3752 (Smith—from DOGE—identifies 18 NOFOs), AR3820 (Riley provides list to Memoli).

process for handling some grants that HHS—*not* NIH—officials determined should be terminated pursuant to those Directives. *See, e.g.*, AR3220–21, AR3453, AR3554, AR3573.

And relatedly, the Directives run afoul of the priorities required by statute and NIH and IC strategic plans—all of which continue to bind the agency. Defendants' change therefore represents precisely the type of "inscrutable" reasoning that is "facially irrational," *Marasco & Nesselbush, LLP v. Collins*, 6 F. 4th 150, 173 (1st Cir. 2021), and based in "factors which Congress has not intended it to consider," *State Farm*, 463 U.S. at 43. For these and the other reasons Plaintiffs previously asserted, the record shows that the Directives and resulting terminations are arbitrary and capricious *See* ECF No. 84 at 31–35; ECF No. 41 at 29–30; ECF No. 71 at 16–17.

**B. There is No Evidence of Reasoned Explanation for Defendants' About-face on Policies and Priorities.**

Second, the record shows that Defendants failed to "supply a reasoned analysis for the change" in its policies or priorities. *Ark Initiative v. Tidwell*, 816 F.3d 119, 127–28 (D.C. Cir. 2016) (quoting *State Farm*, 463 U.S. at 42)*; see also* ECF No. 41 at 30–31; ECF No. 71 at 17. The APA "demand[s] that [the agency] display awareness that it *is* changing position" and "show that there are good reasons for the new policy," particularly when the "new policy rests upon factual findings that contradict those which underlay its prior policy." *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009); *Massachusetts v. Nat'l Insts. of Health ("NIH")*, No. 25-CV-10338, 2025 WL 702163 at *20 (D. Mass. Mar. 5, 2025). Indeed, "an about-face . . . owing to facts changed from those underlying the prior view requests that the new facts be addressed explicitly by reasoned explanation for the change of direction." *NLRB v. Lily Transp. Corp.*, 853 F.3d 31, 36 (1st Cir. 2017) (Souter, J.). In those circumstances, a "more detailed justification" may be required. *See Housatonic River Initiative v. U.S. Env't Prot. Agency, New England Region*, 75

F.4th 248, 270 (1st Cir. 2023) (quoting *F.C.C.*, 556 U.S. 502 at 515); *Ass'n of Am. Universities*, 2025 WL 1414135 at *12.

But the record fails to show *any* reasoning for the changes, especially in light of the reasoned previous conclusions of NIH and external scientists who reviewed and approved the projects through a rigorous process. *See supra*, Background Section I; *see also* ECF No. 41 at 8–11, 29–30 & nn. 25 & 26. Instead, the record reflects no more than "conclusory policy goals" parroted across the Directives and throughout their implementation. *Ass'n of Am. Universities*, 2025 WL 1414135 at *12. This is especially egregious in light of the years-long efforts by Plaintiffs and Members to apply for, refine, implement, and report on their projects. *See* ECF No. 29–30 & nn.25 & 26. Indeed, Defendants acknowledge that there are "thousands of additional pages in *each* grant file related to the grant application and approval process." ECF No. 86-1 at 1 n.1 (emphasis added). Their lack of reasoning is "even more egregious in light of the drastic change" from the longstanding existing policies and priorities under which NIH has awarded funding. *See NIH*, 2025 WL 702163 at *18.

**C. There is No Evidence Defendants Considered Substantial Reliance Interests.**

Third, the record shows that, in creating and implementing the Directives, Defendants ignored "serious reliance interests that must be taken into account." *DHS*, 140 S. Ct. 1891 at 1913; *Orr v. Trump*, No. 1:25-CV-10313-JEK, 2025 WL 1145271 at *18 (D. Mass. Apr. 18, 2025). Plaintiffs have previously submitted evidence describing some of the reliance interests at stake, and rely on that evidence here. *See* ECF No. 41 at 31, 39–43. The record confirms Defendants "fail[ed] to address" those interests, including, "how [the] research will be conducted absent" government funding, a concern of particular importance "considering the number of [researchers] and associations that have made clear that research will have to be cut, as other funding sources will not be able to make up the shortfall." *NIH*, 2025 WL 702163 at *17; *see also id*. at *20; *AIDS*

*Vaccine Advoc. U.S. Coal. v. Dep't of State*, 766 F. Supp. 3d 74, 82 (D.D.C. 2025). There is no evidence showing Defendants even considered "the risk to human life as research and clinical trials are suspended," "the life, careers, and advancement that will be lost as these budgets are indiscriminately slashed," and most critically, "the health of those whose hopes rely on clinical trials and the financial investment that will be lost as research is disrupted." *NIH*, 2025 WL 702163 at *20 (issuing preliminary injunction regarding NIH's rate change notice).

In fact, the only documents in the record that come close to reflecting *any* consideration of any reliance issues are the May 7 and May 15 Directives, which acknowledge the likely disruption to training and employability of NRSA fellows, and to the career trajectory and funding opportunities available to Early-Stage Investigators flowing from the Directives. AR3245, AR3531. But those were generated *after* the vast majority of NOFOs at issue were unpublished and are therefore at most impermissible *post hoc* papering for those actions. *See DHS*, 140 S. Ct. 1891, at 1909–10. And even for terminations that occurred after May 7, those Directives suggest minimal and wholly insufficient steps to mitigate a small part of the harm Defendants are causing and reflect no balancing of the reasons for terminating training opportunities against the impact on the careers of hundreds of early career researchers and the overall scientific endeavor.

This "lack of reasoned explanation is particularly troubling in light of decades of industry reliance on [NIH's] prior policy." *Ass'n of Am. Universities*, 2025 WL 1414135, at *12–13 (quotation omitted) (no steps taken to identify reliance interests). Because Defendants did not "assess whether there are reliance interests, determine whether they [are] significant, and weigh any such interests against competing policy concerns," the Directives are arbitrary and capricious. *NIH*, 2025 WL 702163, at *19 (quoting *DHS*, 140 S.Ct. 1891, at 1915).

## III. THE DIRECTIVES ARE CONTRARY TO STATUTE.

The Directives are "in excess of statutory jurisdiction, authority, or limitations," 5 U.S.C. § 706(2)(C), for three independent grounds, each of which is sufficient to set the Directives aside. The Directives (1) flout congressional mandates to fund research into health disparities; (2) run counter to congressional mandates to address the underrepresentation of racial minorities, women, and those from economically disadvantaged backgrounds in the biomedical field; and (3) subvert the priorities identified in congressionally mandated strategic plans and the requirement that such priorities must be sufficiently funded. Defendants not only violate the relevant statutory requirements—they turn them on their head by *defunding* exactly what Congress has *required* to fund. And in a role not contemplated by the statutory scheme, DOGE individuals, not NIH officials, served as decision-makers in determining what NIH funds.

First, 42 U.S.C. Ch. 6A, which governs the NIH, mandates that the agency fund research into health disparities. Congress made this requirement clear by, for example:

- Establishing the National Institute on Minority Health and Health Disparities (NIMHD) with the purpose of "conduct[ing] and support[ing] . . . research, training, dissemination of information, and other programs with respect to minority health conditions and other populations with health disparities." 42 U.S.C. § 285t(a);

- Requiring that the NIMHD director "shall . . . give priority to conducting and supporting minority health disparities research," *id.* at § 285t(b), and "shall" develop a plan and budget that "give[s] priority in the expenditure of funds to conducting and supporting minority health disparities research," *id.* at § 285t(f)(1)(D);

- Mandating that the NIH Director "shall" ensure that the ICs foster collaboration between their various clinical research projects and encourage such projects to "utilize diverse study populations, with special consideration to biological, social, and other determinants of health that contribute to health disparities[.]" *Id.* at § 282(b)(8)(D)(ii);

- Directing that the NIH Director "shall assemble accurate data" for the purposes of "assessing research priorities, including— (A) information to better evaluate . . . progress in reducing health disparities; and (B) data on study populations of clinical research, . . . which— (i) specifies the inclusion of— (I) women; [and] (II) members of minority groups[.]" *Id.* at § 282(b)(4);

- Requiring that the NIH Director "shall . . . encourage efforts to improve research related to the health of sexual and gender minority populations, including by— (1) facilitating increased participation of sexual and gender minority populations in clinical research . . . ; (2) facilitating the development of valid and reliable methods for research relevant to sexual and gender minority populations; and (3) addressing methodological challenges." *Id.* at § 283p; and

- Mandating that the NIH Director "shall . . . ensure that (A) women are included as subjects in each project of . . . [clinical] research; and (B) members of minority groups are included as subjects in . . . [clinical] research" unless inclusion of women and members of minority groups would be inappropriate to the health of the research subjects or to the purposes of the research, or is inappropriate for some other circumstance as designated by the NIH Director. *Id.* at § 289a-2(a)(1) & (b).

Second, Congress has mandated that NIH increase diversity within the biomedical field by, for example:

- Requiring that NIH "shall" issue grants "in a manner that will result in the recruitment of women, and individuals from disadvantaged backgrounds (including racial and ethnic minorities)" through Kirschstein-NRSA, 42 U.S.C § 288(a)(4);

- Directing that NIH "shall" "develop, modify, or prioritize policies, as needed, within the National Institutes of Health to promote opportunities for new researchers and earlier research independence, such as policies to . . . enhance workforce diversity" via the Next Generation of Researchers Initiative. *Id.* at § 283*o*(b)(2), including by "increas[ing] opportunities for new researchers to receive funding." *Id.*;

- Mandating that the HHS Secretary and NIH Director "shall, in conducting and supporting programs for research, research training, recruitment, and other activities, provide for an increase in the number of women and individuals from disadvantaged backgrounds (including racial and ethnic minorities) in the fields of biomedical and behavioral research." *Id.* at § 282(h);

- Insisting that NIH "shall" fund institutions to "support[] programs of excellence in biomedical and behavioral research training for . . . members of minority health disparity populations or other health disparity populations" through the National Institute on Minority Health and Health Disparities (NIMHD) and grants made under this provision require applicants to agree to expend the grant for these purposes. *Id.* at § 285t-1(a), (b).

Third, Congress requires NIH to develop and submit to Congress a five-year strategic plan that, among other things, "shall . . . (B) consider . . . (iii) biological, social, and other determinants of health that contribute to health disparities . . ." and the NIH Director "shall ensure" funding is

"sufficiently allocated for research projects identified in strategic plans[.]" *Id.* at § 282(b)(5), (b)(6), (m)(1) & (m)(2)(b)(iii). Accordingly, the current 2021–2025 strategic plan prioritizes "improving minority health and reducing health disparities," "enhancing women's health," undergoing rapid vaccine development "to mitigate emerging infectious disease outbreaks, such as COVID-19," and continuing to enhance the biomedical workforce through inclusion of underrepresented groups. ECF No. 38-4 at 19, 27–28, 16–17, 32–24. In turn, NIMHD's current strategic plan explicitly sets out goals and research priorities to diversify the medical field.[19] ECF No. 38-16 at 17–31. Furthermore, the Director of each IC "shall take into consideration, as appropriate—(i) the mission of the . . . [IC] and the scientific priorities identified in the [NIH] strategic plan[.]" 42 U.S.C. § 284(b)(3)(B).

The Directives flagrantly violate each of these Congressional mandates. They recast research into health disparities as verboten "studies based on diversity, equity, and inclusion (DEI)," and condemn as "unscientific" any "research programs based on gender identity" and other disfavored topics.[20] The Directives require the identification and termination of research projects that purportedly fall within these categories, and forbid the issuance of further awards on these topics.[21] Similarly, they require the systemic identification and termination of programs designed

[19] ICs additionally promulgate their own strategic plans. 42 U.S.C. § 282(m)(3).

[20] *February 21 Directive*, AR2930 (NIH must "ensure that it is not supporting low-value and off-mission research programs, including but not limited to studies based on [DEI] and gender identity" and that [r]esearch programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry[.]"); *Priorities Directive*, AR2171 (listing "China," "DEI," and "Transgender issues" as "research activities that NIH no longer supports"); *Revised Priorities Directive*, AR3221, AR3226 (stating that "ICs should hold all awards to entities located in South Africa . . ." and adding "Vaccine Hesitancy," and "COVID" to the list of research activities NIH no longer supports); *May 7 Directive*, AR3562–63, AR3567 (marking the definition of health disparities as "pending," changing "Transgender issues" to "Gender-Affirming Care," and adding "Climate Change" and "Influencing Public Opinion" to the list of research activities NIH no longer supports).

[21] *Secretarial Directive*, AR0004 ("Agency personnel shall briefly pause all payments made to . . . grantees related to DEI . . . for internal review[.] . . . Such review shall include . . . a review of . . . grants to determine whether [they] are in the best interest of the government and consistent with current policy priorities."); *Supplemental Guidance*, AR0016 ("If the sole purpose of the grant . . . or supplement supports DEI activities, then the award must be fully restricted."); *May 7 Directive*, AR3548 (directing ICOs to "review the specific aims/major goals of the project" to "completely excise all non-priority activities" and specifying that "[w]hether the NOFO was unpublished or expired naturally, if

to diversify the biomedical field. *See, e.g.*, AR3548 ("ICO's must not issue the award" if "[t]he sole purpose of the project is related to an area that is no longer an NIH/HHS priority/authority (e.g., diversity supplements, diversity fellowships, . . . etc."). That is, rather than issue grants that fund disparities research and grants seeking to diversify the biomedical profession, Defendants are defunding grants precisely because they have identified the grants as serving those purposes.

The grant terminations pursuant to these Directives have been massive in scale and sweeping in their substantive scope. As detailed *supra*, and pursuant to the Directives, Defendants have terminated research on a startling array of health conditions, often because they examine health disparities in the population. *See supra*, Background Section III; *see also* Ex. 55 (Ex. A); ECF Nos. 38-27 ¶ 13, Ex. A; 72-3 (Ex. A). While Defendants have claimed in prior briefing that they *are* "preserving grants [researching] health disparities" and asserted they terminated "DEI grants that [NIH] determined did not promote health," ECF No. 66 at 32, they have failed to define "DEI grants"—and the record flatly contradicts their claim. Indeed, in attempting to show that NIH continues to fund disparities research, Defendants pointed to a smattering of 25 remaining grants, and of the grants they identified, at least five were already or have now been terminated, two ended before the Lorsch Declaration they proffered identifying these 25 grants was signed, and four more projects will end this calendar year.[22] By July of 2026, only four of the 25 grants will remain. *Id*.

Likewise, the mass termination of pipeline grants and programs pursuant to the Directives subverts Congress's direction that NIH address the underrepresentation of certain groups in the medical field. Defendants have systematically identified the very programs designed to do so,

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the sole purpose was DEI or another category that does not effectuate NIH/HHS priorities, ICO's [sic] cannot make the award.").

[22] *See* ECF No. 72-4 ¶ 3, *see also Compare* Ex. 55 (Ex. A) (Showing termination on Mar. 28, 2025 of MD014127 *Achieving American Indian Youth Energy and Mental Health Balance* and MD016961 *Long-Term Effects of Hurricane Maria on Healthcare Delivery, Migration and Mortality Among People with Kidney Failure in Puerto Rico*) *with* ECF No. 66-2 (listing both grants as "Not Terminated").

unpublished funding opportunities for those programs, conducted sweeping terminations of existing grants, and withdrawn or refused to review pending applications for those programs. *See supra,* n.14. Entire grant programs specifically designed to diversify the biomedical workforce, in furtherance of Congressional mandates, *see supra*, have been categorically eliminated. *See id.* (detailing the termination of NRSA training programs); *May 7 Directive*, AR3575 (FAQ on "programs that have been terminated[] in whole (e.g., MOSAIC K99/R00)").[23] NIH has excised all references to workforce diversity from newly-posted T32 and T35 NRSA opportunities, *see* ECF No. 72-05, 72-06, has revised instructions for institutional training grant applications to eliminate previously required diversity recruitment plans, ECF No. 72-7 at 4, and has revised "peer review processes to eliminate consideration of Plans for Enhancing Diversity (PEDP) across all opportunities." ECF No. 72-8 at 6.

NIH's "hard funding restrictions" to grants that "promote[] or take[] part in diversity, equity, and includsion [sic] ('DEI')" AR0016, and its consistent instruction to staff to "completely excise all DEI activities" and/or "all non-priority activities," AR2166; AR3231; AR3548; AR3517, demonstrate that the Directives require the *full restriction* of awards that address health disparities and the underrepresentation of certain groups in the biomedical profession. Defendants have, and continue to, implement this full restriction and excision, actions that squarely conflict with Congressional mandates.

And finally, the record reveals that DOGE members, *not* NIH officials, dictate, inform, and guide decision-making around which grants and NOFOs are terminated and which grants and NOFOs avoid scrutiny. S*ee supra*, Argument Section II.A. Congressional authority flows

[23] As demonstrated in Plaintiffs' Reply in Support of Plaintiffs' Motion for a Preliminary Injunction, and discussed further *infra*, Defendants' efforts in prior filings to show that they continue to preserve grants addressing health disparities and the recruitment of researchers from disadvantaged backgrounds are either distorted or flatly belied by the record. *See* ECF 71 at 8–10.

exclusively to HHS and NIH, not DOGE, an entity not contemplated within the statutory scheme. NIH's reliance on DOGE as arbiter of NIH policy is thus in excess of its statutory authority.

## IV. THE DIRECTIVES ARE NOT IN ACCORDANCE WITH LAW.

Section 706(2)(A) of the APA requires a Court to "hold unlawful and set aside" final agency actions which are "not in accordance with law." 5 U.S.C. § 706(2)(A). A court must uphold agency action if it is "(1) devoid of legal errors; and (2) supported by any rational review of the record." ECF No. 84 at 27–28 (internal quotes and citations omitted). Because the challenged actions are replete with legal errors, including that they violate relevant statutes and regulations, and also lack the requisite rational review, they must be set aside.

First, as Plaintiffs have previously argued, the Directives require terminations in a manner that fails to satisfy either of the requirements of the HHS regulation that governs unilateral grant terminations. *See* 45 C.F.R. § 75.372(a) (2024); *see also* ECF No. 41 at 33; ECF No. 71 at 14–15. That regulation allows for unilateral termination only where the grantee "fails to comply with the terms and conditions of the award" or "for cause." 45 C.F.R. § 75.372(a)(1) (2024). As other courts have emphasized, the plain language of the regulation mandates that these are the exclusive conditions under which HHS and its sub-agencies may terminate a grant. *See, e.g.*, *Pol'y & Rsch., LLC v. United States Dep't of Health & Human Servs.*, 313 F. Supp. 3d 62, 76 (D.D.C. 2018); *Healthy Teen Network v. Azar*, 322 F. Supp. 3d 647, 651 (D. Md. 2018).

The record shows that the Directives instructed termination under 2 C.F.R. § 200.340 on the basis that "the award no longer effectuates agency priorities." *See supra*, Background Section II. But that is not a permissible basis for termination under HHS regulations. *See* ECF Nos. 84 at 30–31; 41 at 33–34; 71 at 14–16. As this Court noted, "it is undisputed that [2 C.F.R. § 200.340] has not yet been adopted by HHS, and will not be adopted until October 2025; accordingly, the regulation is apparently inapplicable here." ECF No. 84 at 30. And although Defendants have tried

to rely on language in the NIH Grants Policy Statements to permit other justifications for terminations, those statements "do[] not, and cannot, trump the agency's formal regulations." *Pol'y & Rsch., LLC*, 313 F. Supp. 3d, at 82; *see also* ECF No. 41 at 34.

Thus, for the reasons already explained by Plaintiffs, the Directives are not in accordance with law because they fail to comply with requirements of 45 C.F.R. § 75.372(a). *See* ECF Nos. 41 at 32–35; 71 at 14–16; *Nat'l Env't. Dev. Ass'ns Clean Air Project v. Env't Prot. Agency*, 752 F.3d 999, 1009 (D.C. Cir. 2014) ("It is axiomatic . . . that an agency is bound by its own regulations . . . Although it is within the power of an agency to amend or repeal its own regulations, an agency is not free to ignore or violate its regulations while they remain in effect.") (cleaned up).

Second, as this Court has emphasized, even if 2 C.F.R. § 200.340 applied—and it does not—"this regulation only allows agencies to terminate . . . agreements 'to the extent authorized by law,'" and 'this regulation cannot authorize actions that contravene statutory requirements, nor does it relieve [the Public Officials] of [their] duty to follow the law.'" ECF No. 84 at 30 (internal case citation omitted). HHS regulations currently limit to non-compliance the circumstances under which unilateral terminations are allowed, and Defendants are bound by these regulations. *Env't Prot. Agency*, 752 F.3d at 1009. Further, this Court noted that the Directives "can **still** be challenged under the APA where the Plaintiffs allege a failure to provide a reasonable explanation." ECF No. 84 at 31 (emphasis in original). For the reasons expressed above in Argument Sections II and III, the Directives fail to satisfy any of those requirements. The record thus shows that the Directives are not in accordance with law.

## V. THE DIRECTIVES SHOULD BE VACATED AND ENJOINED.

Plaintiffs seek a declaration that the Directives are unlawful, vacatur of those Directives as required under the APA, and a permanent injunction—independent of but overlapping with vacatur—to redress Plaintiffs' injuries. Vacatur, by its nature, voids the Directives and all efforts

to implement them; restores the conditions that existed before the Directives issued including all grant and application-related obligations; and necessarily benefits non-parties, *i.e.*, everyone harmed by the Directives will necessarily benefit if the Directives are vacated.

Vacatur is warranted because the Directives violate 5 U.S.C. §706(2). *See* ECF No. 1 at ¶¶ 209, 212, 215, 225, 232 (alleging violations of §706(2), which if successful requires vacatur).[24] This Court has recognized and applied this standard practice: agency actions that violate Section 706(2) must be set aside, "as is the usual course in successful APA challenges." *Victim Rts. L. Ctr. v. Cardona*, No. CIV 20-11104-WGY, 2021 WL 3516475, at *1 (D. Mass. Aug. 10, 2021) (vacating Department of Education regulation upon concluding it was arbitrary and capricious). Vacatur is especially appropriate when, as here, "an agency fails to explain its reasoning adequately." *Harrington v. Chao*, 280 F.3d 50, 60 (1st Cir. 2002). Thus, the Directives must be set aside and cannot be relied upon by Defendants in any way.

Vacating the Directives also reinstates the status quo from before they issued. *See Orr*, 2025 WL 1145271, at *24 ("[w]hen a court vacates an agency's rules under 5 U.S.C. § 706(2), the vacatur restores the status quo before the invalid rule took effect") (cleaned up); *Indep. U.S. Tanker Owners Comm. v. Dole*, 809 F.2d 847, 855 (D.C. Cir. 1987) ("present rule will be vacated and conditions returned to the *status quo ante*, before the [unlawful rule] took effect"); *see also Montana Wildlife Fed'n v. Haaland*, 127 F.4th 1, 51 (9th Cir. 2025) (requiring Bureau of Land Management to return $36 million to buyers of land leases after vacating lease sales made under unlawful policy). The same result should apply here. The Directives are unlawful, and Defendants

[24] *Cf. Massachusetts Lobstermen's Ass'n, Inc. v. Nat'l Marine Fisheries Serv.*, No. CV 24-10332-WGY, 2024 WL 2194260 (D. Mass. Apr. 16, 2024), *rev'd and remanded sub nom. Massachusetts Lobstermen's Ass'n, Inc. v. Menashes*, 127 F.4th 398 (1st Cir. 2025) (vacating agency rule after consolidating the plaintiffs' Rule 65 motion seeking non-vacatur relief with expedited trial on the merits of their §706(2) claims); *Corner Post, Inc. v. Bd. of Governors of Fed. Rsrv. Sys.*, 603 U.S. 799, 831 (2024) (Kavanaugh, J., concurring) ("the D.C. Circuit—which handles the lion's share of the country's administrative law cases—has likewise long recognized vacatur as the usual relief when a court holds that agency rules are unlawful.").

have terminated grants and failed to consider applications pursuant to those Directives; thus, if the Directives are vacated, actions taken pursuant to the Directives must be vacated.

Returning to the status quo here means that all efforts to implement the Directives must be vacated, including grant terminations and the withdrawal or refusal to review applications for research or programs targeted by the Directives. *See W.C. v. Bowen*, 807 F.2d 1502, 1505 (9th Cir. 1987) ("Agency action taken under a void rule has no legal effect."). NIH's obligation to honor formerly-existing awards and consider then-pending applications must, in the interest of justice, spring back to life. *See, e.g., Harmon v. Thornburgh*, 878 F.2d 484, 495 n.21 (D.C. Cir. 1989) ("When a reviewing court determines that agency regulations are unlawful, the ordinary result is that the rules are vacated—not that their application to the individual petitioners is proscribed"). Although courts do not always nullify actions taken pursuant to vacated agency action,[25] neither the Supreme Court nor First Circuit has endorsed any such hesitation, and significant precedent exists in support of doing so to implement a return to the status quo.

The Ninth Circuit's analysis in *W.C.* is instructive. In that case, the district court vacated a set of adverse decisions to Social Security claimants, requiring not only benefits going forward but also restoring prior ALJ benefits decisions. *W.C.*, 807 F.2d at 1505. The Ninth Circuit affirmed, holding that, because the program under which the adverse decisions were made violated the APA,

[25] *See e.g. D.A.M. v. Barr*, 486 F. Supp. 3d 404, 414-416 (D.D.C. 2020) (declining to vacate removal orders despite vacatur of Transit Ban under which orders issued); *see also Allied-Signal, Inc. v. U.S. Nuclear Regul. Comm'n*, 988 F.2d 146, 151 (D.C. Cir. 1993). But *D.A.M.*, for its part, is distinguishable. The court there emphasized that vacatur restored the prior regulatory status quo, *i.e.*, the invalid agency rule was replaced by any preexisting rule it had superseded. *Id*. at 415. Implicit in the court's reasoning is that under previously existing rules, ICE was authorized to issue removal orders. *See id*. at 416 ("order vacating the Transit Ban means the government cannot issue any more orders of removal *under that rule,* but it does not mean that petitioners' removal orders (along with thousands of others) were automatically extinguished[.]") (emphasis added). Indeed, the INA already conferred removal authority on the relevant agencies. *See Cap. Area Immigrants' Rts. Coal. v. Trump*, 471 F. Supp. 3d 25, 33-34 (D.D.C. 2020) (discussing removal authority before Transit Ban). The Transit Ban was thus an unlawful expression of existing authority. *Id*. at 57. That preexisting authority, however, allowed the court to tacitly justify the results (removal orders) despite the unlawful means (Transit Ban). Here, by contrast, the regulatory status quo required NIH to honor grant awards and consider properly submitted applications. No previous rule existed under which NIH was authorized to purge disfavored grants as it saw fit. *See supra*, Argument Section IV.

"the ALJ's decisions [that had been reversed by the review program] must be reinstated and the claimants provided disability benefits." *Id.* at 1506. This result flowed logically from the unique nature of vacatur; once the review program decisions were vacated, the regulatory status quo–the preexisting ALJ decisions awarding benefits–were reinstated. *See id.*

Vacatur necessarily provides relief to not only Plaintiffs and Members, but also to non-parties whose grants were terminated or applications withdrawn pursuant to the Directives. The Supreme Court's decision in *DHS* illustrates this point. There, the then-Acting DHS Secretary rescinded the Deferred Action for Childhood Arrivals (DACA) program, which permitted work authorization and eligibility for Social Security and Medicare benefits to a specific subset of immigrants. 140 S. Ct. 1891, 1906–1910. The Acting Secretary explained that the desired effect of her recission was that no new applications would be accepted. *Id.* at 1903. The Supreme Court held that the Acting Secretary "violated the APA" because she had not adequately explained the reasons for her decision nor considered reliance interest in making her decision, and therefore "the rescission must be vacated." *Id*. at 1901. The unlawfully rescinded DACA program was reinstated and DHS was obligated to administer DACA as it had before. This included processing applications it had stopped accepting, because each such application had been an effort to implement the unlawful recission—regardless of whether the applicants were a party to the suit.

The same is true here. The Directives violate the APA and must be vacated; thus, relief must flow not only to Plaintiffs and Members, but to *all* researchers whose grants were terminated to implement the void-Directives regardless of whether they are party to this suit.[26]

[26] *See Career Colls. & Schs. of Tex. v. Dep't of Educ.*, 98 F.4th 220, 255 (5th Cir. 2024) ("Nothing in the text of Section 705, nor of Section 706, suggests that either preliminary or ultimate relief under the APA needs to be limited to [the associational plaintiff] or its members"); *E. Bay Sanctuary Covenant v. Biden*, 993 F.3d 640, 681 (9th Cir. 2021) ("Because of the broad equitable relief available in APA challenges, a successful APA claim by a single individual can affect an 'entire' regulatory program."); *O.A. v. Trump*, 404 F. Supp. 3d 109, 153 (D.D.C. 2019) ("The D.C. Circuit has 'made clear that '[w]hen a reviewing court determines that agency regulations are unlawful, the ordinary result is that the rules are vacated—not that their application to the individual petitioners is proscribed.'"");

Vacatur alone, however, is insufficient to redress Plaintiffs' injuries. Although vacatur will void the Directives and actions taken to implement the Directives, Defendants continue to issue new similar directives, including since Plaintiffs filed their Complaint. *See* AR3548. Vacatur cannot stop NIH from issuing a new and similarly unlawful directive tomorrow, which would have the same pernicious effects as the Directives at issue here. Plaintiffs therefore ask for a permanent injunction as detailed in the accompanying proposed order.

To obtain a permanent injunction, a plaintiff must show:

> (1) actual success on the merits of its claims; (2) that he/she would be irreparably injured in the absence of injunctive relief; (3) that the harm suffered from the defendant's conduct would exceed the harm to the defendant accruing from the issuance of an injunction; and (4) that the public interest would not be adversely affected by an injunction.

*Doe v. Rhode Island Interscholastic League*, 137 F.4th 34, 40 (1st Cir. 2025) (citation and internal quotation marks omitted).

Success on the merits is established as described above. On factor two, Plaintiffs and the broader public have suffered and will continue to suffer irreparable harm because of the Directives, including job loss, threatened job loss, loss of training and mentoring opportunities, compromised studies, data collection, and statistical analyses. See ECF No. 41 at 39–43; *see also supra*, Background Section IV. "As for the third and fourth factors, the Supreme Court has explained that when 'Congress has spoken in the plainest of words, making it abundantly clear' what the public's priorities are, it is not the court's place to review such priorities." *Mass. Lobstermen's Ass'n*, 2024 WL 2194260, at *7. Congress has spoken here—through its requirement that agencies engage in reasoned decision-making, *see* 5 U.S.C. 706(2)(A) and, most fundamentally, through its numerous

*See also* Transcript of Oral Argument at 73, *Trump v Casa, Inc*. Case No. 24A884, available at www.supremecourt.gov/oral_arguments/argument_transcripts/2024/24a884_c07d.pdf (government describing vacatur as "indivisible remedy").

mandates that NIH has violated here. *See* ECF No. 1 at ¶ 229 (describing relevant statutory provisions); *see also supra*, Argument Section III; ECF No. 84 at 37. Given the ongoing harm to Plaintiffs and the public caused by the Directives, factors three and four are easily satisfied.

## CONCLUSION

For the reasons discussed here and in Plaintiffs' prior briefing, ECF Nos. 41 and 71, Plaintiffs respectfully request that the Court grant their requested relief. *See* Ex. A.

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Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that on June 9, 2025 a true and correct copy of the above document was filed via the Court's CM/ECF system and that a copy will be sent automatically to all counsel of record.

June 9, 2025

*/s/ Matthew D. Brinckerhoff*
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