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-BEM Leave to File Excess Pages Granted April 14, 2025 (ECF No. 29)

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

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INTRODUCTION

For decades, the National Institutes of Health ("NIH") has fulfilled its congressionally mandated mission to advance scientific knowledge and improve public health through a robust system of research grants to external institutions. This system—developed over generations and governed by specific statutory and regulatory frameworks—follows rigorous procedures designed to ensure that taxpayer dollars fund the most promising scientific research without disruption.

That all changed in January 2025, when Defendants began an unprecedented and ideologically driven purge of hundreds of projects that, according to Defendants, "no longer effectuate[] agency priorities." Defendants have issued multiple overlapping directives to eradicate projects that purportedly involve forbidden topics including "DEI," "gender identity," and "transgender issues." Without defining what these terms encompass, Defendants have relied on them for boilerplate terminations of *years* of research on a wide span of health issues such as cancer, Alzheimer's, and brain injury. Likewise, Defendants have terminated en masse grants and programs designed to address the underrepresentation of racial minorities, women, and economically disadvantaged scientists in the biomedical field.

Plaintiffs Ibis, Brittany Charlton, Katie Edwards, Peter Lurie, Nicole Maphis and members of Plaintiffs APHA and UAW (collectively, "Plaintiffs and Members") are researchers whose work was funded by grants that Defendants have terminated or for whom review of grant applications has been suspended. They seek this Court's intervention to stop the ongoing upheaval caused by Defendants' unlawful and unconstitutional actions. As set forth below, they are entitled to preliminary injunctive relief. First, Plaintiffs are likely to show that Defendants violated separation of powers principles by subverting congressional mandates around NIH funding priorities, acted contrary to law, regulation, and in an arbitrary and capricious manner in issuing the directives and

by terminating grants and suspending application review processes, and have issued directives that are unconstitutionally vague. Second, Plaintiffs and Members will suffer irreparable harm ranging from disruptions to their own careers to lost opportunities to contribute to science and public health. Finally, the balance of the equities and the public interest strongly favor an injunction. Accordingly, Plaintiffs request that the Court enjoin Defendants' implementation and enforcement of the directives, terminations, and suspension of application processes.

FACTUAL BACKGROUND

I. Funding Structure of NIH

Since it was created by Congress nearly 100 years ago, NIH has been involved in countless medical breakthroughs, and has grown to comprise twenty-seven institutes and centers ("ICs"), each focusing on a different disease or biological system. Ex. 1.[1]

Operating under the United States Department of Health and Human Services ("HHS"), NIH is the primary source of federal funding for biomedical and public health research in the United States, providing almost 50,000 competitive grants to more than 300,000 researchers across the country at more than 2,500 universities, medical schools, and other research institutions outside the agency ("extramural research"). Ex. 2. NIH received annual appropriations from Congress of $48 billion in 2024 and nearly the same amount in a continuing resolution in 2025. *Id*. Ex. 3.

A. Statutes, Regulations, Policies, and Strategic Plans Govern Funding Priorities

Congress has authorized NIH's funding of extramural research through a number of express statutory mandates. For example, Section 301 of the Public Health Service Act ("PHSA") provides Congress's overarching authorization for NIH to "promote the coordination of[] research, investigations, experiments, demonstrations, and studies related to the causes, diagnosis,

[1] Citations to "Ex. []" refer to the numbered exhibits attached to the Declaration of Jessie J. Rossman dated April 25, 2025.

treatment, control, and prevention of physical and mental diseases and impairments," including through extramural research. 42 U.S.C. § 241(a), (a)(3); *see also* §§ 284(b)(1)(A), 284(b)(2)(A) (conferring similar authority on the directors of NIH's individual ICs).

Congress has also defined specific purposes for which NIH and the ICs must fund research, as discussed below. *See infra*, Argument Sections III.A and III.B.3. Statutes require NIH to fund research that promotes health equity and reduces health disparities across diverse populations. *See, e.g.*, 42 U.S.C. § 282(b)(8)(d)(ii) (special consideration given to biological, social, and other determinants of health that contribute to health disparities); 42 U.S.C. § 282(m)(2)(b)(iii); 42 U.S.C. § 283(p) (mandate to consider "disease burden in the United States," expressly including the LGBTQ+ population). And statutes require NIH to increase recruitment of groups underrepresented in the biomedical research field, including racial minorities, women, and those from economically disadvantaged backgrounds. *See* 42 U.S.C § 288(a)(4) (diversification of research field).

In addition, NIH is under statutory mandate to develop, submit to Congress, and publish a five-year strategic plan that identifies research priorities and facilitates collaboration across the ICs. 42 U.S.C. § 282(m)(1). NIH's Strategic Plan for 2021–2025 prioritizes "improving minority health and reducing health disparities"; "enhancing women's health"; "addressing public health challenges across the lifespan"; "promoting collaborative science"; "leveraging data science for biomedical discovery"; undergoing rapid vaccine development "to mitigate emerging infectious disease outbreaks, such as COVID-19, Ebola virus disease (EVD), and influenza (flu)"; and continuing to enhance the biomedical workforce through inclusion of underrepresented groups. Ex. 4 at 8, 16–17, 32–24. NIH must ensure its resources "are sufficiently allocated for" these priorities. 42 U.S.C. § 282(b)(6). ICs also promulgate their own strategic plans. *Id.* § 282(m)(3).

B. Funding Process for NIH and ICs

1. Project-based Grants and Pipeline Grants

NIH awards considerable funding through grants for scientific and biomedical research projects ("Project-based Grants"). These grants provide *billions* of dollars each year to critical research, and fund everything from salaries to benefits to research supplies, as well as real research costs that are not readily attributed to specific projects. Ex. 26 ¶ 15.

In addition to Project-based Grants, NIH awards grants to institutions and individuals for career development or training ("Pipeline Grants"). Some Pipeline programs, such as Ruth L. Kirschstein National Research Service Awards ("Kirschstein-NRSA"), are congressionally mandated. 42 U.S.C. § 288(a)(1)(A). "Institutional training grants" ("T32s") cover the costs of pre- or postdoctoral students, while individual grants—typically classified as F-series ("Fellowship") or K-Series ("Career Development")—provide stipends to researchers at all stages of their career, cover tuition and costs, and fund research expenses. Ex. 26 ¶ 19; Ex. 32 ¶ 6. Programs under which pipeline grants are awarded to fulfill Congress's mandate that NIH diversify the research field include the Initiative for Maximizing Student Development ("IMSD"), Maximizing Opportunities for Scientific and Academic Independent Careers ("MOSAIC"), Institutional Research and Academic Career Development Award ("IRACDA"), Undergraduate Research Training for Student Enhancement ("U-RISE") and Maximizing Access to Research Careers ("MARC"). *See, e.g.*, Ex. 5 at 11.3.3.3; Ex. 27 ¶¶ 17–21; Ex. 23 ¶¶ 33, 50–51; Ex. 42 ¶ 5.

2. Grant Application and Review Process

NIH receives about 50,000 grant applications per year. Ex. 26 ¶ 26. All applications undergo a rigorous peer-review process, as required by statute, regulation and NIH protocols. *See, e.g.,* 42 U.S.C. § 289(a); 42 C.F.R. § 52.5; Ex. 5 at 2.4; Ex. 23; Ex. 26 ¶¶ 26, 38–39.

ICs post Notices of Funding Opportunities ("NOFOs"), which identify the criteria that will be used to assess each application. Ex. 5 at 2.4.1.3; Ex. 26 ¶ 27. Each application is assigned to a "study section," composed of 20–30 independent researchers with the expertise to review and score applications for scientific and technical merit. *Id.* ¶¶ 28–29. Fewer than half the applications proceed to the next stage of review, during which advisory councils of 10–12 scientists make recommendations based on each IC's priorities and portfolio. *Id.* at ¶¶ 29, 31; Ex. 5 at 2.4. Each IC's director makes the final funding decision. 42 U.S.C. § 284(b)(2); Ex. 5 at 2.4.4, Ex. 26 ¶ 32. Upon selection, a successful applicant receives a Notice of Award ("NOA") that specifies, among other things, the amount of the award and its duration. *Id.* Prior to 2025, NIH had three application cycles per year, with preset periods for study section and advisory council meetings and earliest project start dates. Ex. 5 at 11.3.3.2, Ex. 26 ¶ 34.

3. Termination Processes Prior to the Current Purge

Given the scientific rigor with which grants are awarded and the governing HHS regulations, terminations at NIH have historically been rare. *See, e.g.*, Ex. 6; Ex. 26 ¶ 38. In response to noncompliance, "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action." Ex. 5 at 8.5.2; *see also* Ex. 26 ¶ 39. While NIH may immediately terminate a grant for noncompliance, it can do so only in very limited circumstances, where termination is "*necessary*, such as to protect the public health and welfare from the effects of a *serious deficiency*." Ex. 5 at 8.5.2 (emphases added). Even where there are concerns about scientific misconduct, such as the fabrication or plagiarism, NIH still seeks to preserve the results of the research if possible. *Id.* at 4.1.27, Ex. 23 ¶ 40.

II. Defendants' Directives and Funding Purge

A. Defendants Issue Ideological Directives that Forbid Certain Research Topics

Since January 20, 2025, Defendants have abandoned this scientifically rigorous and methodical approach. Shortly after inauguration, President Trump issued Executive Order No. 14151, which instructs the Attorney General and others to "[c]oordinate the termination of all discriminatory programs, including illegal DEI and 'diversity, equity, inclusion, and accessibility' (DEIA) mandates, policies, programs, preferences, and activities in the Federal Government"; Executive Order No. 14168, which directs that "federal funds shall not be used to promote gender ideology"; and Executive Order No. 14173 which requires the Director of the Office of Management and Budget ("OMB") to "[t]erminate all 'diversity,' 'equity,' 'equitable decision-making,' 'equitable deployment of financial assistance, 'advancing equity,' and like mandates, requirements, programs, or activities, as appropriate."

On January 27, 2025, OMB responded with a memorandum directing all federal agencies—including NIH—to "temporarily pause all activities related to obligation or disbursement of all Federal financial assistance, and all other relevant agency activities that may be implicated by," among other things, the above-mentioned executive orders, including "financial assistance for . . . DEI, woke gender ideology, and the green new deal." Ex. 7 at 2.

HHS and NIH issued directives through various documents beginning January 2025 (hereinafter, "the Directives")[2] to curtail NIH support (and terminate billions of dollars of scientific funding) for previously published funding opportunities and previously awarded grants that purportedly "no longer effectuate[] agency priorities."

[2] As reflected in the proposed order, Plaintiffs include in "the Directives" all the directives referred to as the "Challenged Directives" in the related matter, *Massachusetts v. Kennedy*, No. 1:25-cv-10814-BEM (D. Mass.), Dkt. 76-1 at 2, including directives that remain nonpublic and undisclosed. For consistency, Plaintiffs rely on the same terminology for any directive mentioned here. Insofar as recent deposition testimony in another proceeding suggests that NIH-issued directives relied upon boilerplate language provided to NIH officials by HHS, *see* Ex. 8 at 17–33, 66–91, "the Directives" encompasses that boilerplate language. *See also* Ex. 9 at 36–38.

On February 10, 2025, the Acting HHS Secretary issued a "Secretarial Directive on DEI-related Funding," directing agencies to "briefly pause" payments made to grantees "related to DEI and similar programs" and stating that "grants may be terminated in accordance with federal law." Ex. 10 at 1. On February 12, the deputy director of extramural research issued a memorandum stating that NIH was "reevaluating the agency's priorities based on the goals of the new administration," and noting that "[a]dditional details on future funding actions . . . will be provided under a separate memo." Ex. 11 at 1. On February 13, the deputy director issued a memorandum announcing "hard funding restrictions" on "awards where the program promotes or takes part in diversity, equity, and includsion [sic] ('DEI') initiatives," and stating that, "[i]f the sole purpose of the grant . . . supports DEI activities, then the award must be fully restricted." Ex. 12 at 1.

On March 4, 2025, NIH issued staff guidance (the "Priorities Directives") stating that the agency would "no longer prioritize research and research training programs that focus on Diversity, Equity and Inclusion (DEI) . . . Prior to issuing all awards . . . or approving requests for carryover, ICs must review the specific aims [to] assess whether the proposed project contains any DEI research activities or DEI language that give the perception that NIH funds can be used to support these activities." Ex. 13 at 1.[3] The document includes language directing NIH officials not to issue awards to projects whose "sole purpose . . . is DEI related (e.g., diversity supplements or conference grant where the purpose of the meeting is diversity)" and scripts "provided to NIH by HHS" to use in grant termination notices, including that "NIH is taking this enforcement action in accordance with 2 C.F.R. § 200.340 as implemented in NIH GPS Section 8.5.2." *Id.* at 6.

Specific topics were to be defunded based on the following pre-set rationales:

- DEI: Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing

[3] In their complaint, Plaintiffs alleged that the Priorities Directives were issued "on or around February 28, 2025." *See* Dkt. 1 ¶ 92.

> 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 harm 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.

Id. at 7.[4]

On March 25, 2025, NIH issued updated guidance on grant terminations (the "Revised Priorities Directives"). Ex. 14. This document specifies NIH officials will receive lists of grants that are "HHS Department Authority Terminations" from the "Director, NIH, or designee," and must issue termination letters for these grants. *Id.* at 6. The Revised Priorities Directives repeats much of the Priorities Directives—including reliance on 2 C.F.R. § 200.340 for the agency's authority to terminate the grants (*see* Ex. 13 at 6; Ex. 14 at 7)—but it adds two other categories of topics of research NIH purports to "no longer prioritize" ("Vaccine Hesitancy" and "COVID") to be terminated with boilerplate language for these terminations. Ex. 14 at 9.

The Directives are still evolving. Just four days ago, on April 21, 2025, NIH announced a new term and condition on "new, renewal, supplement, or continuation awards." Ex. 15. The notice threatens termination if grantees promote DEI or "discriminatory equity ideology," or if they engage in a "prohibited boycott." *Id.*

[4] A third forbidden topic was "China," meaning research projects in China or in Chinese universities. *Id.*

B. Defendants Terminate Grants

Beginning on February 28, 2025, NIH issued boilerplate termination notices consistent with the Directives, including to Plaintiffs and Members. Each notice purports to rely on 2 C.F.R. § 200.340(a)(2) and repeats the template language of the Directives. The following are examples:

- "This award no longer effectuates agency priorities. 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. 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."[5]

- "This award no longer effectuates agency priorities. 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."[6]

The notices offer no explanation of how the agency reached its decision, no analysis of any data, and no individualized discussion of grants.[7] And as with the Directives, the notices fail to define critical terms including "diversity, equity, and inclusion" or "DEI"; "artificial and non-

[5] *See, e.g.*, Ex. 22 ¶ 12; Ex. 23 ¶¶ 17, 47; Ex. 24 ¶¶ 11, 20 (at Ex. C), 34 (at Ex. F); Ex. 30 ¶ 18; Ex. 31 ¶ 18; Ex. 34 ¶ 18.

[6] *See, e.g.*, Ex. 23 ¶ 34; Ex. 28 ¶ 16; Ex. 29 ¶ 23 (at Ex. E) (stating that "so-called diversity, equity, and inclusion ('DEI') studies are often used to support unlawful discrimination . . . which harms the health of Americans."); Ex. 32 ¶ 15 (at Ex. C) (same); Ex. 33 ¶ 18 (at Ex. C).

[7] *See, e.g.*, Ex. 20 ¶¶ 20 (at Ex. C), 34 (at Ex. F), 39 ("[E]ach of these termination notices failed to offer any individualized explanation of why the grant was cancelled and failed to discuss any of the data or analysis from our application, any annual progress report, or other related material."); Ex. 24 ¶ 13; Ex. 29 ¶ 23 (at Ex. E) (using stock language about "research programs based primarily on artificial and non-scientific categories . . ." to justify termination of a grant funding an online resource hub); Ex. 32 ¶ 15 (at Ex. C) (using stock language about "research programs based primarily on artificial and non-scientific categories . . ." to justify termination of a training grant); Ex. 33 ¶ 18 (at Ex. C). Several Plaintiffs and Members received revised NOAs that included substantially similar statements justifying the termination. *See* Ex. 19 ¶¶ 16–19 (at Ex. D), 31–32 (at Ex. F); Ex. 20 ¶¶ 21 (at Ex. D), 35 (at Ex. G), 38; Ex. 24 ¶ 11 (at Ex. D); Ex. 28 ¶ 17 (at Exs. E, F); Ex. 29 ¶ 28 (at Ex. F); Ex. 30 ¶ 16 (at Ex. D); Ex. 31 ¶¶ 16, 18 (at Ex. C); Ex. 32 ¶ 16 (at Ex. D); Ex. 33 ¶ 18 (at Ex. D).

scientific categories"; "amorphous equity objectives"; "[t]ransgender issues"; "gender identity"; or "COVID-related." Each notice then includes the following (or something substantially similar):

> Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision," no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.[8]

After stating no corrective action is possible, confusingly, each notice outlines an appeals process.[9]

Defendants have also sent termination notices or orders to stop work en masse to grantees for various pipeline programs such as MOSAIC, IMSD, IRCADA, U-RISE and MARC—all programs that seek to address the underrepresentation of certain groups in the biomedical fields—notifying them that the entire programs have been terminated prior to the project end dates.[10] This has interrupted all ongoing grant work and means that grantees will no longer be able to obtain non-competitive renewals in subsequent budget periods.[11] The notices provide no explanation for the terminations other than "changes in NIH/HHS priorities."[12] No new priorities are listed, nor is any explanation given of how the individual grant does not align with those unspoken priorities.[13]

C. Defendants Delay and Suspend Grant-Awarding Processes

Defendants have withdrawn NOFOs for pipeline programs that seek to address diversity and underrepresentation years ahead of scheduled end dates. For pending applications, Defendants

[8] *See, e.g.*, Ex. 34 ¶ 18.
[9] *See, e.g.,* Ex. 19 (at Exs. C, G, K); Ex. 20 ¶ 46 (at Exs. C, D); Ex. 24 ¶ 18 (at Ex. D); Ex. 28 ¶ 21 (at Ex. D); Ex. 30 (at Ex. C); Ex. 34 ¶ 38 (at Ex. B); Ex. 37 ¶ 19 (at Exs. C, F).
[10] *See, e.g.*, Ex. 36 ¶ 10 (at Ex. C); Ex. 38 ¶ 10 (at Ex. D); *see also* Ex. 23 ¶¶ 42–43 (describing how the MARC program has been terminated); Ex. 25 ¶ 10a–b; Ex. 27 ¶ 15; Ex. 35 ¶¶ 7, 11, 14, 19); Ex. 39 ¶¶ 11, 16; Ex. 42 ¶ 12 (at Ex. F) (describing how the IMSD program has been terminated).
[11] *See, e.g.*, Ex. 25 ¶ 10b; Ex. 35 ¶¶ 11, 14, 19; Ex. 36 ¶ 13; Ex. 38 ¶¶ 10–12.
[12] *See, e.g.*, Ex. 23 ¶¶ 43, 53; Ex. 25 ¶¶ 13–14; Ex. 35 ¶¶ 14–16; Ex. 36 ¶ 10 (at Ex. C); Ex. 38 ¶ 10 (at Ex. D); Ex. 39 ¶ 16; Ex. 42 ¶ 12.
[13] *See, e.g.*, Ex. 23 ¶¶ 43, 53; Ex. 25 ¶ 13; Ex. 35 ¶¶ 15–16; Ex. 36 ¶ 10 (at Ex. C); Ex. 38 ¶ 10 (at Ex. D); Ex. 39 ¶ 16; Ex. 42 ¶ 12.

have withheld decisions, removed submitted applications from study sections or withheld NOAs on previously approved submissions.[14] Defendants also suspended for some weeks the regularly scheduled study section and Advisory Committee meetings required to approve grant applications prior to funding. Ex. 26 ¶¶ 5; 33. Because NIH will not accept duplicate or highly overlapping applications under review at the same time, *see* Ex. 5 at 2.3.7.4, applicants for whom NIH has suspended review may be unable to pursue other funding opportunities for the same proposal. Despite largely similar appropriations to NIH in 2025 from prior years, *see supra*, Background Section I, NIH has significantly reduced funding new grants, including an approximately 69% reduction in the number of new awards from February to mid-March as compared to the same period in the prior year. Ex. 26 ¶ 9.

III. The Directives and Terminations Cause Profound Harm

Between February 28 and April 18, 2025, NIH terminated at least 755 grants. Ex. 27 ¶ 11. The total budget allocated across these grants was approximately $3.0 billion. *Id.* ¶ 15. Approximately $1.4 billion has already been spent, leaving an estimated $1.6 billion in unspent value. *Id.* Terminated projects span a range 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. *Id.* ¶ 13. These figures also include Pipeline Grants to support, train, and recruit scientists. *Id.* at ¶ 12 (Ex. A) (listing terminated grants included Pipeline Grants like FIRST, MARC, and U-RISE); *id.* ¶¶ 18-19, 22-25. Such grants have been terminated across the board, and future opportunities have disappeared from NIH's website. *Id.* ¶ 23.

[14] *See, e.g.*, Ex. 21 ¶¶ 9–14; Ex. 37 ¶¶ 11, 15.

Plaintiffs' and Members' grants were among Defendants' purge.[15] The termination of Project-based Grants has resulted in stalled, diminished, or ruined studies; staff jobs have been cut; and future contributions to public health are now limited or eviscerated. *See infra*, Argument Section IV. The terminations of Pipeline Grants have cut funding and programming for Plaintiffs and Members that is foundational for early scientific careers. *See id.* Plaintiffs and Members waiting on stalled applications are in limbo, with no idea how to recalibrate their career plans.

ARGUMENT

I. Legal Standard

To issue a preliminary injunction, "[t]he district court must consider the 'movant's likelihood of success on the merits; whether and to what extent the movant will suffer irreparable harm in the absence of preliminary injunctive relief; the balance of relative hardships [and equities]; and the effect, if any, that either a preliminary injunction or the absence of one will have on the public interest.'" *U.S. Ghost Adventures, LLC v. Miss Lizzie's Coffee LLC*, 121 F.4th 339, 347 (1st Cir. 2024) (citation omitted). When the government opposes the injunction, the final two factors merge. *Nken v. Holder*, 556 U.S. 418, 435–36 (2009).

II. Jurisdiction

A. Plaintiffs Have Standing.

To establish standing, "a plaintiff must show (i) an injury in fact that is concrete, particularized, and actual or imminent; (ii) likely caused by the defendant; and (iii) likely be redressed by judicial relief." *TransUnion LLC v. Ramirez*, 594 U.S. 413, 423 (2021) (cleaned up). "[L]os[ing] out on federal funds . . . is a sufficiently concrete and imminent injury to satisfy Article

[15] *See, e.g.*, Ex. 19 ¶ 6; Ex. 20 ¶¶ 8–10, 24–25, 38; Ex. 23 ¶¶ 43, 53; Ex. 25 ¶ 5 (UAW represents 75,000 workers who rely on funding from NIH), *id.* at ¶¶ 6, 10 (detailing disruption to members' careers), *id.* at ¶¶ 11, 13; Ex. 28 ¶ 15; Ex. 29 ¶ 23; Ex. 30 ¶ 9; Ex. 31 ¶ 8; Ex. 32 ¶ 15; Ex. 33 ¶¶ 10, 17, 27; Ex. 34 ¶ 17; Ex. 35 ¶ 14; Ex. 36 ¶ 10; Ex. 38 ¶ 10; Ex. 39 ¶ 16; Ex. 42 ¶ 12.

III." *Dep't of Com. v. New York*, 588 U.S. 752, 767 (2019); *Union of Concerned Scientists v. Wheeler*, 377 F. Supp. 3d 34, 41–42 (D. Mass. 2019) ("[i]t is clear that" co-investigator on EPA research grant forced to give up role as result of EPA directive "has standing to assert her claims"), *rev'd in part on other grounds by Union of Concerned Scientists v. Wheeler*, 954 F.3d 11 (1st Cir. 2020). An associational plaintiff has "standing to bring suit on behalf of its members when its members would otherwise have standing to sue in their own right, the interests at stake are germane to the organization's purpose, and neither the claim nor the relief requested requires the participation of individual members in the lawsuit." *Friends of the Earth, Inc. v. Laidlaw Env't. Servs. (TOC), Inc.*, 528 U.S. 167, 181 (2000).

The termination of Plaintiffs' and Members' Project-based and Pipeline Grants and stalling of applications give rise to a sufficiently concrete injury. They have lost, and stand to lose, millions of dollars that will severely impact scientific research and cause untold harm. *See infra*, Argument Section IV.

B. The Tucker Act Does Not Deprive This Court of Jurisdiction.

This Court has jurisdiction to hear this case under the APA, which provides that any "person suffering legal wrong because of agency action … is entitled to judicial review thereof" where they are "seeking relief other than money damages." 5 U.S.C. § 702. Where, as here, Plaintiffs seek equitable relief enjoining final agency action, the APA provides for judicial review in district court. *See generally* 5 U.S.C. § 704; *Bowen v. Massachusetts,* 487 U.S. 879 (1988).

Despite this black letter law, in several pending cases, the government has attempted to hide behind the Tucker Act, which confers jurisdiction to the Court of Federal Claims (CFC) over certain claims against the government that seek "liquidated or unliquidated damages in cases not sounding in tort." 28 U.S.C. § 1491 (a)(1). But, as several district courts have recently held in

analogous situations, the Tucker Act presents no bar to this Court's jurisdiction because Plaintiffs seek only equitable and prospective relief—*not* money damages. *See infra.* Note 18.

1. This Court Has Jurisdiction under the "Rights and Remedies" Test.

Generally, the Administrative Procedure Act ("APA") confers jurisdiction on the district courts over suits against administrative agencies, except for limited cases which seek only "money damages" and thus belong in the CFC. *Bowen,* 487 U.S. at 880. The critical inquiry is whether "the essence of an action is in contract[.]'" *Massachusetts v. Nat'l Insts. of Health*, No. 25-CV-10338, 2025 WL 702163, at *5 (D. Mass. Mar. 5, 2025) (quoting *Am. Sci. & Eng'g, Inc. v. Califano*, 571 F.2d 58, 63 (1st Cir. 1978)). Courts look to two factors: (1) the "source of the rights" and (2) the "relief sought." *Massachusetts*, 2025 WL 702163, at *5–6 (adopting the framework set forth in *Megapulse, Inc. v. Lewis*, 672 F.2d 959, 968 (D.C. Cir. 1982)). Here, the default rule applies, as the rights invoked and remedies sought make clear that this is not a contract claim.

a. The Source of Plaintiffs' Rights Is Not a Contract.

The rights Plaintiffs seek to vindicate are not rooted in a contract with the government, but rather in statutory, regulatory, and constitutional law. Counts I to V of the complaint assert that three sets of actions by NIH and HHS—issuance of Directives mandating that grants be terminated in response to an undefined "change in agency priorities," termination of grants, and refusal to consider grant applications—are arbitrary, capricious, and unlawful under the APA. The final two counts allege the Directives and terminations violate the Constitution (Count VI for void for vagueness pursuant to the Fifth Amendment and Count VII for separation of powers).

None of these claims arises from violation of the terms and conditions of any contract with Plaintiffs or Members. Indeed, "Plaintiffs have not requested the Court to examine any contract or grant agreement created between the parties. Rather, they have asked this Court to review and

interpret the governing federal statute and regulations." *Massachusetts*, 2025 WL 702163, at *6; *see also Woonasquatucket River Watershed Council v. United States Dep't of Agric.*, No. 1:25-CV-00097-MSM-PAS, 2025 WL 1116157, at *6 (D.R.I. Apr. 15, 2025), *39–41. Because every claim is rooted in Defendants' unlawful violation of a statute, regulation, or the U.S. Constitution, "the gravamen of Plaintiffs' Complaint[] does not turn on terms of a contract between the parties; it turns on federal [law]." *Massachusetts*, 2025 WL 702163, at *6.

Moreover, NIH grants are *not* contracts. NIH has consistently maintained that grants are a legal instrument distinct from contracts. Ex. 16. And both statutes and regulations compel that position. Congress, in granting Defendants the authority to issue grants out of their appropriated funds, has repeatedly and explicitly differentiated between "grants" and "contracts."[16] HHS regulations governing federal awards make clear that a "grant agreement" is an instrument, distinct from a contract, designed to "carry out a public purpose authorized by a law of the United States . . . and not to acquire property or services for the Federal awarding agency[.]" 45 C.F.R. § 75.2. Given these repeated indications that neither NIH, Congress, nor HHS intended these grants to be contracts or seek a direct benefit in exchange for offering them, the agreements themselves lack the essential characteristics of a contract. *Dep't of Pub. Welfare v. United States,* 48 Fed. Cl. 785, 788–92 (2001) (detailing the elements of a contract necessary for Tucker Act jurisdiction).

b. Plaintiffs Seek Relief That Can Only Be Provided by the Court—the CFC Cannot Provide Adequate Relief.

[16] *See, e.g.,* 42 U.S.C. § 241(a)(3, 7) (separately listing the Secretary's authority to "make grants-in-aid to universities, hospitals, laboratories, and other public or private institutions" from the authority to "enter into contracts"); 42 U.S.C. § 288(b)(2) (differentiating between IC Directors' authority to enter into grants versus contracts); 42 U.S.C. § 289a(a) (distinguishing between "applications made for grants and cooperative agreements" and "applications made for biomedical and behavioral research and development contracts").

The relief sought also confirms this Court's jurisdiction. The APA provides for review in the district courts of a "final agency action for which there is no other adequate remedy in a court." 5 U.S.C. § 704. Plaintiffs seek declaratory and injunctive relief aimed at the unlawfulness of the Directives, terminations, and withholding of standard application review. Without equitable relief setting aside Defendants' actions, scientific research will go unpublished and undiscovered, research participants will be harmed, jobs will be lost, and emerging researchers' careers will be upended. *See infra*, Argument Section IV. The CFC is unable to remedy any of these ongoing injuries. *See Bowen*, 487 U.S. at 905 (holding CFC "does not have the general equitable powers of a district court"); *Katz v. Cisneros,* 16 F.3d 1204, 1209 (Fed. Cir. 1994) (CFC cannot provide "[a]n adjudication of the lawfulness of [an agency's] regulatory interpretation" that "will have future impact on the ongoing relationship between the parties"); *Gonzales & Gonzales Bonds & Ins. Agency, Inc. v. Dep't of Homeland Sec*., 490 F.3d 940 (Fed. Cir. 2007).

Any financial consequences from the relief sought do not transform this into a case for money damages. As the Supreme Court has long recognized, "[t]he fact that a judicial remedy may require one party to pay money to another is not a sufficient reason to characterize the relief as 'money damages.'" *Bowen*, 487 U.S. at 893.[17] Rather, "[t]o the extent that the Court's order 'engenders' the result of payment to [Plaintiffs], 'this outcome is a mere byproduct' of the Court's 'primary function of reviewing the [government's] interpretation of federal law.'" *Woonasquatucket*, 2025 WL 1116157, at *14 (quoting *Bowen*, 487 U.S. at 910). Here, Plaintiffs do not seek financial compensation for injuries suffered but rather seek to preserve their ongoing and prospective relationships with NIH. *See Massachusetts*, 2025 WL 702163, at *7.

[17] *See also Am. Ass'n of Colls. for Tchr. Educ. v. McMahon,* No. 1:25-CV-00702-JRR, 2025 WL 863319. at *3 (D. Md. Mar. 19, 2025) (citation omitted) ("[A] suit which does not seek monetary damages does not arise under the Tucker Act simply because the plaintiff's success will result in eventual monetary gain from the government.").

2. The Supreme Court's *Per Curiam* Order in *Department of Education v. California* Does Not Affect This Court's Jurisdiction.

The above analysis is not changed by the Supreme Court's recent *per curiam* order in *Dep't of Educ. v. California,* which dissolved a temporary restraining order requiring the disbursement of teacher training funds and noted, without deciding the jurisdictional issue, that the Tucker Act "grants the [CFC] jurisdiction over suits based on 'any express or implied contract with the United States.'" *Dep't of Educ. v. California*, 145 S. Ct. 966, 969 (2025). Numerous courts have properly read the narrow nature of this order and concluded that district courts have jurisdiction over cases involving unlawful termination and withholding of grants consistent with longstanding Supreme Court precedent.[18] This Court should do the same. Unlike *Dep't of Educ*., Plaintiffs assert *both* statutory and constitutional claims seeking prospective and equitable relief. Moreover, the Plaintiffs in *Dep't of Educ.* never argued that the grants were not contracts, and the claims here do not rely on the terms and conditions of grant documents. For all these reasons, the Tucker Act does not apply to Plaintiffs' claims.

III. Plaintiffs Have Established a Likelihood of Success on the Merits.

A. Defendants' Directives and Terminations of NIH Grants Violate Separation of Powers Principles [Count VII].

By issuing the Directives and terminating hundreds of NIH grants designed to diversify the biomedical workforce and address health disparities, Defendants have contravened congressional

[18] *See Maine v. United States Dep't of Agric.*, No. 1:25-CV-00131-JAW, 2025 WL 1088946, at *19 n.8 (D. Me. Apr. 11, 2025) (finding that Supreme Court's *per curiam* opinion's "precedential value is … limited" and noting that *Bowen* and its progeny continue to govern); *see also Chi. Women in Trades v. Trump*, No. 25-C-2005, 2025 WL 1114466, *8–10 (N.D. Ill. Apr. 14, 2025) (distinguishing the *per curium* opinion and rejecting Tucker Act argument because claims did not arise out of a contract, claims are not contract claims in essence given constitutional claims, plaintiffs sought exclusively injunctive relief, and CFC could not provide an adequate remedy); *Woonasquatucket*, 2025 WL 1116157, at *14 ("The Government overreads the three-page stay order . . . The Supreme Court's brief treatment of *Bowen* and *Great-West Life* in *California* and the cursory mention of potential jurisdictional issues do not appear to settle all jurisdictional issues here."); *Climate United Fund v. Citibank, N.A*., No. 25-CV-698 (TSC) 2025 WL 1131412, at *11 (D.D.C. Apr. 16, 2025) (finding that "reinstatement of [EPA] grants and recovery of specific money" constitutes equitable relief, and noting that Plaintiffs sought equitable and declaratory relief which CFC cannot grant).

mandates that NIH fund such research, usurping the legislative prerogative in violation of separation of powers principles. The Constitution grants and limits the powers of each branch of the federal government—these "carefully defined limits on the power of each Branch must not be eroded." *Immigr. & Naturalization Serv. v. Chadha*, 462 U.S. 919, 958 (1983). The power of the President, and executive agencies by extension, is thus subject to certain constraints. *In re Aiken Cnty.*, 725 F.3d 255, 259 (D.C. Cir. 2013) (Kavanaugh, J.) "When the President takes measures incompatible with the expressed or implied will of Congress, his power is at its lowest ebb[.]" *Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579, 637 (1952) (Jackson, J. concurring).

The executive branch has a duty to "take care that" enacted laws are "faithfully executed" and "may not decline to follow a statutory mandate . . . simply because of policy objections." U.S. Const. art. II, § 3; *Aiken Cnty.*, 725 F.3d at 259. And "[t]here is no provision in the Constitution that authorizes the President to enact, to amend, or to repeal statutes." *Clinton v. City of New York*, 524 U.S. 417, 438 (1998). Instead, the Executive's role in lawmaking is sharply circumscribed by the Presentment Clause. U.S. Const., art. I, § 7, cl. 2 & cl. 3. Presidents "may initiate and influence legislative proposals," and may veto a bill, *Clinton*, 524 U.S. at 438, but cannot strike or pick and choose among the provisions of a law that they find unappealing. *Id.* at 448–49.

Defendants' Directives and terminations not only fail to faithfully execute explicit congressional mandates—they fundamentally subvert them. The portion of the United States Code governing NIH, 42 U.S.C. Ch. 6A, is replete with language mandating that NIH make efforts to diversify the biomedical workforce. For example, Congress:

- Requires 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).

- Requires 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).[19]

- Mandates 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).

- Requires 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). This includes "increas[ing] opportunities for new researchers to receive funding." *Id.*

Congress has also mandated that NIH fund research into health disparities. For example:

- The purpose of the NIMHD is to "conduct and support . . . research, training, dissemination of information, and other programs with respect to minority health conditions and other populations with health disparities." *Id.* at § 285t(a). To effectuate this mission, the NIMHD director "shall in expending amounts appropriated under this subpart 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).

- The HHS Secretary and 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).

- The NIH Director "shall develop and submit" to Congress a strategic plan that "shall . . . (B) consider . . . (iii) biological, social, and other determinants of health that contribute to health disparities . . ." *id.* at § 282(m)(2), and the NIH Director "shall ensure" funding is "sufficiently allocated for research projects identified in strategic plans[.]" *Id.* at § 282(b)(6).

- 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.

[19] Indeed, NIMHD's strategic plan explicitly sets out goals and research priorities to diversify the medical field. Ex. 16 at 17–31.

Defendants' Directives violate these mandates, unilaterally rewriting laws with which they disagree. The Directives and termination notices explicitly and categorically state that funding related to "amorphous equity objectives," "so-called diversity, equity, and inclusion ('DEI')," or "gender identity" "no longer effectuate[] agency priorities" and that "it is the policy of NIH not to prioritize such research programs."[20] Defendants claim that research into "DEI" or "gender identity" is "often unscientific" and "do[es] nothing to enhance the health of many Americans."[21] They assert that efforts to diversify the workforce "support unlawful discrimination."[22] Defendants have instructed NIH officials to "completely excise all DEI activities," demonstrating a wide-ranging effort to defund anything related to diversifying the biomedical research field and researching health disparities, despite Congress's clear instructions to the contrary. Ex. 13 at 1.

Defendants' across-the-board pipeline terminations similarly disregard Congress's lawmaking power. Kirschstein-NRSA grants *must* support the recruitment of women and people from disadvantaged backgrounds, but NIH has stripped all mention of workforce diversity from newly posted T32 Kirschstein-NRSA funding opportunities, cancelled those Kirschstein-NRSA and other programs designed to increase recruitment of underrepresented groups, and terminated the grants awarded under such programs.[23] These sweeping terminations directly violate Congress's instructions to NIH that it prioritize diversifying the biomedical workforce.

[20] *See, e.g.*, Ex. 19 ¶ 34; Ex. 20 ¶¶ 20, 34; Ex. 22 ¶ 12; Ex. 28 ¶ 16; Ex. 29 ¶ 23; Ex. 30 ¶ 18; Ex. 32 ¶ 15; Ex. 33 ¶ 18 (at Ex. E); Ex. 34 ¶ 17.
[21] *See, e.g.*, Ex. 19 ¶ 47; Ex. 20 ¶¶ 20, 34; Ex. 29 ¶ 23; Ex. 30 ¶ 18; Ex. 31 ¶ 18; Ex. 32 ¶ 15; Ex. 33 ¶ 18 (at Ex. E); Ex. 34 ¶ 18.
[22] *See, e.g.*, Ex. 29 ¶ 23; Ex. 32 ¶ 15; Ex. 33 ¶ 18 (at Ex. E).
[23] *See, e.g.*, Ex. 23 ¶¶ 31–56; Ex. 27 ¶¶ 17–25 (describing termination of eight separate programs designed to diversify the biomedical research field); Ex. 35 ¶¶ 14–16; Ex. 36 ¶ 10 (termination of MOSAIC); Ex. 38 ¶ 10 (termination of IRACDA); Ex. 39 ¶¶ 6–7; Ex. 40 ¶ 10–17 (inferring cancellation of F31 diversity program given notice in November 2024 that his application would be funded but, as of this filing, still no word and funding); Ex. 42 ¶¶ 9, 12 (termination of IMSD); *see also supra*, Background Section II.B.

NIH has also eliminated research that fulfills unequivocal congressional requirements to address health disparities, including a five-year grant to study reasons why Black women in the United States have higher rates of infertility than white women, a grant testing implications of a reduction in the income gap on the health and wellness of older African American men, grants that studied the harmful effects of societal or systemic stressors, and the health-protective effects of social support, education, and school-based mental health interventions, and many other disparity related studies.[24]

Defendants' failure to uphold their constitutional responsibility to take care that these laws are faithfully executed and their brazen attempt to strike the portions of the law with which they disagree violate separation of powers principles and must be enjoined.

B. Plaintiffs Are Likely to Succeed on Their APA Claims.

1. The Directives and Terminations Constitute Final Agency Actions.

Under the APA, final agency actions: (1) "mark the consummation of the agency's decision making process"; and (2) are those "by which rights or obligations have been determined, or from which legal consequences will flow." *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997). Such actions are sufficiently discrete to permit review if they have "an actual or immediately threatened effect." *Greater Bos. Legal Servs. v. United States Dep't of Homeland Sec.*, No. 21-CV-10083-DJC, 2023 WL 2540892 *2 (D. Mass. Mar. 16, 2023) (citations omitted); *see also Biden v. Texas*, 597 U.S. 785, 808–09 (2022) (holding agency memoranda were final agency action, noting they "bound" agency staff by preventing them from continuing certain programs).

Here, the Directives meet both prongs by (1) articulating NIH's settled position to not fund research on certain topics and (2) resulting in direct legal consequences. *See Bennett*, 520 U.S. at

[24] *See, e.g.*, Ex. 19 ¶ 8; Ex. 20 ¶¶ 9–11, 24–27, 38; Ex. 22 ¶ 7; Ex. 28, ¶¶ 8 & 15; Ex. 24 ¶¶ 3–5; Ex. 27 ¶¶ 13, 14, 16, Ex. A; Ex. 30 ¶ 11; Ex. 31 ¶ 9; Ex. 33 ¶¶ 11–12, 27; Ex. 34 ¶¶ 11–12; Ex. 37 ¶¶ 10–12, 20; Ex. 41 ¶¶ 8–9, 17.

177–78. For example, the Priorities Directive reflects NIH's decision to "no longer prioritize research and research training programs that focus on [DEI]," describes grants that "must" be terminated, and gives mandatory instructions for implementation. Ex. 13 at 1. This had an obvious "actual or immediately threatened effect"—hundreds of grants, affecting billions of research dollars, have been terminated (and will continue to be terminated absent injunctive relief). As discrete, final agency actions, the Directives are therefore reviewable under the APA. *See New York v. Trump,* 133 F.4th 51 (1st Cir. 2025) (holding that implementation of "categorical funding freezes" constitutes "discrete final agency action"); *Woonasquatucket*, 2025 WL 1116157, at *15 (same for agency guidance that paused funding). Likewise, the terminations also announce the agency's decision to end each award or program, *Bennett*, 520 U.S. at 177, and have clear legal consequences, including immediate loss of funding. *See Massachusetts*, 2025 WL 702163, at *15.

And neither the Directives nor terminations are part of the "narrow[]" class of agency actions committed to agency discretion, and thus unreviewable in federal court. *Dep't of Com. v. New York*, 588 U.S. at 772; *see also* 5 U.S.C. § 701(a)(2). Because "meaningful standard[s]" in statute and regulation cabin agency discretion here, *see supra*, Argument Section III.A and *infra*, Argument Sections III.B.3 and III.D, the actions are reviewable. *Dep't of Com.*, 588 U.S. at 772; *see also Lincoln v. Vigil*, 508 U.S. 182, 193 (1993) ("[A]n agency is not free simply to disregard statutory responsibilities[.]"). Indeed, Defendants' claim to have acted in line with federal regulation—specifically, 2 C.F.R. § 200.340—is itself subject to review under the APA.

2. Defendants' Directives and Terminations Are Arbitrary and Capricious [Count I].

An agency's action is arbitrary and capricious under 5 U.S.C. § 706 (2)(A) if it "relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence

before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). Courts must ensure "that agency decisions are founded on a reasoned evaluation of the relevant factors" by "carefully reviewing the record and satisfying itself that the agency has made a reasoned decision." *Massachusetts*, 2025 WL 702163, at *16 (quotation omitted). Defendants' actions do not meet this standard.

First, the Directives and terminations fail to provide adequate reasoning. Agencies must offer "genuine justification for important decisions, reasons that can be scrutinized by courts and the interested public." *Dep't of Com.*, 588 U.S. at 785 (2019). Defendants' boilerplate statements that certain grants "no longer effectuate[] agency priorities," fall short because they "fail to provide basic notice by omitting any specificity about the reason that [NIH] found any individual grant 'inconsistent with . . . [its] priorities.'" *Am. Ass'n of Colls. for Teacher Educ.,* 2025 WL 833917, at *21.

Defendants' failure to include *any* data analysis is also damning. To support its decisions, an "agency must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choices made." *State Farm*, 463 U.S. at 43 (cleaned up); *see also Am. Ass'n of Colls. for Teacher Educ.*, 2025 WL 833917, at *21 (use of boilerplate corroborates that agency has failed to "consider individual, or any, data or information," in violation of APA). The Directives and terminations cite no project-specific information or data to explain why each project no longer "effectuates agency priorities." This is especially egregious in light of the yearslong efforts by Plaintiffs and Members to apply for, refine,

implement, and report on their projects.[25] Moreover, the boilerplate language across the Directives and termination letters asserting that the projects, including research into serious health concerns like breast cancer, Alzheimer's Disease, and smoking cessation, lack "scientific validity," "rigor," or "public health benefit" directly contradict the reasoned previous conclusions of NIH and external scientists who reviewed and approved the projects through a rigorous process, and make no attempt to acknowledge—much less grapple with—this obvious inconsistency.[26] Ex. 26 ¶ 5.

Second, Defendants failed to articulate or explain any supposed changes in their policies and priorities. When an agency changes a policy or practice, it "is obligated to supply a reasoned analysis for the change." *Ark Initiative v. Tidwell*, 816 F.3d 119, 127–28 (D.C. Cir. 2016) (quoting *State Farm*, 463 U.S. at 42). Indeed, 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." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009).

[25] *See, e.g.*, Ex. 2 ¶¶ 8, 19; Ex. 19 ¶ 12 (noting that time-sensitive research was "an intense and compressed process" for which Charlton set aside personal milestones); Ex. 20 ¶¶ 13–16, 29, 32, 39; Ex. 23 ¶ 36; Ex. 28 ¶ 12 ("the project was the result of four years of intensive effort"); Ex. 29 ¶ 13 ("During the final weeks [of assembling the application], I worked 196 hours over 11 days."); Ex. 30 ¶ 14 ("The application for this grant was the culmination of over a decade of research."); Ex. 31 ¶ 6 (noting that application process for each grant "often require[es] months or even years of preparation"); Ex. 32 ¶ 11 ("It is not an exaggeration to say that I spent thousands of hours working on the application . . . I spent about a 6-month period intensively writing the application, and in the end the application package was over 550 pages"); Ex. 33 ¶¶ 15–16; Ex. 34 ¶ 15 ("I have spent countless hours over six years developing this project. . . . I applied at least five times before my application was granted. Each time the application was sent back, I worked to incorporate feedback from NIH"); Ex. 35 ¶ 10; Ex. 37 ¶ 17; Ex. 39 ¶ 10; Ex. 40 ¶ 9; Ex. 41 ¶ 7.

[26] *See, e.g.*, Ex. 19 ¶ 23 (noting that reviewers scored grant in top seventh percentile); Ex. 20 ¶¶ 12–15, 28–30; Ex. 21 ¶ 14 (explaining that a study section member shared that Maphis's MOSAIC proposal was "highly regarded" and that "everyone was upset" when it was removed from consideration); Ex. 23 ¶ 39 ("Most applicants need to revise their entire application, which would include updating all tables and data presented, collecting new biosketches, and addressing any concerns raised in a completely new ~500-page application which would then be submitted for a subsequent round of the same rigorous review process"); Ex. 30 ¶ 14 (noting that grant scored in the first percentile); Ex. 32 ¶ 11 (describing how the proposal was revised after study section proffered constructive criticism on the program plan); Ex. 37 ¶¶ 12, 19 (explaining "perfect score" on MOSAIC proposal); Ex. 38 ¶ 15 ("Over the following years, I submitted several versions of the application to NIH and refined the application in response to NIH reviews to highlight the public health significance of studying HIV and aging[.]"); Ex. 40 ¶¶ 5, 7, 10, 12 (explaining notice he received that his F31 diversity proposal would be funded); Ex. 41 ¶ 7.

The Directives and termination notices do not clearly explain any departure from existing priorities—a fact made "even more egregious in light of the drastic change" from the existing policies under which the awards had been authorized. *Massachusetts*, 2025 WL 702163, at *18. The Directives and terminations run afoul of the priorities required by statute and NIH and IC strategic plans—all of which continue to bind the agency. This represents precisely the type of "inscrutable reasoning" that is "facially irrational." *Marasco & Nesselbush, LLP v. Collins*, 6 F. 4th 150, 173 (1st Cir. 2021).

Moreover, Defendants' purported change in priorities appears to be driven, at least in part, by actors outside of NIH in the so-called Department of Government Efficiency ("DOGE"). A reported analysis of metadata from NIH termination notices suggests that a DOGE employee authored the letter. Ex. 17 at 2. NIH staff have also described DOGE involvement in the terminations. Ex. 8 at 30-32; Ex. 9 at 36. It defies logic that NIH's rigorous decision-making process, including its two-step, highly standardized peer-review, can be undone by an outside actor who has no role in the agency's statutorily-defined processes.

Third, the Directives and terminations recklessly ignore "serious reliance interests that must be taken into account," *Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 591 U.S. 1, 30 (2020) and consequently unleash devastating consequences on Plaintiffs and Members, their research, study participants, and the populations that would benefit from the research findings. NIH is "not writing on a blank slate"—it must "assess whether there are reliance interests, determine whether they [are] significant, and weigh any such interests against competing policy concerns." *Massachusetts*, 2025 WL 702163, at *19 (quoting *Regents*, 591 U.S. 1, 33 (2020)).

Instead, NIH slashed grants with shocking disregard for the enormous impact of those actions. These terminations callously ignore the budgets that funded the staff on these projects,

"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." *Massachusetts*, 2025 WL 702163, at *20 (issuing preliminary injunction regarding NIH's rate change notice). The Directives and terminations contain no evidence that Defendants weighed any—much less all—of these interests against their purported changes in policy. *See id.* at *38 (quoting *Regents*, 591 U.S. at 33 (cleaned up)).

Fourth, and finally, in issuing and implementing the Directives and terminations, Defendants have acted "arbitrarily and capriciously" by "act[ing] in a manner that is contrary to [the agency's] own regulations or a congressional statute," for the reasons discussed below in Argument Section III.B.3. *Pol'y & Rsch., LLC v. United States Dep't of Health & Human Servs.*, 313 F. Supp. 3d 62, 72 (D.D.C. 2018).

3. Defendants' Directives and Terminations Are Contrary to Law Because They Violate Congress's Mandates and the HHS Regulations. [Counts II and III].

The Directives and terminations are "not in accordance with law" and are "in excess of statutory jurisdiction, authority, or limitations." 5 U.S.C. § 706(2)(A), (C). As discussed above, Defendants' actions run directly counter to both congressional mandates and the priorities detailed in NIH and IC strategic plans to address health disparities and the underrepresentation of certain groups in the biomedical field. *See supra*, Argument Section III.A. They thus not only violate separation of powers principles but are also contrary to law and beyond Defendants' statutory authority. *See, e.g.*, *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 125 (2000) ("an administrative agency . . . may not exercise its authority 'in a manner inconsistent with the administrative structure Congress enacted into law.'") (internal citation omitted).

Defendants' actions are also contrary to law because HHS regulations do not authorize Defendants to terminate grants based on an assertion that the "award no longer effectuates agency priorities." *See, e.g.*, Ex. 13. HHS regulations allow NIH to unilaterally terminate a grant only if the grantee "fails to comply with the terms and conditions of the award" or "for cause," 45 C.F.R. § 75.372(a) (2024), and neither the Directives nor the termination letters rely on either of these grounds. *See supra*, Background Section II.A and II.B. These regulations also apply to termination of multi-year grants before their project end dates. *Pol'y & Rsch., LLC*, 313 F. Supp. 3d at 84.

As authority for terminating grants, Defendants erroneously rely on OMB's Guidance for Federal Financial Assistance at 2 C.F.R. § 200 (OMB Uniform Guidance)—and specifically 2 C.F.R. § 200.340, which since 2020 has included provisions allowing for termination under certain circumstances where "an award no longer effectuates the program goals or agency priorities."[27] But the OMB Uniform Guidance applies to a grantmaking agency only if the agency implements the guidance in its regulations and only in the form that the agency adopts. 2 C.F.R. § 1.105 (c) (2024) ("[T]he OMB guidance is not regulatory. Federal agency regulations . . . may give regulatory effect to the OMB guidance, to the extent that the agency regulations require compliance with all or portions of the OMB guidance.").

Critically, the provision of the OMB Uniform Guidance on which Defendants rely is *not* currently in effect for HHS. In 2014, HHS adopted the original version of 2 C.F.R. § 200.340, which—like HHS's governing regulations today—allowed for NIH to unilaterally terminate grants only where grantees violate an award's terms and conditions or for cause. *See* 78 Fed. Reg. 78590

[27] The 2020 version of the OMB Uniform Guidance allowed for unilateral termination "to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities." See 2 C.F.R. § 200.340(a)(2) (2020); 85 Fed. Reg. 49506 at 49559 (Aug. 13, 2020). In 2024, OMB renumbered the provision and revised it to allow for unilateral termination "pursuant to the terms and conditions of the Federal award, including, to the extent authorized by law, if an award no longer effectuates the program goals or agency priorities." 2 C.F.R. § 200.340(a)(4).

(Dec. 26, 2013); 79 Fed. Reg. 75871 (Dec. 19, 2014). Although OMB subsequently revised 2 C.F.R. § 200.340 to allow for termination where "an award no longer effectuates the program goals or agency priorities," *HHS declined to adopt that language*, even when it subsequently adopted other revisions to its grant regulations,[28] and to this day HHS regulations do not give it the authority to terminate grants on that basis. HHS published an interim final rule in October 2024 that will bring HHS regulations into near total conformity with the OMB Uniform Guidance, including with 2 C.F.R. § 200.340, but that change is not effective *until October 1, 2025*. 89 Fed. Reg. 80,055, 80,056 (Oct. 10, 2024).

The Directives erroneously instruct NIH to inform grantees whose awards are being terminated that "NIH is taking this enforcement action in accordance with 2 C.F.R. § 200.340 as implemented in NIH [Grants Policy Statement] Section 8.5.2." Ex. 13 at 6. But Section 8.5.2 of the Grants Policy Statement currently only incorporates the 2 C.F.R. § 200.340 procedures for termination "if a recipient has failed to comply with the terms and conditions of award" Ex. 5 at 8.5.2. This is because the NIH Grants Policy Statement is "intended to be compliant with governing statutes and the requirements of 2 C.F.R. § 200, as modified by previously approved waivers and deviations;" and "in the case of a conflict, the statutes and regulations govern." Ex. 5 at 3. The NIH Grants Policy Statement did not adopt OMB's revisions to 2 C.F.R. § 200 allowing termination "if an award no longer effectuates the program goals or agency priorities" until HHS's October 2024 rulemaking, and as noted, that change will not be effective until October 2025.

The Directives' instruction to terminate NIH grants based on 2 C.F.R. § 200.340 because they "no longer effectuate[] agency priorities," and the termination letters' reliance on that basis,

[28] HHS revised its regulations in 2016 and retained the three limited conditions for termination in 45 C.F.R. § 75.372. *See* Federal Awarding Agency Regulatory Implementation of Office of Management and Budget's Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards; Technical Amendments, 81 Fed. Reg. 3004 (Jan. 20, 2016).

is therefore contrary to binding HHS regulations. 5 U.S.C. § 706(2)(A); *see also Massachusetts*, 2025 WL 702163, at *19 (issuing preliminary injunction against NIH where it issued policy directly conflicting with the language of HHS regulations, "disregarding an existing regulation and regulatory structure) (citing *FCC*, 556 U.S. at 515 (2009) ("An agency may not . . . simply disregard rules that are still on the books.")); *Pol'y. & Rsch., LLC*, 313 F. Supp. 3d at 72.

4. Defendants' Directives and Terminations Are Contrary to Constitutional Right [Count IV].

The Directives and terminations are "contrary to constitutional right, power, privilege, or immunity." 5 U.S.C. § 706(2)(B). When final agency action is contrary to constitutional rights, the APA requires it be "set aside." *Bos. All. of Gay, Lesbian, Bisexual & Transgender Youth v. HHS*, 557 F. Supp. 3d 224, 243 (D. Mass. 2021) (citing 5 U.S.C. § 706(2)(B)). For reasons explained above in Argument Section III.A and below in Argument Section III.C, Defendants' actions violate separation of powers principles and the Due Process Clause—and thus violate the APA.

C. The Directives and Terminations Are Unconstitutionally Vague [Count VI].

The Directives are void for vagueness. "It is a basic principle of due process that an enactment is void for vagueness if its prohibitions are not clearly defined." *Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972). A law or policy is unconstitutionally vague if it (1) "fails to give a person of ordinary intelligence fair notice that his contemplated conduct is forbidden" or (2) "encourages arbitrary and discriminatory enforcement." *Papachristou v. Jacksonville*, 405 U.S. 156, 162 (1972). This doctrine applies to administrative policies and federal agency guidelines. *Fed'l Commc'ns Comm'n v. Fox Television Stations, Inc.*, 567 U.S. 239, 254 (2012) (holding that the FCC's indecency policy invited arbitrary enforcement).

Here, the "prohibitions" in the Directives "are not clearly defined," encouraging arbitrary enforcement by Defendants. *See Fox Television Stations*, 567 U.S. at 253. "[P]recision and

guidance are necessary so that those enforcing the law do not act in an arbitrary or discriminatory way." *Id.* Defendants fail to define any of the research areas or topics that purportedly "no longer effectuate[] agency priorities" in the Directives or termination notices, forbidding research using undefined terms such as "Diversity, Equity, and Inclusion" or "DEI"; "amorphous equity objectives," "Transgender issues," "gender identity," and "COVID-related research." *See supra*, Background Sections II.A and II.B.

Indeed, individuals working at NIH when the Directives went into effect have themselves explicitly noted the inherent vagueness of the Directives and termination notices. When asked about the boilerplate paragraphs in the termination notices that explained the basis of grant terminations, Liza Bundesen, the acting director of NIH's Office of Extramural Research between February 14 and March 7, 2025, *see,* Ex. 9 at 27:19–28:4, repeatedly stated that she found their operative language to be "vague" and that she did not "know what they mean" *see Id.* at 61:21-62:12. For example, when asked whether the statement "Research programs based on gender identity are often unscientific" is true, Ms. Bundeson responded, "I don't know. It's a – it's a vague phrase." *Id.* at 42:6–17; 46:8–14 ("this is a very vague statement"). When asked if she agreed with the statement, "Research programs based on gender identity do nothing to enhance the health of many Americans," she responded, "In my opinion, that's a very vague statement[.]" *Id.* at 48:9–17. And when asked about the statement that "many such studies ignore, rather than seriously examine, biological realities," she responded, "I don't understand the basis of the sentence. It's unclear to me." *Id.* at 49:16–24. As NIH officials themselves cannot explain the contours of these forbidden topics, the Directives "encourage[] arbitrary and discriminatory enforcement." *See Papachristou*, 405 U.S. at 162.

The Directives and terminations also fail to provide "fair notice" of what is prohibited. *See Fox Television Stations*, 567 U.S. at 254. There is no way for Plaintiffs and Members to know why or how their individual projects "fail[] to effectuate[] agency priorities."[29] This lack of notice limits Plaintiffs' and Members' ability to meaningfully address Defendants' concerns about their projects in their appeals, or—to the extent necessary—revise their projects to align with any purported agency priorities.[30] Because the Directives and terminations have not allowed Plaintiffs and Members to "know what is required of them so they may act accordingly," they must be enjoined. *See Fox Television Stations*, 567 U.S. at 253.

D. Defendants Are Violating Plaintiffs' Rights under the APA and Constitution by Suspending or Delaying the Grant Application Process [All Counts].

Plaintiffs are also likely to succeed on the merits of their claims pertaining to Defendants' failure to review and decide Plaintiffs' grant applications. First, as explained above, Defendants are implementing the Directives by systemically suspending normal review processes for applications for pipeline grants. *See supra*, Background Section II.C These actions contravene congressional mandates to diversify the biomedical workforce—and thus violate separation of powers. *See supra*, Argument Section III.A.

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[29] *See, e.g.*, Ex. 29 ¶ 25 ("[I]t is unclear to me what criteria NIH used to determine that the Coordinating Center 'no longer effectuates agency priorities.'"); Ex. 19 ¶ 18; Ex. 20 ¶¶ 22, 36, 39, 45–46; Ex. 21 ¶ 12 (explaining that NIH told her she will not receive comments on her MOSAIC application because "all review related data was deleted from the system[.]"); Ex. 27 ¶ 20; Ex. 28 ¶ 18; Ex. 30 ¶ 19; Ex. 31 ¶ 19; Ex. 33 ¶¶ 20, 26, 27; Ex. 34 ¶ 20; Ex. 35 ¶¶ 14–16; Ex. 37 ¶ 20.

[30] *See, e.g.*, Ex. 19 ¶ 59 ("I am actively appealing these terminations, but am at a loss for how to do so."); Ex. 20 ¶¶ 39 ("I am uncertain why the projects no longer effectuate agency priorities, how I can revise these projects to align with agency priorities, and how I can align future grant applications with these priorities."), 45–46; Ex. 24 ¶ 13; Ex. 28 ¶ 26 ("I remain uncertain about how to respond to NIH's assessment that my project 'no longer aligns with agency priorities,' especially since I do not understand how my research is considered 'based on DEI'); Ex. 30 ¶ 32 ("I also did not know how to recharacterize my project in my appeal to fit within the asserted new agency priorities because I do not understand the terms used as the basis for the termination."); Ex. 31 ¶ 35 (expressing confusion on "how to recharacterize my project in my appeal . . . because I do not understand the terms used as the basis for termination"); Ex. 32 ¶ 24 ("I have appealed this decision, however I found it very difficult to write the appeal because . . . I wasn't sure how to recharacterize [my project] to fit within the asserted new agency priorities"); Ex. 33 ¶¶ 20, 26 ("I also do not understand why the grant was terminated, and I had no idea how to address any agency concerns or recharacterize or revise my project for the purposes of appeal, especially in light of the lack of information provided by NIH"), 27, 28; Ex. 34 ¶ 37.

Second, Defendants' failure to review and decide grant applications pursuant to NIH's standard processes also violates the APA. This failure to act is itself reviewable final agency action, because it has the same impact on Plaintiffs' and Members' rights as would an express application denial. *See Hi-Tech Pharmacal Co. v. U.S. Food & Drug Admin.*, 587 F. Supp. 2d 1, 10 (D.D.C. 2008) (allowing judicial review of an agency's failure to act under § 706(2)).

Defendants' failure to review Plaintiffs' and Members' grant applications violates § 706(2) under the same arbitrary and capricious analysis set forth in Argument Section III.B.2 above. Defendants' actions are contrary to constitutional right, *see supra*, Argument Section III.B.4, and statutes and regulations governing NIH's process of scientific review of applications. *See, e.g.*, 42 U.S.C. §§ 289a (requiring peer review of grant applications); §284a(e) (requiring that advisory councils meet at least three times each fiscal year); 42 C.F.R. §§ 52h.7 (requiring peer review of applications); 52.5 (requiring evaluation and disposition of all applications).

Defendants have also violated 5 U.S.C. §§ 706(1) and 555 (b) because they have unlawfully withheld or unreasonably delayed consideration of Plaintiffs' grant applications. To prevail under § 706(1), Plaintiffs must show that (1) the action in question is "a discrete agency action that it is required to take," and (2) the agency failed to take, or unreasonably delayed in taking, that action. *Norton v. S. Utah Wilderness All.*, 542 U.S. 55, 64 (2004).

Both are satisfied here. First, NIH is required by law and regulation to evaluate all applications through its standard scientific review process, including study-section and advisory-council review, and issue decisions on applications—discrete agency actions it is refusing to take. *See* Ex. 26 ¶ 5.

Second, to decide if an agency has unreasonably delayed a discrete and required action, courts look to the "*TRAC* factors," including whether the agency's timeline is governed by a "rule

of reason" and whether human health and welfare are at stake. *Town of Wellesley v. FERC*, 829 F.2d 275, 277 (1st Cir. 1987) (applying *Telecomms. Rsch. & Action Ctr. v. FCC*, 750 F.2d 70 (D.C. Cir. 1984) (*TRAC*)).[31]

Here, NIH's own published timetables provide a "rule of reason" that NIH has defied. *See Ashtari v. Pompeo*, 496 F. Supp. 3d 462, 470 (D.D.C. 2020) (evaluating rule of reason based in part on internal policy guidance). More fundamentally, "delays that might be reasonable in the sphere of economic regulation are less tolerable when human health and welfare are at stake." *TRAC*, 750 F.2d at 80. Defendants' inaction is jeopardizing public health in the same ways their terminations are, as discussed above and *infra*, and as described in a related lawsuit before this Court. *See Memorandum of Law in Support of Plaintiffs' Motion for a Preliminary Injunction*, ECF No. 78, at 36–38, *Massachusetts v. Kennedy*, 1:25-cv-10814-BEM (D. Mass.) Accordingly, the Court should order NIH to evaluate and decide Plaintiffs' and Members' applications pursuant to the standard NIH review process.

IV. Plaintiffs Will Be Irreparably Harmed Absent a Preliminary Injunction.

Plaintiffs and Members are "likely to suffer irreparable harm in the absence of preliminary relief." *Voice of the Arab World, Inc. v. MDTV Med. News Now, Inc.*, 645 F.3d 26, 32 (1st Cir. 2011) (quoting *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008)). Without reinstatement of terminated grant funding, many Plaintiffs and Members will be unable to continue

[31] The *TRAC* court explained that: "(1) the time agencies take to make decisions must be governed by a 'rule of reason'; (2) where Congress has provided a timetable or other indication of the speed with which it expects the agency to proceed in the enabling statute, that statutory scheme may supply content for this rule of reason; (3) delays that might be reasonable in the sphere of economic regulation are less tolerable when human health and welfare are at stake; (4) the court should consider the effect of expediting delayed action on agency activities of a higher or competing priority; (5) the court should also take into account the nature and extent of the interests prejudiced by delay; and (6) the court need not "find any impropriety lurking behind agency lassitude in order to hold that agency action is 'unreasonably delayed.'" 750 F.2d at 80 (citations omitted).

their projects.[32] Some have already paused their studies, jeopardizing and, in some cases, eliminating the ability to perform statistical analyses on any data collected.[33] And although they are trying to secure replacement funding, most do not anticipate being able to raise nearly enough to allow their projects to continue absent restoration of the terminated grants.[34] This will also result in lost salaries, as well as the termination of other project staff.[35] Indeed, some staff have already been let go because of these cuts,[36] and some Plaintiffs and Members had planned to hire new staff but are no longer able to do so.[37] Many Plaintiffs and Members will have to take on additional responsibilities, taking away critical time from their research.[38] And applicants are in an administrative limbo: without funding but also unable to move forward with other applications.[39] Because this "loss is so great as to threaten the existence" of the work of Plaintiffs and Members,

[32] *See, e.g.*, Ex. 19 ¶ 56; Ex. 20 ¶¶ 37 ("And at this time, we do not anticipate being able to secure sufficient additional funding to allow us to resume this study for future cohorts."), 23, 40; Ex. 22 ¶ 17; Ex. 24 ¶ 17; Ex. 28 ¶ 21; Ex. 34 ¶ 25.

[33] *See, e.g.*, Ex. 30 ¶¶ 25–26 (data unusable for analysis and biospecimen samples discarded); Ex. 19 ¶ 54; Ex. 20 ¶¶ 23 ("[W]ithout sufficient additional funding, which at this time I do not anticipate securing, we will not have money to pay for an individual with the pertinent statistical background and expertise to analyze data."), 37 ("But because 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 analyses—at not as intended with a comparison group."), 40; Ex. 28 ¶ 21; Ex. 31 ¶ 30; Ex. 33 ¶ 21; Ex. 34 ¶ 30.

[34] *See, e.g.*, Ex. 20 ¶ 41 ("And although 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 to secure the amount of funding (millions of dollars) that we would have had with those terminated grants."); Ex. 21 ¶ 21; Ex. 29 ¶ 31 ("If [Business Name] is forced to pay these costs out-of-pocket, it would bankrupt the business"); Ex. 33 ¶¶ 23, 26; Ex. 34 ¶ 25; Ex. 35 ¶ 2; Ex. 36 ¶ 15; Ex. 37 ¶ 22; Ex. 42 ¶ 13.

[35] *See, e.g.*, Ex. 19 ¶¶ 51–52; Ex. 20 ¶ 41; Ex. 24 ¶ 17; Ex. 25 ¶¶ 10, 16; Ex. 28, ¶ 22; Ex. 29 ¶¶ 34–35; Ex. 30 ¶ 23; Ex. 31 ¶ 24 ("In total, at least 35 people across teams will be losing their jobs or a portion of their income as a result of this grant termination."), 25–27; Ex. 32 ¶ 21; Ex. 33 ¶ 23 ("Because of the termination of this grant and the other grant terminated by NIH, I will likely have to lay off at least two staff members."); Ex. 34 ¶¶ 25–27; Ex. 21 ¶ 21 (expressing worry over potential job loss because of lack of funding); Ex. 37 ¶ 25 ("I do not know how much longer my job will be safe.").

[36] *See, e.g.*, E*x*. 19 ¶ 51; Ex. 20 ¶ 41 ("several staff have already been terminated, and more terminations are soon to happen because of a lack of funding resulting from the termination of these grants").

[37] *See, e.g.*, Ex. 20 ¶ 23; Ex. 28 ¶ 22; Ex. 31 ¶ 28 ("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."); Ex. 32 ¶ 13.

[38] *See, e.g.*, Ex. 20 ¶¶ 41–42; Ex. 28 ¶ 23; Ex. 31 ¶¶ 27 ("I have lost my summer salary and will have to teach a higher course load to compensate, which will also make it harder for me to conduct research."), 30; Ex. 34 ¶¶ 27, 29 ("This increased workload and lack of adequate funding makes it impossible to sustain the research project.").

[39] *See, e.g.*, Ex. 21 ¶ 19; Ex. 29 ¶ 10; Ex. 34 ¶ 34–35; Ex. 37 ¶ 16; Ex. 40 ¶¶ 5, 10–17, 21.

it is "irreparable." *Vaqueria Tres Monjitas, Inc. v. Irizarry*, 587 F.3d 464, 485 (1st Cir. 2009) (internal citations omitted); *see also Aids Vaccine Advoc. Coal. v. United States Dep't of State*, No. CV 25-00400 (AHA), 2025 WL 752378, at *20 (D.D.C. Mar. 10, 2025).

That alone distinguishes this case from *Department of Education v. California*, 604 U.S. __ (2025). There, the district court had enjoined the federal government from terminating various education-related grants. *Id.* at 1. In staying the preliminary injunction, the Supreme Court emphasized that movants had "represented . . . that they have the financial wherewithal to keep their [grant-funded] programs going" during the pendency of the litigation. *Id.* at 2. By contrast, Plaintiffs and Members have not and cannot make any such representation.[40] *Id.* Thus, the "ensuing irreparable harm" from the project terminations would *not* "be of their own making." *Id.*

Further, "there can be no do over and no redress" for Plaintiffs' and Members' research. *See League of Women Voters of U.S. v. Newby*, 838 F.3d 1, 9 (D.C. Cir. 2016) (citation omitted). Most immediately, some study participants will have treatment or intervention interrupted.[41] With studies shutting down prematurely, data collected will be of little or no use for drawing statistical inferences or deriving programmatic or policy recommendations.[42] Research participants may lose

[40] *See, e.g.*, Ex. 20 ¶¶ 37, 41 ("I do not anticipate being able to secure nearly enough to secure the amount of funding (millions of dollars) that we would have had with those terminated grants."), 42 ("I don't see how else to fund these programs besides through the now-terminated NIH grants."); Ex. 31 ¶¶ 24, 26 ("I do not anticipate being able to secure alternative funding to make up long-term for the salary of these team members."); Ex. 33 ¶ 23; Ex. 34 ¶ 25 ("It is now uncertain whether my co-researchers and I will have the necessary funding to continue our critical research.").

[41] *See, e.g.*, Ex. 30 ¶¶ 27–28; Ex. 32 ¶ 13.

[42] *See, e.g.*, Ex. 20 ¶¶ 23 ("Collectively, these methodological and statistical issues will prohibit our ability to draw conclusions from the data we have collected and restrict the possible recommendations that can be developed to benefit sexual minority men (including racial/ethnic sexual minority men) across the U.S."), 37 ("We also will not have statistical power to conduct analyses given that our sample size will fall short of what was proposed/intended."), 40; Ex. 31 ¶ 32 ("Since we had to abruptly pause our data collection, we cannot draw conclusions and run analyses, and the anticipated research product focused on measurement development will not be completed."); Ex. 33 ¶ 21; Ex. 34 ¶ 30 ("[N]ow that we have lost funding, the data will be analyzed but will not be able to be disseminated via publications and conference presentations, and we will not be able to effectively apply the lessons we have learned from the data, making it essentially useless for the purposes of this program intervention.").

trust in the research process and experience heightened stigma.[43] More broadly, the public will miss out on the opportunity to benefit from the research Defendants have abruptly halted—important work on some of the most pressing public 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 disproportionately affect minority communities.[44] *See* Ex. 27 ¶ 13.

Termination of grant funding also poses a risk to Plaintiffs' and Members' career progression, as NIH grants not only fund their research but are critical to securing faculty positions by demonstrating the scientific rigor and impact of their work.[45] Recipients of Pipeline Grants, meanwhile, are losing not only the external funding that is required to support their early career work but also the training, networking and collaboration with other grantees and mentors, as well as the expert affirmation of their work that comes from emerging through NIH's rigorous review

[43] *See, e.g.*, Ex. 19 ¶¶ 53–55; Ex. 30 ¶¶ 24, 27, 29; Ex. 31 ¶¶ 29, 33 ("Even if I were able to find funding to continue the work, I would almost certainly not be able to have the study's former participants work with me again—the LGBTQIA+ caregivers' trust with the researcher has been broken."); Ex. 33 ¶¶ 21, 22 ("Recruiting participants for the study required building relationships and contacts within the community. The abrupt termination of the project harmed the trust we built with community partner organizations and members of the community who participated in the study."); Ex. 34 ¶¶ 30–31.

[44] *See, e.g.*, Ex. 20 ¶¶ 23, 37, 40 ("My co-investigators and I will have an impaired—and in some cases, foreclosed—ability to . . . develop recommendations to address health disparities experienced by vulnerable subpopulations—including sexual and gender minority individuals, LGBTQ+ youth, and people of color."); Ex. 21 ¶¶ 22–24; Ex. 22 ¶ 17; Ex. 28 ¶ 23; Ex. 29 ¶ 37; Ex. 32 ¶ 23 ("There will be a dearth of important innovations designed to improve the lives of people experiencing these horrible conditions. We cannot even know what lifechanging treatments will now go undiscovered without this funding."); Ex. 33 ¶ 24 ("As we are witnessing the first generation of people with HIV living to reach old age, we also have our first opportunity to study how aging is affected by HIV, related medications, and other factors like discrimination. If studies like mine are unable to continue, we will lose a cohort of aging people and their experiences, as well as the opportunity to learn from them."); Ex. 34 ¶¶ 32–33; Ex. 35 ¶ 34 ("As a result, individuals living with Alzheimer's disease or related dementias may be left without support systems that reflect their actual care networks[.]"); Ex. 37 ¶¶ 25–27; Ex. 39 ¶ 17–18; Ex. 41 ¶ 17.

[45] *See, e.g.*, Ex. 20 ¶¶ 41-42; Ex. 21 ¶ 22; Ex. 25 ¶¶ 10, 16; Ex. 30 ¶ 31; Ex. 31 ¶ 31 ("After spending two decades building my career and securing an R01—one of the premier grants in my field—having NIH swiftly take it away is a significant personal and professional setback."); Ex. 32 ¶ 21; Ex. 34 ¶¶ 25, 27 ("This disruption comes at a critical point in my career as I am actively working toward promotion from Associate Professor to Full Professor."); Ex. 35 ¶¶ 20–21; Ex. 36 ¶ 15; Ex. 37 ¶¶ 22–24; Ex. 39 ¶¶ 17–18a; Ex. 40 ¶¶ 19–22 (first-time applicant for F31 diversity grant explaining impact of likely loss of this funding stream); Ex. 41 ¶ 16.

processes.[46] Undergraduate students have been left without money to pay for tuition and housing, and post-doctoral researchers have been deprived of promised funding just as they are applying for faculty positions dependent on bringing such funding to an institution.[47] Some could have initially applied for parallel programs that have not been terminated, but now they no longer meet the eligibility criteria.[48] "By its very nature injury to goodwill and reputation not easily measured or fully compensable in damages is often held to be irreparable." *Ross-Simons of Warwick, Inc. v. Baccarat, Inc.*, 102 F.3d 12, 20 (1st Cir. 1996) (cleaned up).

Finally, as other courts in this District have emphasized when analyzing the irreparable harm that results from terminating NIH grants, "[i]t is impossible to accurately measure or compensate humans who lose their lives from a pause in research," and "[i]t is impossible to measure the value of discovery from scientists who choose to leave, or of the potential students who now never become scientists at all." *See Massachusetts*, 2025 WL 702163, at *31. Those "losses are compounding and will result in even greater disruption to ongoing research and clinical trials." *Id.* Thus, Plaintiffs' and Members' injuries "cannot be adequately compensated for by . . . a later-issued permanent injunction," and therefore they will suffer irreparable harm absent a preliminary injunction. *See Rio Grande Cmty. Health Ctr., Inc. v. Rullan*, 397 F.3d 56, 76 (1st Cir. 2005); *see also Ross-Simons of Warwick*, 102 F.3d at 19.

V. The Public Interest and the Balance of Equities Strongly Favor Entry of a Preliminary Injunction.

[46] *See, e.g.*, Ex. 21 ¶¶ 18, 22; Ex. 23 ¶ 48; Ex. 25 ¶¶ 10, 16; Ex. 35 ¶¶ 20–21; Ex. 36 ¶¶ 7, 15, 17; Ex. 37 ¶¶ 22–24; Ex. 38 ¶¶ 5, 13; Ex. 39 ¶¶ 15, 17–18; *see* Ex. 40 ¶¶ 19–22 (first-time F31 diversity applicant explaining impact of likely loss of this opportunity).

[47] *See, e.g.*, Ex. 23 ¶ 46 (describing how undergraduate students rely on MARC funding to pay their tuition, food costs, and housing costs); Ex. 32 ¶ 21 (describing the consequences of funding termination for postdoctoral fellow); Ex. 36 ¶ 15; Ex. 41 ¶ 16.

[48] *See, e.g.*, Ex. 36 ¶ 18; Ex. 40 ¶ 21 ("I cannot possibly submit another F31 application, because the time from submission to funding takes approximately nine months, after which I will have already graduated.").

At the outset, Plaintiffs' "extremely high likelihood of success on the merits is a strong indicator that a preliminary injunction would serve the public interest." *League of Women Voters*, 838 F.3d at 12. Moreover, the chaos from Defendants' actions threatens the public's interest in having an orderly and well-functioning government. "There is a substantial public interest in having governmental agencies abide by the federal laws that govern their existence and operations." *Id.* (cleaned up). Defendants' sweeping, arbitrary, and sudden terminations of hundreds of grants comprising billions of dollars' worth of funding of important research flagrantly violates both statutory law and their own regulations. *See supra*, Argument Section III.A–C. Absent injunctive relief, this chaos will only continue. The research itself also has a clear public value as evidenced by the rigorous application and peer-review process. *See supra*, Background Section I.B.2; *see also Massachusetts*, 2025 WL 702163 at *32 ("Courts have consistently held there is a strong public interest in health and safety.") (collecting cases). And as discussed above, the harm from suddenly cutting off that research is just as clear. *See supra*, Argument Section IV; *see also Massachusetts*, 2025 WL 702163 at *28–29.

The balance of harms favors Plaintiffs. Defendants would merely be required to roll back their unlawful Directives and set aside their unlawful terminations. "There is generally no public interest in the perpetuation of unlawful agency action." *League of Women Voters*, 838 F.3d at 12; *see also Rodriguez v. Robbins*, 715 F.3d 1127, 1145 (9th Cir. 2013) (the Government "cannot suffer harm from an injunction that merely ends an unlawful practice."). Because an injunction would merely prohibit and correct Defendants' unlawful conduct, the balance of the equities counsels in favor of such relief.

Finally, no security should be required, as Defendants will suffer no harm from the absence of a bond. *See Pineda v. Skinner Servs., Inc.*, 22 F.4th 47, 57 (1st Cir. 2021).

CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that the Court grant their motion for a preliminary injunction.

[signatures on following page]

Dated: April 25, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on April 25, 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.

April 25, 2025

/s/ Jessie J. Rossman
Jessie J. Rossman

APPENDIX A

TABLE OF ABBREVIATIONS

Abbreviation	Meaning
CFC	Court of Federal Claims
DOGE	Department of Government Efficiency
HHS	Department of Health and Human Services
ICs	Institutes and Centers
IMSD	Initiative for Maximizing Student Development program
IRACDA	Institutional Research and Academic Career Development Award program
Kirschstein-NRSA	Ruth L. Kirschstein National Research Service Award
MARC	Maximizing Access to Research Careers program
MOSAIC	Maximizing Opportunities for Scientific and Academic Independent Careers program
NIH	National Institutes of Health
NIHGPS	NIH Grants Policy Statement
NIMHD	National Institute on Minority Health and Health Disparities
NOA	Notice of Award
NOFO	Notice of Funding Opportunity
OMB	Office of Management and Budget
PHSA	Public Health Service Act, 42 U.S.C. Ch. 6A
U-RISE	Undergraduate Research Training Initiative for Student Enhancement

APPENDIX B

EXHIBITS IN SUPPORT OF
PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

EXH. NO.	TITLE & ACCOMPANYING EXHIBITS
1	National Institutes of Health (NIH), *Institutes at NIH*
2	NIH, *Budget*
3	NIH, *NIH Operates Under a Continuing Resolution (NOT-OD-25-084)*
4	NIH-Wide Strategic Plan 2021-2025 (2020)
5	NIH Grants Policy Statement (Apr. 2024)
6	Katherine J. Wu, *The NIH's Grant Terminations Are 'Utter and Complete Chaos,'* Atlantic (Mar. 14, 2025)
7	Memorandum for Heads of Executive Departments and Agencies (Jan. 27, 2025)
8	Transcript of April 3, 2025 Deposition of Michelle Bulls, *Washington v. Trump*, No. 2:25-cv-00244-LK (W.D. Wash. 2025)
9	Transcript of April 4, 2025 Deposition of Liza Bundesen, *Washington v. Trump*, No. 2:25-cv-00244-LK (W.D. Wash. 2025)
10	Department of Health & Human Services (HHS), Secretarial Directive on DEI-Related Funding (Feb. 10, 2025)
11	NIH Review of Agency Priorities Based on the New Administration's Goals (Feb. 12, 2025)
12	Supplemental Guidance to Memo Entitled- NIH Review of Agency Priorities Based on the New Administration's Goals (Feb. 13, 2025)
13	Staff Guidance—Award Assessments for Alignment with Agency Priorities – March 2025
14	NIH Grants Management Staff Guidance – Award Assessments for Alignment with Agency Priorities – March 2025 (Mar. 25, 2025)
15	NIH, *Notice of Civil Rights Term and Condition of Award (NOT-OD-25-090)*
16	NIH Minority Health and Health Disparities Strategic Plan 2021-2025
17	Avi Asher-Schapiro et al., *Elon Musk's Demolition Crew*, ProPublica (Feb. 6, 2025)

18	Email from Michelle Bulls with Subject "Award Revision Guidance and List of Terminated Grants via letter on 3/12" (March 13, 2025)
19	Declaration of Plaintiff Brittany Charlton A. R61 Notice of Award (Aug. 25, 2024) B. R61 Funding Announcement (Sept. 1, 2022) C. R61 Termination Notice (Mar. 12, 2025) D. R61 Revised Notice of Award (Mar. 14, 2025) E. R01 Notice of Award (May 16, 2021) F. R01 No-Cost Extension (Feb. 18, 2025) G. R01 Termination Letter (Mar. 21, 2025) H. Sexual and Gender Minority Populations in NIH-Supported Research I. R01 Administrative Supplement Grant Notice of Award (Sep. 3, 2024) J. Notice of Special Interest (Dec. 2, 2021) K. R01 Administrative Supplement Termination Notice (Mar. 21, 2025)
20	Declaration of Plaintiff Katie Edwards A. R01 Notice of Award (Jul. 22, 2022) B. CDC Webpage C. R01 Grant Termination Notice (Mar. 12, 2025) D. R01 Revised Notice of Award (Mar. 20, 2025) E. R34 Notice of Award (Oct. 12, 2023) F. R34 Grant Termination Notice (Mar. 21, 2025) G. R34 Revised Notice of Award (Mar. 25, 2025)
21	Declaration of Plaintiff Nicole Maphis A. NIH Notice of Interest in Diversity B. MOSAIC PAR (Jul. 23, 2024) C. NIH/NIAAA Email (Mar. 4, 2025) D. Mulholland Post (Mar. 13, 2025) E. Study Section Meeting Roster (Mar. 4, 2025) F. NIH/NIAAA Email (Mar. 17, 2025) G. K99/R00 PAR (Apr. 24, 2024) H. NIH Standard Due Dates Webpage
22	Declaration of Plaintiff Peter Lurie A. NIH-Wide Strategic Plan for Fiscal Years 2021-2025
23	Declaration of Georges C. Benjamin on behalf of Plaintiff American Public Health Association (APHA) A. MARC program PAR (Feb. 23, 2021) B. MARC Termination Email (Apr. 2, 2025) C. IMSD program PAR (Jan. 26, 2021) D. IMSD Termination Email (Apr. 2, 2025)

24	Declaration of Plaintiff Ibis Reproductive Health A. R01 Notice of Award (Feb. 9, 2024) B. R01 Notice of Award (Aug. 20, 2024) C. R01 Notice of Award (Aug. 28, 2024) D. Termination Letter (Mar. 21, 2025) E. Revised Notice of Award (Mar. 25, 2025) F. Revised Notice of Award (Mar. 25, 2025)
25	Declaration of Neal Sweeney on behalf of Plaintiff United Automobile, Aerospace and Agricultural Implement Workers of America (UAW)
26	Declaration of Jeremy Berg
27	Declaration of Scott Delaney A. List of Terminated Grants B. NRSA T32 PAR (Nov. 15, 2024) C. NRSA T32 PAR (Mar. 31, 2025)
28	Declaration of APHA Member 1 A. NIMHHD Notice of Award (June 19, 2019) B. NIH-Wide Strategic Plan 2016-2020 C. NIH-Wide Strategic Plan 2021-2025 D. Grant Termination Letter (Feb. 28, 2025) E. Revised Notice of Award (Feb. 28, 2025) F. Revised Notice of Award (Mar. 6, 2025)
29	Declaration of APHA Member 2 A. HEAL Initiative RFA (May 5, 2022) B. Notice of NIH's Interest in Diversity (Nov. 22, 2019) C. Notice of Award (Sept. 28, 2022) D. Notice of Supplemental Award (Aug. 26, 2024) E. Termination Letter (Mar. 21, 2025) F. Revised Notice of Award (Mar. 24, 2025) G. Revised Notice of Supplemental Award (Mar. 24, 2025)
30	Declaration of APHA Member 4 Sari Reisner A. National HIV Strategy for the United States 2022-2025 B. R01 Notice of Award (Sept. 10, 2024) C. R01 Grant Termination (Mar. 21, 2025) D. R01 Revised Notice of Award (Mar. 24, 2025)
31	Declaration of APHA Member 5 Jace Flatt A. R01 Notice of Award (Jul. 31, 2023) B. R01 Funding Opportunity Announcement (June 9, 2022) C. R01 Revised Notice of Award (Mar. 24, 2025)

	D. Sexual and Gender Minority Populations in NIH-Supported Research (Aug. 28, 2019)
32	Declaration of APHA Member 7 A. NRSA PA (Mar. 20, 2020) B. Notice of Award (Jun. 14, 2024) C. Termination letter (Mar. 21, 2025) D. Revised Notice of Award (Mar. 21, 2025)
33	Declaration of APHA Member 9 Jesus Ramirez-Valles A. Notice of Award (Sept. 9, 2022) B. Understanding and Addressing the Impact of Structural Racism and Discrimination on Minority Health and Health Disparities RFA (Mar. 23, 2021) C. Termination Letter (Mar. 21, 2025) D. Revised Notice of Award (Mar. 24, 2025) E. Termination Letter (Mar. 12, 2025)
34	Declaration of APHA Member 10 Annelise Mennicke A. Notice of Award (Apr. 24, 2024) B. Notice of Grant Termination (Mar. 20, 2025)
35	Declaration of UAW Pre-Member 1 A. MOSAIC Notice of Award B. MOSAIC PAR (Aug. 15, 2019) C. MOSAIC Termination Notice (Apr. 11, 2025)
36	Declaration of UAW Pre-Member 7 A. MOSAIC Notice of Award B. MOSAIC PAR (Aug. 17, 2021) C. MOSAIC Termination (Apr. 2, 2025) D. NIGMS Training email
37	Declaration of UAW Member 3 A. MOSAIC PAR (Aug. 17, 2021) B. NIA K99/ROO webpage (Mar. 25, 2025)
38	Declaration of UAW Member 9 A. IRACDA NIH RePORTER Webpage B. IRACDA PAR (Sep. 19, 2019) C. IRACDA Fellowship Offer Letter D. IRACDA Termination Email (Apr. 2, 2025) E. IRACDA co-director Email (Apr. 3, 2025)
39	Declaration of UAW Member 10

	A. IRACDA project details, NIH RePORTER website B. IRACDA PAR (Sept. 9, 2019) C. Email terminating IRACDA Program (Apr. 2, 2025)
40	Declaration of UAW Member 11 Delaney Sullivan A. Strategic Vision for Improving Human Health at The Forefront of Genomics B. F31-Diversity PA (Sept. 12, 2023) C. NIH/NHGRI email (Jan 6, 2025) D. NIH/NHGRI email (Nov. 22, 2024) E. eRA Status Information (Feb. 19, 2025) F. Sullivan email to NIH (Feb. 4, 2025) G. F31-Diversity PA (Mar. 6, 2025)
41	Declaration of UAW Member 12 Amanda Perez A. Notice of Award (Aug. 2, 2023) B. MOSAIC PAR (Aug. 17, 2021) C. Email from NIH Program Officer (Sep. 1, 2023) D. MOSAIC project details RePORTER website (June 26, 2024) E. MOSAIC PAR (Jul. 23, 2024)
42	Declaration of UAW Member 13 A. IMSD project details, NIH RePORTER website B. IMSD PAR (Oct. 25, 2018) C. IMSD Notice of Appointment (Oct. 1, 2024) D. IMSD approval email (Jan. 7, 2025) E. Revised IMSD Notice of Appointment (Jan. 31, 2025) F. IMSD Termination Email (Apr. 2. 2025)