

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

COMMONWEALTH OF  
MASSACHUSETTS; STATE OF  
CALIFORNIA; STATE OF MARYLAND;  
STATE OF WASHINGTON; STATE OF  
ARIZONA; STATE OF COLORADO;  
STATE OF DELAWARE; STATE OF  
HAWAI‘I; STATE OF MINNESOTA;  
STATE OF NEVADA; STATE OF NEW  
JERSEY; STATE OF NEW MEXICO;  
STATE OF NEW YORK; STATE OF  
OREGON; STATE OF RHODE ISLAND;  
and STATE OF WISCONSIN,

*Plaintiffs,*

v.

ROBERT F. KENNEDY, JR., in his official  
capacity as Secretary of Health and Human  
Services; UNITED STATES DEPARTMENT  
OF HEALTH AND HUMAN SERVICES;  
JAYANTA BHATTACHARYA, in his  
official capacity as Director of the National  
Institutes of Health; NATIONAL  
INSTITUTES OF HEALTH; NATIONAL  
CANCER INSTITUTE; NATIONAL EYE  
INSTITUTE; NATIONAL HEART, LUNG,  
AND BLOOD INSTITUTE; NATIONAL  
HUMAN GENOME RESEARCH  
INSTITUTE; NATIONAL INSTITUTE ON  
AGING; NATIONAL INSTITUTE ON  
ALCOHOL ABUSE AND ALCOHOLISM;  
NATIONAL INSTITUTE OF ALLERGY  
AND INFECTIOUS DISEASES;  
NATIONAL INSTITUTE OF ARTHRITIS  
AND MUSCULOSKELETAL AND SKIN  
DISEASES; NATIONAL INSTITUTE OF  
BIOMEDICAL IMAGING AND  
BIOENGINEERING; EUNICE KENNEDY  
SHRIVER NATIONAL INSTITUTE OF  
CHILD HEALTH AND HUMAN  
DEVELOPMENT; NATIONAL INSTITUTE

No. 1:25-cv-10814

ON DEAFNESS AND OTHER COMMUNICATION DISORDERS; NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH; NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES; NATIONAL INSTITUTE ON DRUG ABUSE; NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES; NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES; NATIONAL INSTITUTE OF MENTAL HEALTH; NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES; NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE; NATIONAL INSTITUTE OF NURSING RESEARCH; NATIONAL LIBRARY OF MEDICINE; NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES; JOHN E. FOGARTY INTERNATIONAL CENTER FOR ADVANCED STUDY IN THE HEALTH SCIENCES; NATIONAL CENTER FOR COMPLEMENTARY AND INTEGRATIVE HEALTH; and CENTER FOR SCIENTIFIC REVIEW,

*Defendants.*

**COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF**

Plaintiffs the Commonwealth of Massachusetts, the State of California, the State of Maryland, the State of Washington, the State of Arizona; the State of Colorado; the State of Delaware; the State of Hawai‘i, the State of Minnesota; the State of Nevada; the State of New Jersey; the State of New Mexico; the State of New York; the State of Oregon; the State of Rhode Island; and the State of Wisconsin allege as follows:

## INTRODUCTION

1. The National Institutes of Health (NIH) is a federal agency responsible for conducting and supporting biomedical research. Widely acknowledged as a “crown jewel” of America’s scientific institutions—a characterization the agency’s director recently reiterated<sup>1</sup>—NIH is the largest public funder of medical research in the world.

2. NIH has “a long and illustrious history [of] supporting breakthroughs in biology and medicine.”<sup>2</sup> NIH scientists pioneered the rubella vaccine, eradicating a disease that, in the 1960s, killed thousands of babies and left thousands more with lifelong disabilities.<sup>3</sup> NIH studies led to the discovery of the BRCA mutation, helping countless Americans reduce their risk of breast and ovarian cancer.<sup>4</sup> NIH research fueled the development of treatments for HIV and AIDS, transforming what used to be a fatal disease into one with a nearly normal life expectancy.<sup>5</sup> These are just a few of many, many examples: over the years, NIH-supported research has had a profound impact on the health and wellbeing of the American people. Indeed, it is hard to find a medical breakthrough in recent years that has *not* been assisted—whether directly or indirectly—by NIH’s pioneering work.<sup>6</sup>

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<sup>1</sup> Opening Statement of Dr. J. Bhattacharya, S. Comm. on Health, Educ., Lab. & Pensions (March 5, 2025), <https://bit.ly/Bhattacharya-Statement>.

<sup>2</sup> *Id.*

<sup>3</sup> Lyons M., *IRP Vaccine Research Stretches Back to the NIH’s Birth*, NIH Intramural Rsch. Prog. (May 18, 2020), <https://irp.nih.gov/blog/post/2020/05/a-long-tradition-of-vaccine-breakthroughs>.

<sup>4</sup> *Enhancing Breast and Ovarian Cancer Care: The Discovery of BRCA1 and BRCA2*, Nat’l Cancer Inst. (March 7, 2014), <https://www.cancer.gov/research/progress/discovery/breca>.

<sup>5</sup> *HIV/AIDS Treatment*, Nat’l Inst. of Allergy & Infectious Disease (Jun. 16, 2020), <https://www.niaid.nih.gov/diseases-conditions/hiv-treatment>.

<sup>6</sup> *See, e.g.,* Ekaterina G. Cleary et al., *Comparison of Research Spending on New Drug Approvals by the National Institutes of Health vs the Pharmaceutical Industry, 2010-2019*, 4 JAMA Health Forum e230511 (2023) (showing NIH funding contributing to 99.4 percent of drugs approved by the U.S. FDA between 2010 and 2019), <https://pmc.ncbi.nlm.nih.gov/articles/PMC10148199/#aoi230016r28>.

3. NIH's activities have also contributed to our Nation's economic security and prosperity. Today, the United States is a global leader in the health and life sciences—thanks, in no small part, to NIH. The agency's grants have allowed America to train the next generation of doctors, researchers, and biomedical entrepreneurs. And they have ensured that crucial innovations take place in American institutions—allowing the United States to reap the economic benefits of those discoveries. The numbers speak for themselves: in Fiscal Year 2024 alone, NIH's more than \$36 billion in awards spurred more than \$94 billion in new economic activity—a return of \$2.56 for every \$1 invested. These investments supported more than 407,000 jobs across every State and the District of Columbia.

4. That critical work is now in jeopardy. By law, NIH provides much of its support for scientific research and training in the form of grants to outside institutions. Since January, however, the current Administration has engaged in a concerted, and multi-pronged effort to disrupt NIH's grants. These efforts are unlawful, and plaintiffs bring this lawsuit to seek relief for the immediate harms they are causing state research institutions.<sup>7</sup>

5. Defendants' destructive efforts have taken the form of across-the-board delays in the review and approval of otherwise-fundable grant applications and widespread terminations of already-issued grants. Plaintiffs challenge both.

6. First, plaintiffs seek relief for the unreasonable and intentional delays currently plaguing the grant-application process. A successful application for NIH funding must typically survive two layers of review: review by a "study section" of subject-matter experts who assess

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<sup>7</sup> In recent months, a number of the plaintiff states have brought lawsuits challenging other unlawful policies and decisions that affect NIH grants. *See* Complaint, *Massachusetts v. NIH*, No. 1:25-cv-10338-AK (D. Mass. Feb. 10, 2025) (ECF No. 1) (challenging recent NIH guidance purporting to alter the methodology for calculating "indirect costs"); Complaint, *New York v. Trump*, No. 1:25-cv-39-JJM-PAS (D.R.I. Jan. 28, 2025) (ECF No. 1) (challenging an OMB directive instituting a temporary funding pause across federal agencies). The agency actions at issue in those cases are distinct from the acts and omissions at issue here.

each proposal’s scientific merit, and review by an “advisory council” that considers funding availability and agency priorities. Since January, however, NIH has upended this process, canceling upcoming meetings of these bodies and indefinitely delaying the scheduling of future meetings. Worse, NIH has indefinitely withheld final decisions on applications that have already received a green light from the applicable study section or advisory council. *Contra, e.g.*, 42 C.F.R. §52.5 (providing that “[a]ll applications” for NIH grants “shall be evaluated” and “will” be approved, rejected, or deferred for discrete reasons). And NIH has delayed the renewal of, and accompanying payments for, multi-year awards up for their annual “noncompetitive” renewal. This systematic delay and inaction “unlawfully withh[olds]” and “unreasonably delay[s]” required agency action—and therefore violates the Administrative Procedure Act (APA), 5 U.S.C. §706(1). It also contravenes separation-of-powers constraints on the Executive Branch—and so violates the Constitution, too.

7. Second, plaintiffs seek relief for NIH’s recent termination of huge swaths of already-issued grants. Since March, NIH has sent hundreds of letters to grant recipients at public research institutions in the plaintiff states announcing that various grants have been terminated because they “no longer effectuate[] agency priorities.” Citing 2 C.F.R. §200.340, each boilerplate letter declares that the grant in question has been terminated because of some connection to “DEI,” “transgender issues,” “vaccine hesitancy,” or another topic disfavored by the current Administration. But §200.340 does not apply here. And even if it did, NIH’s terminations are still unlawful. The agency has failed to acknowledge—let alone provide “good reasons for”—any changes in agency policy supposedly justifying the terminations. *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009). And the shoddy justifications defendants have provided ignore important and relevant considerations and run counter to the available evidence. *See Motor*

*Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). For these and other reasons, the challenged terminations violate the APA, 5 U.S.C. §706(2).

8. The challenged delays and terminations have caused—and, if left unchecked, will continue to cause—direct, immediate, significant, and irreparable harm to the plaintiffs and their public research institutions. Plaintiffs are collectively awaiting NIH’s decisions on billions of dollars in requested research funding, including millions of dollars in funding for projects that received top marks from the relevant NIH study section. Despite securing a “fundable” score, these applications remain in suspended animation—neither approved nor denied—making it impossible for plaintiffs to plan for the future. And now, NIH has started canceling grants already issued to plaintiffs’ public institutions, clawing back millions of dollars (and counting) in already-awarded money. The result of these disruptions has been, in a word, devastating. In Massachusetts, for example, the growing uncertainty has forced the Commonwealth’s flagship public research institution, the University of Massachusetts, to rescind several dozen offers from prospective biomedical-sciences graduate students for the upcoming academic year, decimating its graduate student program and jeopardizing important lines of research.

9. For all these reasons, plaintiffs seek swift relief from this Court. The Court should order NIH to undertake the grant-application review process as the law requires. And it should set aside the NIH’s unlawful termination of plaintiffs’ already-issued grants.

#### **JURISDICTION AND VENUE**

10. This action arises under the APA, 5 U.S.C. §701 *et seq.*; the Public Health Service Act (PHSA), 42 U.S.C. §201 *et seq.*; and federal regulations governing NIH grants. This Court has jurisdiction under 28 U.S.C. §1331.

11. Venue is proper in this district under 28 U.S.C. §1391(e)(1). Defendants are federal agencies and officers sued in their official capacities. The Commonwealth of Massachusetts is a

resident of this judicial district and a substantial part of the events or omissions giving rise to this Complaint occurred within this district.

## **PARTIES**

### **I. Plaintiffs**

12. The Commonwealth of Massachusetts is a sovereign state of the United States of America. Massachusetts is represented by Attorney General Andrea Joy Campbell, the Commonwealth's chief legal officer.

13. The State of California is a sovereign state of the United States of America. California is represented by Attorney General Rob Bonta, the State's chief legal officer.

14. The State of Maryland is a sovereign state of the United States of America. Maryland is represented by and through its chief legal officer, Attorney General Anthony G. Brown.

15. The State of Washington is a sovereign state of the United States of America. Washington is represented by Attorney General Nicholas W. Brown, the State's chief legal officer.

16. The State of Arizona is a sovereign state of the United States of America. Arizona is represented by Attorney General Kristin K. Mayes, the State's chief law enforcement officer.

17. The State of Colorado is a sovereign state of the United States of America. Colorado is represented by and through its Attorney General Phil Weiser. The Attorney General acts as the chief legal representative of the State and is authorized by Colo. Rev. Stat. §24-31-101 to pursue this action.

18. The State of Delaware is a sovereign state in the United States of America. Delaware is represented by Attorney General Kathy Jennings, who is the State's chief law enforcement officer.

19. The State of Hawai‘i is a sovereign state of the United States of America. Hawai‘i is represented by Attorney General Anne Lopez, who is the State’s chief law enforcement officer.

20. The State of Minnesota is a sovereign state of the United States of America. Minnesota is represented by Attorney General Keith Ellison, the State’s chief legal officer.

21. The State of Nevada, represented by and through Attorney General Aaron D. Ford, is a sovereign State within the United States of America. The Attorney General is the chief law enforcement of the State and is authorized to pursue this action under Nev. Rev. Stat. §228.110 and Nev. Rev. Stat. §228.170.

22. The State of New Jersey is a sovereign state in the United States of America. New Jersey is represented by Attorney General Matthew Platkin, who is the State’s chief law enforcement officer.

23. The State of New Mexico is a sovereign state of the United States of America. New Mexico is represented by Attorney General Raúl Torrez, who is the State’s chief law enforcement officer.

24. The State of New York is a sovereign state of the United States of America. As a body politic and a sovereign entity, it brings this action on behalf of itself and as trustee, guardian, and representative of all residents, and political subdivisions of New York. Attorney General Letitia James is the chief law enforcement officer for New York.

25. The State of Oregon is a sovereign state in the United States of America. Oregon is represented by Attorney General Dan Rayfield, who is the State’s chief legal officer. Attorney General Rayfield is authorized by statute to file suit in federal court on behalf of the State of Oregon to protect the interests of the State. Or. Rev. Stat. §180.060.



26. The State of Rhode Island is a sovereign state of the United States of America. Rhode Island is represented by Attorney General Peter F. Neronha, the State's chief legal officer.

27. The State of Wisconsin is a sovereign state in the United States of America. Wisconsin is represented by Josh Kaul, the Attorney General of Wisconsin, who is the chief law enforcement officer of Wisconsin and is authorized to sue on behalf of the State, including its public universities.

## **II. Defendants**

28. Robert F. Kennedy, Jr., is the Secretary of Health and Human Services. He is sued in his official capacity.

29. The United States Department of Human and Health Services (HHS) is a federal cabinet department.

30. Jayanta Bhattacharya is the Director of NIH. He is sued in his official capacity.

31. NIH is a federal agency organized under the PHSA, *see* 42 U.S.C. §§203, 281; it is housed within HHS.

32. The following institutes and centers are federal agencies established under the PHSA, *see* 42 U.S.C. §281, and housed within NIH: the National Cancer Institute; the National Eye Institute; the National Heart, Lung, and Blood Institute; the National Human Genome Research Institute; the National Institute on Aging; the National Institute on Alcohol Abuse and Alcoholism; the National Institute of Allergy and Infectious Diseases; the National Institute of Arthritis and Musculoskeletal and Skin Diseases; the National Institute of Biomedical Imaging and Bioengineering; the Eunice Kennedy Shriver National Institute of Child Health and Human Development; the National Institute on Deafness and Other Communication Disorders; the National Institute of Dental and Craniofacial Research; the National Institute of Diabetes and Digestive and Kidney Diseases; the National Institute on Drug Abuse; the National Institute of

Environmental Health Sciences; the National Institute of General Medical Sciences; the National Institute of Mental Health; the National Institute on Minority Health and Health Disparities; the National Institute of Neurological Disorders and Stroke; the National Institute of Nursing Research; the National Library of Medicine; the National Center for Advancing Translational Sciences; the John E. Fogarty International Center for Advanced Study in the Health Sciences; the National Center for Complementary and Integrative Health; and the Center for Scientific Review.

## **FACTUAL AND LEGAL BACKGROUND**

### **III. Congressional Authorization and Appropriation for NIH Research**

#### **A. Creation and Structure of NIH**

33. NIH traces its origins to the 1887 establishment of the Hygienic Laboratory, a component of the Marine Hospital Service dedicated to the study of epidemic diseases. Subsequent statutes have transformed that single laboratory into the multifaceted agency at the center of this suit. In 1902, the laboratory assumed responsibility for testing and regulating vaccines and biologic products with the passage of the Biologics Control Act, ch. 1378, 32 Stat. 728. In 1930, Congress redesignated the laboratory as the National Institute (singular) of Health and established fellowships for biological and medical research. *See* Ransdell Act, ch. 251, 46 Stat. 379. In 1937, Congress created the National Cancer Institute, authorizing the new institute to award research grants to nonfederal scientists and to fund fellowships for young researchers. *See* National Cancer Institute Act, ch. 565, 50 Stat. 559. In 1944, Congress made the National Cancer Institute a division of NIH and expanded NIH's support for biomedical research. PHSA, ch. 373, 58 Stat. 682. And in 1948, following the creation of several additional subsidiary institutes, Congress gave the umbrella agency its current name: the National Institutes (plural) of Health. *See* National Heart Act, ch. 481, 62 Stat. 464.

34. Today, NIH is made up of 27 institutes and centers—or “ICs,” in NIH parlance—each focusing on a different disease or body system. According to the agency, “NIH’s mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.”<sup>8</sup>

35. NIH carries out its mission through both “intramural” research (that is, research conducted in-house at NIH) and “extramural” research (that is, research conducted at outside institutions with NIH financial support). Twenty-five of the agency’s institutes and centers—all named as defendants in paragraph 32 above—are involved in issuing or reviewing applications for extramural funding opportunities.<sup>9</sup>

36. NIH is the primary source of federal funding for biomedical and public health research in the United States. In fiscal year 2024, NIH spent over \$36 billion on over 60,000 research grants, awarded to recipients in each of the fifty States and the District of Columbia.<sup>10</sup>

37. In addition to supporting numerous scientific breakthroughs (*see supra*, paragraph 2), NIH funds are also critical to the education and training of the next generation of scientists and researchers. NIH’s financial awards support postdoctoral fellows, graduate students, and early-career investigators whose work advances scientific discovery and innovation. These funds not only provide financial support, but also enable mentorship, access to cutting-edge resources, and

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<sup>8</sup> *Mission and Goals*, NIH (Oct. 24, 2024), <https://www.nih.gov/about-nih/what-we-do/mission-goals>.

<sup>9</sup> The remaining two are the NIH Clinical Center (a research hospital) and the NIH Center for Information Technology (an administrative component responsible for computing and information technology).

<sup>10</sup> *See NIH’s Role in Sustaining the U.S. Economy*, United for Medical Research, at 5 (Mar. 2025), [https://www.unitedformedicalresearch.org/wp-content/uploads/2025/03/UMR\\_NIH-Role-in-Sustaining-US-Economy-FY2024-2025-Update.pdf](https://www.unitedformedicalresearch.org/wp-content/uploads/2025/03/UMR_NIH-Role-in-Sustaining-US-Economy-FY2024-2025-Update.pdf) (tabulating NIH research grants awarded, FY2024); *see also NIH Awards by Location & Organization*, NIH, <https://report.nih.gov/award/index.cfm> (searchable results); *Research Project Grants*, NIH, <https://report.nih.gov/nihdatabook/category/4> (Jan. 2024) (identifying historical data through 2023, and reporting more than 40,000 competitive grant awards in 2022 and 2023).

participation in collaborative research environments that are essential for developing the skills, experience, and professional networks needed to sustain the biomedical research enterprise.

**B. Congressional Authorization for NIH Research**

38. NIH's extramural research activities stem from statutory directives: Congress has enacted laws authorizing NIH and its constituent institutes and centers to conduct research and award grants, and it has supplied funding for those activities through regular appropriations.

39. Section 301 of the PHSA, 42 U.S.C. §241, contains Congress's overarching authorization for NIH (as a component of the "Public Health Service") to conduct research and award grants. Subsection (a) of that paragraph states:

The Secretary [of Health and Human Services] shall conduct in the Service, and encourage, cooperate with, and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man, including water purification, sewage treatment, and pollution of lakes and streams.

And subsection (a)(1) states that:

The Secretary may make grants-in-aid to universities, hospitals, laboratories, and other public or private institutions, and to individuals for such research projects as are recommended by the advisory council to the entity of the Department supporting such projects and make, upon recommendation of the advisory council to the appropriate entity of the Department, grants-in-aid to public or nonprofit universities, hospitals, laboratories, and other institutions for the general support of their research.

40. Section 405 of the PHSA, 42 U.S.C. §284, imposes similar responsibilities and confers similar authority on the directors of NIH's institutes and centers. Among other things, each director "shall encourage and support research, investigations, experiments, demonstrations, and studies in the health sciences," *id.* §284(b)(1)(A), and, to that end, "may make grants and cooperative agreements . . . for research, training, or demonstrations," *id.* §284(b)(2)(A). *See also* 42 U.S.C. §282 (similar, for the NIH director).

### C. Congressional Authorization for Specific Programs and Priorities

41. Other sections of the PHSA provide more specific directives to each of NIH's constituent institutes and centers, detailing the ICs' general purposes and establishing initiatives and programs within each of them. *Cf.* 42 U.S.C. §284(b)(1) (providing that, in carrying out the purposes of section 301 of the PHSA, the Secretary, acting through the Director of each research institute within NIH, "shall encourage and support research, investigations, experiments, demonstrations, and studies in the health sciences" with respect to the human disease or disorder or other aspects of human health for which the national research institutes were established). Some of these statutory provisions are directly at odds with the "policy priorities" defendants now invoke to terminate plaintiffs' NIH grants.

42. To take just one example, as described in greater detail below (*see infra*, paragraphs 93-107, 129-141), defendants have purported to terminate already-issued research grants based on their perceived connection to "DEI." This newly stated policy against diversity, equity, and inclusion is inconsistent with at least the following express statutory directives:

- Congress has provided that the 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." 42 U.S.C. §282(h).
- Congress has provided that the NIH director shall "encourage efforts to improve research related to the health of sexual and gender minority populations, including by (1) facilitating increased participation of sexual and gender minority populations in clinical research supported by the National Institutes of Health, and reporting on such participation, as applicable; (2) facilitating the development of valid and reliable methods for research relevant to sexual and gender minority populations; and (3) addressing methodological challenges." 42 U.S.C. §283p.
- Congress has directed various NIH institutes and centers to conduct research related to women's health or reproductive health. For example, it has instructed the National Cancer Institute to "expand, intensify, and coordinate the activities of the Institute with respect to research on breast . . . cancers of the reproductive system of women." 42 U.S.C. §285a-6. And it has required the National Heart, Lung, and Blood Institute to conduct research into

the prevalence of certain heart conditions in women, “including African-American women and other women who are members of racial or ethnic minority groups.” *Id.* §285b-7a(c)(1)

- Congress has established a National Institute on Minority Health and Health Disparities to support research and training “with respect to minority health conditions and other populations with health disparities.” 42 U.S.C. §285t(a).<sup>11</sup>
- Congress has established an Office of Research on Women’s Health within NIH to “determine the extent to which women are represented among senior physicians and scientists of the national research institutes and among physicians and scientists conducting research with funds provided by such institutes, and as appropriate, carry out activities to increase the extent of such representation.” 42 U.S.C. §287d(e).
- Congress has instructed the Secretary of Health and Human Services to award Ruth L. Kirschstein National Research Service Awards “in a manner that will result in the recruitment of women, and individuals from disadvantaged backgrounds (including racial and ethnic minorities), into fields of biomedical or behavioral research and in the provision of research training to women and such individuals.” 42 U.S.C. §288(a)(4).

#### **D. Congressional Directives Regarding NIH Priority-Setting**

43. In addition to the above directives, Congress has also established a public process to identify the research priorities of NIH and its institutes and centers. Every six years, the NIH director must “develop and submit to the appropriate committees of Congress and post on the [NIH’s website] a coordinated strategy (to be known as the ‘National Institutes of Health Strategic Plan’) to provide direction to the biomedical research investments made by the National Institutes of Health, to facilitate collaboration across the institutes and centers, to leverage scientific opportunity, and to advance biomedicine.” 42 U.S.C. §282(m)(1). Each of NIH’s institutes and centers similarly develops and promulgates a strategic plan that publicly articulates its research priorities. *Id.* §282(m)(3).

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<sup>11</sup> The statutory term “minority health conditions” is defined to mean conditions that are unique to, or more prevalent among, or treated differently in, or understudied with respect to “individuals who are members of” “racial and ethnic minority group[s]”—*i.e.*, “American Indians (including Alaska Natives, Eskimos, and Aleuts); Asian Americans; Native Hawaiians and other Pacific Islanders; Blacks; and Hispanics.” 42 U.S.C. §§285t(c)(2)-(3), 300u-6(g)(1).

44. NIH has previously followed Congress’s direction and publicized its research priorities. In September 2019, the NIH director began the process of updating the agency’s priorities in biomedical and behavioral research areas, research capacity, and research conduct. Between October 2019 and July 2020, NIH gathered feedback from its institutes and centers, their advisory councils, external stakeholders, and the general public. The Strategic Plan published in 2020 stated that, among other things, NIH would prioritize “improving minority health and reducing health disparities; enhancing women’s health; addressing public health challenges across the lifespan; promoting collaborative science; and leveraging data science for biomedical discovery.”<sup>12</sup> Similarly, the plan stated that NIH “supports a comprehensive spectrum of immunology and infectious disease research focused on developing improved or novel vaccines, including the rapid development of new vaccines to mitigate emerging infectious disease outbreaks, such as COVID-19, Ebola virus disease (EVD), and influenza (flu).”<sup>13</sup>

#### **E. Congressional Appropriations for NIH Extramural Research**

45. Most of NIH’s funding comes from annual discretionary appropriations from Congress.<sup>14</sup> For years, Congress has made appropriations for NIH research with this statutory and regulatory framework in mind and generally has appropriated specific amounts to each of NIH’s institutes and centers to carry out the purposes set forth in the authorizing statutory provisions described above.<sup>15</sup>

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<sup>12</sup> NIH, *NIH-Wide Strategic Plan, Fiscal Years 2020-2025* at 3 (2020), <https://bit.ly/NIHSP2125>.

<sup>13</sup> *Id.* at 8.

<sup>14</sup> Some of NIH’s funding is from mandatory funding sources or available due to specific transfer or budgetary rules, but the “vast majority” comes from annual discretionary Congressional appropriations. *National Institutes of Health Funding: FY1996-FY2025*, Cong. Research Serv. Rep. (June 25, 2024), <https://www.congress.gov/crs-product/R43341>.

<sup>15</sup> *See, e.g.*, Consolidated Appropriations Act, 2023, Pub. L. No. 117-328, div. H, tit. II, 136 Stat. 4459, 4861-4865; Consolidated Appropriations Act, 2022, Pub. L. No. 117-103, div. H, tit. II, 136 Stat. 49, 448-452; Consolidated

46. In recent years, Congress has specifically rejected efforts to significantly cut NIH’s funding. For example, in 2017, as part of its fiscal year 2018 budget proposal, the first Trump Administration sought to reduce NIH annualized spending by \$5.8 billion, to \$25.9 billion.<sup>16</sup> The proposal’s primary method of achieving these cuts was by slashing the “indirect cost rate” for NIH grants, capping it at 10% across the board. This proposal drew bipartisan criticism. The Senate Appropriations Committee reported that the proposal would “radically change the nature of the Federal Government’s relationship with the research community,” would “abandon[]” the Government’s “long-established responsibility” for research infrastructure, and would jeopardize “biomedical research nationwide.” S. Rep. No. 115-150, at 109 (2017). To avoid this possibility, Congress enacted statutory language (which it has readopted in every subsequent appropriations measure) barring NIH or any other agency from restructuring or modifying the existing approach to indirect costs. *See Consolidated Appropriations Act, 2018*, Pub. L. No. 115-141, div. H, §226, 132 Stat. 348, 740. And ultimately, rather than enacting the Administration’s proposal of cutting NIH funding to \$25.9 billion, Congress’s all-in appropriation to NIH for fiscal year 2018 was \$37.3 billion—higher than the prior fiscal year’s appropriation.<sup>17</sup>

47. In subsequent budget proposals, the Administration generally sought to increase, not decrease, NIH’s funding. Its Fiscal Year 2020 budget proposal touted the Administration’s prioritization of “critical health research” and proposed a \$33 billion appropriation to NIH—about

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Appropriations Act, 2021, Pub. L. No. 116-260, div. H, tit. II, 134 Stat. 1182, 1573-1577; Further Consolidated Appropriations Act, 2020, Pub. L. No. 116-94, div. A, tit. II, 133 Stat. 2534, 2562-2565; Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019, Pub. L. No. 115-245, div. B, tit. II, 132 Stat. 2981, 3074-3076; Consolidated Appropriations Act, 2018, Pub. L. No. 115-141, div. H, tit. II, 132 Stat. 348, 720-723; Consolidated Appropriations Act, 2017, Pub. L. No. 115-31, div. H, tit. II, 121 Stat. 135, 524-526; *see also, e.g.*, Consolidated Appropriations Act, 2008, Pub. L. No. 110-161, div. G, tit. II, 121 Stat. 1844, 2173-2177.

<sup>16</sup> *See* Off. of Mgmt. & Budget, *Major Savings and Reforms: Budget of the U.S. Government Fiscal Year 2018*, at 43 (2017), <https://bit.ly/OMBFY18>.

<sup>17</sup> NIH, *History of Congressional Appropriations, Fiscal Years 2010-2019*, at 1, <https://bit.ly/42p9Lya>.

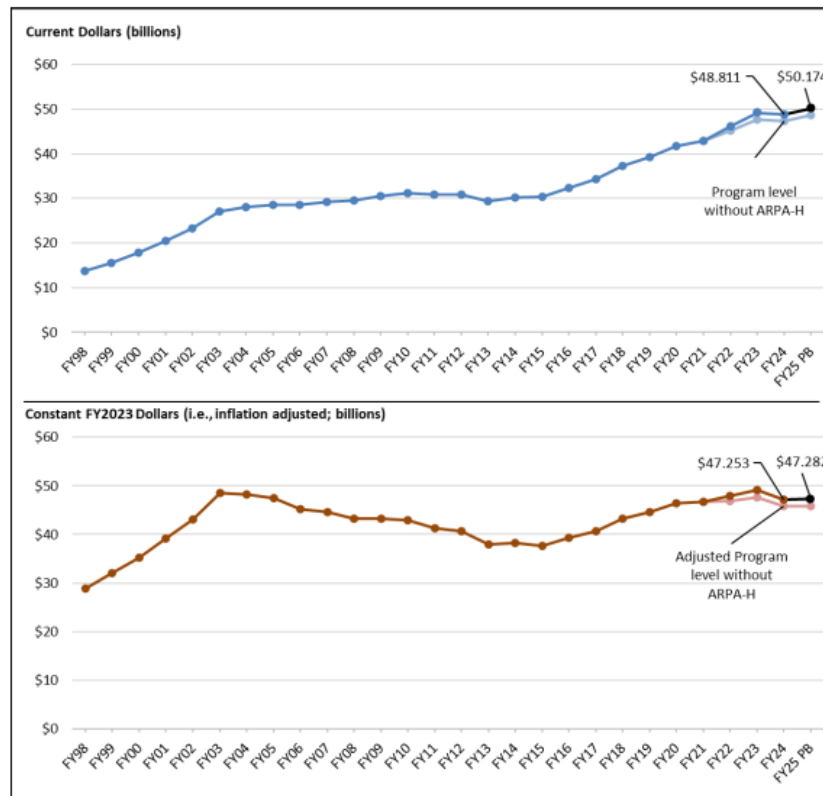


\$6 billion higher than its 2017 proposal.<sup>18</sup> Similarly, the Fiscal Year 2021 budget reiterated the Administration’s commitment to prioritizing “critical health research” and “support[ing] innovation,” and proposed providing \$38 billion to NIH.<sup>19</sup> Ultimately, Congress appropriated even more funds to NIH than the Administration requested for fiscal year 2021: about \$42.9 billion.<sup>20</sup>

48. Overall, from Fiscal Years 2017 through 2023, NIH funding increased annually, which is consistent with NIH’s stable, and generally increasing, funding for more than 20 years:<sup>21</sup>

**Figure 1. NIH Funding, FY1998-FY2025 Request**

Program Level Funding in Current and Projected Constant (FY2023) Dollars.



<sup>18</sup> Off. of Mgmt. & Budget, *Budget of the U.S. Gov’t, Fiscal Year 2020*, at 46, <https://bit.ly/OMBFY20>.

<sup>19</sup> Off. of Mgmt. & Budget, *A Budget for America’s Future, Fiscal Year 2021*, at 54, [bit.ly/OMBFY2021](https://bit.ly/OMBFY2021).

<sup>20</sup> NIH, *Supplementary Appropriation Data Table for History of Congressional Appropriations, Fiscal Years 2020-2025*, at 1, [bit.ly/42dM1M4](https://bit.ly/42dM1M4).

<sup>21</sup> *National Institutes of Health Funding: FY1996-FY2025*, Cong. Research Serv. Rep. (June 25, 2024), <https://www.congress.gov/crs-product/R43341>.

49. Congress's appropriations to NIH for Fiscal Year 2024 were no different. Consistent with past appropriations for NIH activities, the Further Consolidated Appropriations Act of 2024 (2024 CAA) appropriates to each of NIH's Institutes and Centers specific amounts "for carrying out section 301 and title IV of the [Public Health Service] Act" with respect to their specific, respective statutory purposes. Pub. L. 118-47, div. D, tit. II, 138 Stat. 460, 656-657. For example, the 2024 CAA appropriates \$7,224,159,000 to the National Cancer Institute "for carrying out section 301 and title IV of the [PHSA] with respect to cancer"; \$3,982,345,000 to the National Heart, Lung, and Blood Institute to carry out the same statutory purposes "with respect to cardiovascular, lung, and blood diseases, and blood and blood products"; and \$2,603,925,000 to the National Institute for Neurological Disorders and Stroke to carry out the same statutory purposes "with respect to neurological disorders and stroke." *Id.*

50. Congress has not enacted a Consolidated Appropriations Act for Fiscal Year 2025, but on March 15, 2025, the President signed the Full-Year Continuing Appropriations and Extensions Act, 2025, commonly known as a "Continuing Resolution" or "CR" (2025 CR). Pub. L. 119-4, 139 Stat. 9. Pursuant to the 2025 CR, Congress appropriated "[s]uch amounts as may be necessary . . . under the authority and conditions provided in applicable appropriations Acts for fiscal year 2024, for projects or activities . . . that are not otherwise specifically provided for, and for which appropriations, funds, or other authority were made available" in the specific appropriations Acts. *Id.*, div. A, §1101(a), 139 Stat. at 11. Congress made limited changes in the 2025 CR with respect to the appropriation to NIH, including rescission of a portion of NIH funding (\$221,000,000 of a \$1.25 billion appropriation) previously appropriated to the "NIH Innovation Account, CURES Act," which is separate from Congress's discretionary appropriations to NIH's

Institutes and Centers. *Id.*, div. A, §1905, 139 Stat. at 32.<sup>22</sup> Otherwise, Congress did not rescind any amounts appropriated to NIH’s institutes or centers and maintained the same level of funding as set forth in the 2024 CAA, through September 30, 2025. *See id.*, div. A, §1101(a)(8), 139 Stat. at 11.

#### IV. The Grant Application and Award Process

51. NIH generally awards extramural grants through a competitive process. At any given time, NIH has over a thousand active funding opportunities supporting a broad range of programs.

52. HHS has promulgated regulations at 45 C.F.R. Part 75, governing the award of grants by HHS and its agencies, including NIH. This includes 45 C.F.R. §52.6(c), which allows HHS to notice a grant award for a “project period,” during which HHS intends to support the project “without requiring the project to recompete for funds.”

53. NIH uses three-character “activity codes” to group and classify these funding opportunities, with the first character typically identifying the major funding category or program type. “For example, activity codes for research and development often start with ‘R,’ training with ‘T,’ fellowship with ‘F,’ and career development with ‘K.’<sup>23</sup> The “R01” code, for example, denotes grants “[t]o support a discrete, specified, circumscribed project to be performed by the named investigator(s) in an area representing his or her specific interest and competencies.”

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<sup>22</sup> Appropriations to the account created by the Cures Act are, “[i]n effect,” “not subject to discretionary spending limits.” *Nat’l Insts. of Health Funding: FY1996-FY2025*, Cong. Research Serv. Rep. (June 25, 2024), <https://www.congress.gov/crs-product/R43341>. Funds may be transferred from the Cures Act account to other NIH accounts “only for the purposes specified in the Cures Act.” *Id.* Congress exempted from any rescission amounts previously designated by Congress as for an “emergency requirement” under the Balanced Budget and Emergency Deficit Control Act of 1985. 2025 CR, div. A, §1101(a)(8), 139 Stat. at 11

<sup>23</sup> *Activity Codes*, NIH (March 28, 2025), <https://grants.nih.gov/funding/activity-codes>; *see Funding Categories*, NIH (Feb. 3, 2025), <https://grants.nih.gov/funding/funding-categories>.

54. The NIH competitive grantmaking process begins with a notice of funding opportunity (NOFO)—*i.e.*, a public announcement in which NIH declares its intention to award funds and outlines the program goals and objectives and conditions for applying. *See* NIH Grants Policy Statement, U.S. Dep’t of Health & Hum. Servs. §2.3.5, at I-51 (Apr. 2024) (NIHGPS).

55. A researcher interested in responding to a NOFO will typically work with the “sponsored research” department at his or her institution to understand what NIH requires in its application submission. At UMass Medical School, for example, the Office of Sponsored Programs assists faculty and staff in locating sources of funding, reviewing and approving proposals, and negotiating grants and contracts.

56. Once a researcher develops a project proposal, that person then submits an electronic grant application to NIH. Applications must conform to 45 C.F.R. Part 75, and must include a detailed research plan outlining the study’s objectives, methodology, and significance; a proposed budget and justification; biosketches for key investigators; and any necessary compliance documentation, such as Institutional Review Board approval for human subject research.

57. A submitted grant application undergoes two layers of evaluation: an initial layer of review by a “scientific review group” (also known as a “study section”), followed by a round of review by an “advisory council.” *See* 42 U.S.C. §§284a, 289a; *see also* NIHGS §2.4, at I-71 (“The peer review system used by NIH, often referred to as the ‘dual review system,’ is based on two sequential levels of review for each application—initial review by [a study section], and a second level of review for scientific merit by the IC National Advisory Council/Board.”). According to NIH, this process “is intended to ensure that applications for funding submitted to NIH are evaluated on the basis of a process that is fair, equitable, timely, and conducted in a manner that strives to eliminate bias.” NIHGS §2.4, at I-71.

58. As noted, the first level of application review is carried out by a study section. The role of study sections is to assess applications' scientific merit and to determine the overall impact that proposed projects will likely have on the relevant field. Governing statutes and regulations require this layer of review—*i.e.*, a favorable study-section recommendation is a prerequisite to a final award of any NIH grant. *See* 42 U.S.C. §§ 284(b)(2)(B), 289a(a); 42 C.F.R. pt. 52h.

59. These groups consist primarily of non-federal scientists who have expertise in relevant scientific disciplines and current research areas. 42 C.F.R. §52h.4. NIH has hundreds of study sections, organized by specialty. In the field of Kidney, Urology, and Digestive Systems, for example, NIH maintains study sections on (1) Drug and Biologic Disposition and Toxicity; (2) Digestive System Host Defense, Microbial Interactions, and Immune and Inflammatory Diseases; (3) Digestive and Nutrient Physiology and Diseases; (4) Environmental Determinants of Disease; (5) Hepatobiliary Pathophysiology; (6) Kidney and Urological Systems Function and Dysfunction; and Pathobiology of Kidney Disease, as well as two “special emphasis panels” on Digestive Sciences Small Business Activities and Renal and Urological Sciences Small Business Activities. Some study sections are housed in NIH's individual institutions and centers, while others are organized centrally in the agency's Center for Scientific Review.

60. Study sections carry out their work—including review of pending applications—at regularly scheduled meetings. These meetings must be noticed in advance in the Federal Register. *See* 42 C.F.R. §52h.3 (“To the extent applicable, the Federal Advisory Committee Act, as amended . . . shall govern the establishment and operation of peer review groups.”); 5 U.S.C. §1009(a)(2) (“[T]imely notice of each meeting [subject to the Federal Advisory Committee Act] shall be published in the Federal Register . . .”).

61. Study sections review and score each grant application according to established criteria set forth in regulations and the NOFO. In particular, the study section assesses the overall impact that the project could have on the research field involved, taking into account:

- (a) The significance of the goals of the proposed research, from a scientific or technical standpoint;
- (b) The adequacy of the approach and methodology proposed to carry out the research;
- (c) The innovativeness and originality of the proposed research;
- (d) The qualifications and experience of the principal investigator and proposed staff;
- (e) The scientific environment and reasonable availability of resources necessary to the research;
- (f) The adequacy of plans to include both genders, minorities, children and special populations as appropriate for the scientific goals of the research;
- (g) The reasonableness of the proposed budget and duration in relation to the proposed research; and
- (h) The adequacy of the proposed protection for humans, animals, and the environment, to the extent they may be adversely affected by the project proposed in the application.

42 C.F.R. §52h.8; *see also* 42 C.F.R. §52a.5 (describing review criteria for NIH research center grants); 42 C.F.R. §52h.11 (describing review criteria for NIH research contracts).

62. As a result of that review, each grant application receives an “overall impact score” from 10 (the best score, denoting high impact) to 90 (the worst score, denoting low impact). Each application also receives a percentile rank expressing the impact score in relation to other applications in that particular institute. Projects deemed “unfundable” by the study section are not given a score and are removed from further consideration.

63. Each fiscal year, NIH’s institutes and centers publish guidance called “paylines” to help applicants interpret their study-section results. These paylines reflect a sort of cutoff: for each category of grants, the payline shows the impact score (or percentile) above which a project is highly likely to be funded. In Fiscal Year 2025, for example, published guidance from the National

Institute of Allergy and Infectious Diseases (NIAID) established a 12th-percentile payline for “R01” awards with new or early-stage principal investigators.<sup>24</sup> In other words, an applicant in that category who received a score from the relevant study section within the 12th percentile could anticipate that NIAID would likely fund his or her project. Study-section scores that meet or exceed the payline in this way are commonly referred to as “fundable” scores.

64. In addition to providing scores and percentiles, study sections also provide each applicant with a “summary statement” that contains, among other things, a brief summary of the study section’s discussion, bulleted critiques from assigned reviewers, and any administrative comments. Applicants can use these summary statements to revise applications and address concerns, if necessary.

65. As noted, the second level of application review is carried out by an advisory council. Unlike the numerous study sections, each NIH institute or center that funds grants has a single advisory council (*i.e.*, there is one advisory council for NIAID, one for the National Cancer Institute, and so on). By statute, NIH advisory councils must meet at least three times per fiscal year. 42 U.S.C. §284a(3). Like study section meetings, advisory council meetings must be noticed in advance in the Federal Register. *See* 41 C.F.R. §102-3.150 (requiring 15 days’ notice).

66. Whereas a study section’s review focuses on scientific merit, an advisory council’s review weighs programmatic and institute-wide considerations. A council considers, among other things, the extent to which an application aligns with the institute or center’s priorities, public health needs, and overall funding availability. The council also reviews the application for other potential barriers, such as ethical issues around human or animal test subjects.

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<sup>24</sup> *NIAID Paylines*, Nat’l Inst. of Allergy & Infectious Diseases (Dec. 17, 2024), <https://www.niaid.nih.gov/grants-contracts/niaid-paylines>.

67. An advisory council makes one of three decisions on each application: an application is recommended for funding, not recommended for funding, or deferred for re-review by the study section. A favorable recommendation from the relevant institute's advisory council is a prerequisite to final award of any grant in excess of \$50,000. 42 U.S.C. § 284(b)(2); *see also* §284a(a)(3)(A)(ii).

68. The advisory council makes funding recommendations to the institute or center director, who ultimately makes the funding decision. In making that decision, the institute or center director shall consider, consistent with the peer-review process: (i) the mission of the national research institute or national center and the scientific priorities identified in the institute or center's strategic plan; (ii) programs or projects funded by other agencies on similar research topics; and (iii) advice by staff and the advisory council or board of such national research institute or national center. 42 U.S.C. §284(b)(3).

69. If the decision is in favor of funding, NIH issues a legally binding Notice of Award (NOA) to the selected grant recipients stating that funds may be requested. NIHGMS §5, at IIA-59.

70. NIH typically does not issue grants as lump-sum awards. Instead, NIH uses a cost-based accounting system, under which grant recipients are authorized to recover their actual, documented costs for conducting research after the grant is awarded. Institutions can then use awards—and indeed, rely on those awards—to obtain a line or letter of credit for the procurement of the resources needed for the project.

71. If NIH approves a project with a multi-year period, the agency typically awards the grant for the first year (the “award year”) at the outset, with funding for subsequent years (the “out years”) subject to a renewal process. In these “noncompetitive” renewals, the application does not



undergo a fresh round of peer review—instead, applicants submit progress reports demonstrating that the grantee is making progress and complying with applicable policies and practices. *See* 42 C.F.R. §52a.6. So long as grantees demonstrate progress and compliance with applicable policies and practices, noncompetitive renewals are approved as a matter of course.

72. NIH’s application and award process follows a predictable calendar each year that is posted in advance. The agency has three standard application cycles per year, with published schedules identifying application due dates, the timing of study section and advisory council review, and the earliest permissible start date for the project. As reflected on the agency’s website,<sup>25</sup> the current triannual schedule is as follows:

<b>Review and Award Cycles</b>			
	<b>Cycle I</b>	<b>Cycle II</b>	<b>Cycle III</b>
Application Due Dates	January 25 - May 7	May 25 - September 7	September 25 - January 7
Scientific Merit Review	June - July	October - November	February - March
Advisory Council Round	August or October *	January	May
Earliest Project Start Date	September or December *	April	July

## **V. Plaintiffs’ Receipt of NIH Grants**

73. Plaintiffs’ state universities and colleges, as well as other research institutions, depend heavily on NIH funding to support biomedical and public health research. At any given time, individual research universities may depend on thousands of NIH grants that support independent research projects across multiple university facilities.

<sup>25</sup> *Standard Due Dates*, NIH (Aug. 23, 2024), <https://grants.nih.gov/grants-process/submit/submission-policies/standard-due-dates>.

74. Plaintiff Massachusetts operates the University of Massachusetts (UMass), the Commonwealth's flagship public research institution, which consists of the UMass Amherst, UMass Boston, UMass Dartmouth, UMass Lowell, and the UMass Chan Medical School. *See generally* Mass. G.L. c. 75, §1. In Fiscal Year 2024, UMass campuses collectively received \$248 million in NIH funding, supporting at least 501 projects.

75. The University of California (UC) is a corporation established by the California Constitution (Article IX, Sec. 9) located within the State of California; it is an exempt state government entity. The UC system consists of 10 research-intensive campuses, 21 health professional sciences schools, 5 NCI-designated cancer centers, and 6 academic medical centers. The UC system's constituent schools and institutions are widely recognized as among the best in the nation, serving as international leaders in the education of health professionals, the development of new cures and treatments, and the provision of healthcare for all Californians regardless of ability to pay. The University of California is one of the nation's leading research institutions, with almost 9% of all U.S. academic research being conducted by UC researchers. Biomedical advancements at UC include the first radiation treatment for cancer, research contributing to the first flu vaccine, the discovery of the role of LDL and HDL cholesterol in heart disease, the invention of modern gene editing, and much more. Every year, UC system researchers submit thousands of NIH grant applications, and the world-leading researchers on UC's faculty serve on numerous NIH study sections and advisory councils to assess grant applications for scientific and technical merit. NIH contracts and grant funding support many of the clinical trial studies at UC's six medical centers.

76. Federal funds are UC's single most important source of support for its research, accounting for more than half of UC's total research awards. In Fiscal Year 2024, UC received a

total of over \$2 billion in NIH contract and grant funding to support more than 5000 research projects. The estimated value of just the NIH grant proposals submitted by the five UC Health Centers as of December 31, 2024, that have not yet been acted upon is approximately \$563 million. Grant proposals awaiting study sections before July 1, 2025, have an annual value of approximately \$312 million, while grants awaiting advisory councils and Notices of Awards have an annual value of approximately \$251 million.

77. Plaintiff California also operates the California State Universities (CSU), the largest four-year public university system in the United States. CSU consists of 23 campuses, nearly a dozen off-campus centers, and over 90 auxiliary organizations (several dedicated to sponsored research). During Fiscal Year 2024, the CSU expended nearly \$90 million in NIH contract and grant funding to support approximately 250 projects across 18 universities with the total multi-year award funding in the hundreds of millions.

78. Plaintiff Maryland operates the University System of Maryland (USM), a system of 12 constituent institutions, including leading research institutions at the University of Maryland, Baltimore (UMB), and the University of Maryland, College Park (UMCP). In fiscal year 2024, UMB received \$213.9 million in active NIH awards and an additional \$34.2 million in NIH pass-through funding; UMCP received \$68 million in funding awarded directly by the NIH and \$9 million in funding awarded on a pass-through basis from the NIH.

79. Plaintiff Washington operates the University of Washington, the largest recipient of federal research funding of any public university in the country. In Fiscal Year 2024, University of Washington received over \$648 million in NIH funding, supporting over 1,220 projects.

80. Arizona State University, Northern Arizona University, and the University of Arizona are instrumentalities of the State of Arizona. In Fiscal Year 2024, those universities together managed approximately 425 NIH awards totaling over \$229 million.

81. Colorado established the University of Colorado Anschutz Medical Campus (CU Anschutz) as the only academic medical research campus in Colorado. *See generally* Colo. Rev. Stat. §23-21-101, *et. seq.* In Fiscal Year 2024, CU Anschutz received \$360 million in NIH funding, which represented 48% of all sponsored awards for the year.

82. Plaintiff Delaware's flagship research institution, The University of Delaware, received \$66 million in NIH funding, supporting 135 projects in Fiscal Year 2024.

83. Plaintiff Hawai'i operates the University of Hawai'i, which houses some 3,000 researchers and enrolls around 30,000 students across 10 campuses. The University of Hawai'i includes the John A. Burns School of Medicine, the University of Hawai'i Cancer Center, the Daniel K. Inouye School of Pharmacy, the School of Nursing and Dental Hygiene, the Thompson School of Social Work, and several other schools that conduct fundamental, translational, clinical and community-based participatory research in health sciences and health care. In Fiscal Year 2024, the University of Hawai'i received more than \$65 million in direct NIH funding, supporting 75 projects.

84. In Minnesota, according to NIH's own database, NIH has awarded tens of millions of dollars to institutions in Minnesota in 2025, primarily the Mayo Clinic and the University of Minnesota.

85. Nevada operates the Nevada System of Higher Education, which includes the University of Nevada, Las Vegas, and the University of Nevada, Reno. In Fiscal Year 2024, the

University of Nevada, Las Vegas received \$11.9 million and the University of Nevada, Reno received \$9.5 million dollars in NIH funding.

86. With respect to Plaintiff New Jersey, Rutgers, the State University of New Jersey, is a leading public research university located in New Jersey. Rutgers has a significant academic and clinical health sciences presence across the State, including numerous research centers and institutes, academic medical centers, and 29 schools and colleges, including colleges of liberal arts and sciences, a school of environmental and biological sciences, a school of engineering, a school of the arts, other professional schools, and graduate programs. In Fiscal Year 2024, Rutgers's campuses collectively received approximately \$250 million in NIH funding to support approximately 1,200 projects.

87. Plaintiff New Mexico operates the University of New Mexico (UNM), which is the state's flagship research university with research centers spanning the fundamental sciences, technology and engineering research, education, humanities and social sciences, and human health. UNM is the only academic health system in the state; it pursues research on improving human health, including substance use disorders, cardiovascular and metabolic disease, infectious diseases and immunity, Alzheimer's disease, kidney disease, cancer, and pediatrics, and more. This research was supported by \$107 million from the NIH in Fiscal Year 2024 and, through early February 2025, estimated NIH funding for Fiscal Year 2025 is over \$126 million

88. New York operates the State University of New York (SUNY), which is comprised of 64 colleges and universities, of which four campuses are designated R1 research institutions. In fiscal year 2024, SUNY received \$237.5 million from NIH to support 894 projects.

89. The Oregon Health and Science University (OHSU) is a public corporation of the State of Oregon and is Oregon's only public academic health center. OHSU is not the only public

recipient of NIH funding in Oregon, but it receives the largest amount of NIH funding. In fiscal year 2024, OHSU received over \$350 million in NIH funding to support 784 projects and over 1,400 researchers. The University of Oregon, Oregon State University, and Portland State University are also public recipients of NIH funding.

90. Plaintiff Rhode Island operates the University of Rhode Island (URI). URI is Rhode Island's flagship public institution. *See* 16 R.I. Gen. Laws Ann. §16-32-3. In fiscal year 2024, URI received \$22.1 million in NIH funding to support over 90 projects.

91. Plaintiff Wisconsin operates the Universities of Wisconsin, which includes prominent research institutions at the University of Wisconsin-Madison (UW-Madison) and University of Wisconsin-Milwaukee (UW-Milwaukee). UW-Madison's research enterprise is particularly robust, encompassing more than \$1.7 billion in annual research expenditures. Approximately one third of sponsored research at UW-Madison is awarded by the NIH. In fiscal year 2024, UW-Madison received direct funding from NIH to support 588 projects, totaling more than \$404 million. UW-Madison funds 4,942 researchers and staff through direct NIH grants, and its work on NIH-funded projects provides scientific education and research training in medical and health sciences, biology, public health, biochemistry, psychology, and other disciplines. In fiscal year 2024, UW-Milwaukee also received funding from NIH to support dozens of projects, totaling \$7.9 million.

### **CHALLENGED AGENCY ACTIONS**

92. This lawsuit arises because defendants are flouting the statutory and regulatory rules governing NIH grantmaking. As explained below, defendants have systematically disrupted the review of pending grant applications, delayed the annual renewal of already-approved multi-year awards, and terminated huge tranches of grants midyear through boilerplate notices. Those

disruptions have caused—and will continue to cause—significant harm to plaintiffs and their institutions.

**I. Executive Orders and Staff Guidance Regarding Topics and Subject Matter Disfavored by the Administration**

93. The present state of disruption traces its origin, at least in part, to a series of executive orders issued on or shortly after Inauguration Day.

94. On January 20, 2025, President Trump signed Executive Order 14151, entitled “Ending Radical Government DEI Programs and Preferencing” (DEI Order). The DEI Order aims to terminate any federal programs that promote “diversity, equity, and inclusion,” “diversity, equity, inclusion, and accessibility,” and “environmental justice.” The order does not define those terms. The order further directs “[e]ach agency, department, or commission head, in consultation with the Attorney General, the Director of OMB, and the Director of OPM” to “terminate, to the maximum extent allowed by law, . . . all . . . ‘equity-related’ grants or contracts.” DEI Order §2(b)(1). The order does not define “equity-related.”

95. The same day, the President signed Executive Order 14168, entitled “Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government” (Gender Ideology Order). The order denies the existence of transgender, nonbinary, intersex, or other gender-nonconforming people and rejects “gender ideology,” which it vaguely defines as “replac[ing] the biological category of sex with an ever-shifting concept of self-assessed gender identity, permitting the false claim that males can identify as and thus become women and vice versa, and requiring all institutions of society to regard this false claim as true.” Gender Ideology Order §§1-2. The order directs all federal agencies to “take all necessary steps, as permitted by law, to” strip federal funds from anyone who promotes “gender ideology,”

demanding that “[e]ach agency shall assess grant conditions and grantee preferences and ensure grant funds do not promote gender ideology.” *Id.* §3(e), (g).

96. The following day, the President signed Executive Order 14173, entitled “Ending Illegal Discrimination and Restoring Merit-Based Opportunity” (Discrimination Order). The order targeted what it called “race- and sex-based preferences under the guise of so-called ‘diversity, equity, and inclusion’ (DEI) or ‘diversity, equity, inclusion, and accessibility’ (DEIA),” but again failed to define those terms. The order requires that “[t]he head of each agency shall include in every contract or grant award . . . [a] term requiring” any federal grant “recipient to certify that it does not operate any programs promoting DEI that violate any applicable Federal anti-discrimination laws.” *Id.* §3(b)(iv)(B). It also threatens civil False Claims Act enforcement against any grantee failing to comply with the Discrimination Order’s vague and undefined terms. *Id.* §3(b)(iv)(A). Likewise, the Discrimination Order threatens lawsuits against private entities that promote DEI. *Id.* §4(b)(v).

97. Defendants have subsequently issued staff guidance to and within NIH on the implementation of the Administration’s executive orders and policy objectives.

98. On February 10, Acting Secretary of Health and Human Services Dorothy Fink issued a new memorandum implementing the President’s Executive Orders related to DEI. That memorandum “DIRECT[ED]” all HHS personnel, including NIH, to “pause all payments made to . . . grantees related to DEI and similar programs for internal review for payment integrity. . . . [I]f after review, the Department has determined that a contract is inconsistent with Department priorities and no longer in the interest of government . . . grants may be terminated in accordance with federal law.”



99. Beginning no later than the second week of February, HHS developed a policy that required the termination of grants related to specific categories of research that were disfavored as a matter of Administration policy. These categories originally focused on “DEI-related” projects, but have evolved to include other disfavored categories, including projects related to gender identity, vaccine hesitancy, and COVID-19.

100. On February 10, 2025, Acting Secretary Fink issued a “Secretarial Directive on DEI-Related Funding,” which stated:

The Department of Health and Human Services has an obligation to ensure that taxpayer dollars are used to advance the best interests of the government. This includes avoiding the expenditure of federal funds on programs, or with contractors or vendors, that promote or take part in diversity, equity, and inclusion (“DEI”) initiatives or any other initiatives that discriminate on the basis of race, color, religion, sex, national origin, or another protected characteristic. Contracts and grants that support DEI and similar discriminatory programs can violate Federal civil rights law and are inconsistent with the Department's policy of improving the health and well-being of all Americans.

The directive went on to state:

For these reasons, pursuant to, among other authorities, FAR 12.403(b) and 49.101 and 45 C.F.R. §75.371- 372, the Secretary of Health and Human Services hereby DIRECTS as follows:

**Agency personnel shall briefly pause all payments made to contractors, vendors, and grantees related to DEI and similar programs for internal review for payment integrity. Such review shall include but not be limited to a review for fraud, waste, abuse, and a review of the overall contracts and grants to determine whether those contracts or grants are in the best interest of the government and consistent with current policy priorities. In addition, if after review the Department has determined that a contract is inconsistent with Department priorities and no longer in the interest of the government, such contracts may be terminated pursuant to the Department's authority to terminate for convenience contracts that are not “in the best interests of the Government,” see FAR 49.101(b); 12.403(b). Furthermore, grants may be terminated in accordance with federal law.**

The February 10 directive did not define the term “related to DEI and similar programs.”

101. On February 12, Mike Lauer, then NIH's Deputy Director for Extramural Research, sent a memo directing that "given recent court orders" in federal court actions related to funding freezes, NIH institutes and centers were "authorized, along with their respective grant management staff, to proceed with issuing awards for all competing, non-competing continuation, and administrative supplements . . . grants."

102. On February 13, Mr. Lauer instructed Chief Grants Management Officers that "[i]f the sole purpose of the grant . . . supports DEI activities, then the award must be fully restricted." It also called for "hard funding restrictions" where the program promotes initiatives that "discriminate" on the basis of race, sex, or other protected characteristics, without defining what constituted such discrimination in a research program. That day, Mr. Lauer resigned from his position with NIH. On information and belief, Mr. Lauer was forced out because of his memorandum the previous day.

103. On or about March 4, NIH issued an updated guidance on "Award Assessments for Alignment with Agency Priorities." It provided staff with the language that terminations must include when a grant is terminated for relation to China, DEI, or "[t]ransgender issues."

104. The March 4 guidance also provided that "diversity supplements" would be canceled and not issued going forward. Diversity Supplements are grants meant to increase diversity in the scientific profession by providing training, mentorship and career development opportunities to individuals from underrepresented populations. In recent notices of funding opportunity, NIH has defined diversity broadly, to include not only "[i]ndividuals from racial and ethnic groups that have been shown by the [National Science Foundation] to be underrepresented in health-related sciences on a national basis," but also "[i]ndividuals with disabilities," and

“[i]ndividuals from disadvantaged backgrounds,” including those who have experienced homelessness, who were in foster care, who experienced poverty, or who are from rural areas.<sup>26</sup>

105. By March 13, the list of scientific research disfavored by the Administration had grown to include yet another topic—vaccine hesitancy—and NIH’s termination of awarded grants grew dramatically. On March 13, 2025, Michelle Bulls, NIH’s Chief Grants Management Officer, instructed the individual institutes on how to issue termination letters, and on what bases. Ms. Bulls instructed that termination letters should include the following language: “It is the policy of NIH not to prioritize [insert termination category language]. Therefore, this project is terminated.” The termination category language that Ms. Bulls provided included terminations for a program’s relation to DEI, gender, and vaccine hesitancy. Hundreds of NIH grants were terminated in the ensuing days.<sup>27</sup>

106. On information and belief, on or before March 19, the Office of Extramural Research (OER) and the Office of Policy for Extramural Research Administration (OPERA) provided additional guidance on how ICs should process grant terminations and communicate with grant recipients regarding such terminations. Included in these instructions was the instruction to speak only of “changes in NIH and/or HHS priorities” and an instruction to “not refer to any Executive Orders.”

107. On March 25, NIH again distributed updated guidance on grant terminations—yet again expanding the list of politically disfavored subject matters. The language for grant terminations continued to include language on DEI, transgender issues, and vaccine hesitancy, but now included yet another topic—COVID-19. As to COVID, the guidance stated that: “The end

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<sup>26</sup> *PA-20-222: Research Supplements to Promote Diversity in Health-Related Research*, NIH, <https://grants.nih.gov/grants/guide/pa-files/pa-20-222.html>.

<sup>27</sup> *HHS Grants Terminated*, HHS, [https://taggs.hhs.gov/Content/Data/HHS\\_Grants\\_Terminated.pdf](https://taggs.hhs.gov/Content/Data/HHS_Grants_Terminated.pdf).

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

## **II. Defendants’ Disruption of Review and Disposition of Pending Applications**

### **A. Delay and Withholding of Advisory Council and Study Section Meetings**

108. As explained above, NIH’s own guidance states that “Cycle II” grant applications, which underwent study-section review last fall, were originally scheduled to have undergone advisory-council review in January of this year. *See supra*, paragraph 72. And “Cycle III” applications, which researchers submitted to NIH last fall, were scheduled to have undergone study-section review in February and March of this year. *See id.* Almost none of that has happened.

109. Although meetings for the advisory councils of 21 different institutes and centers had been scheduled for January and February 2025 via publications in the Federal Register, all but one were abruptly canceled after Inauguration Day. (The remaining meeting, for the advisory council of the National Institute of Child Health and Human Development, had already taken place on January 13, 2025, *i.e.*, seven days before the change in Administration.)

110. Similarly, over 230 study-section meetings that had been scheduled for January and February 2025 via publications in the Federal Register were likewise cancelled after Inauguration Day—often with just a day’s notice (and no notice of cancellation in the Federal Register). In contrast, in prior years cancellations and amendments to noticed meetings were rare. According to an analysis of Federal Register notices, only an average of four cancellation notices were issued each year between Fiscal Years 2010 and 2024, and even amendments—which typically provide a new date immediately—were uncommon, with an average of around 100 each year.

111. Between January 21 and March 3, defendants also suspended the scheduling of future advisory-council or study-section meetings; no notices for future meetings appeared in the Federal Register during that time. On January 21, 2025, Acting Secretary Fink issued a memorandum directing, among other things, that no notices be submitted for publication to the Federal Register unless approved by a presidential appointee. On February 7, 2025, upon information and belief, an NIH official emailed a researcher that submissions to the Federal Register “are now on hold indefinitely.” Throughout February (and continuing into March), multiple webpages from the NIH institutes stated: “At the present time, all Federal advisory committee meetings have been canceled until further notice. Additional information will be forthcoming as it becomes available. We apologize for any inconvenience.”

112. Defendants resumed publishing notices of upcoming study-section and advisory-council meetings in the Federal Register in early March, but the number of meetings scheduled for this fiscal year remains at a level far below the number of such meetings in every fiscal year since 2010, and even further below the number that would be required to make up for the meetings not held in January and February.

113. Based on an analysis of notices posted in the Federal Register, defendants have held around 770 study section meetings to review grant applications in Fiscal Year 2025 to date. That represents a sharp and unprecedented drop from prior years. From Fiscal Years 2010 through 2024, NIH held between approximately 1,390 and 1,600 meetings over the same period, with an average of about 1,480. The Fiscal Year 2025 figure thus reflects a decline of nearly 50% relative to that historical baseline. That same analysis shows that defendants have held only *three* advisory committee meetings to review grant applications to date in Fiscal Year 2025; from Fiscal Years

2010 through 2024, NIH held between 20 and 30 meetings over the same time period, with an average of about 26.

114. Despite the shortfalls and cancellations, defendants are not picking up the pace. The number of study section meetings held in February and March for Fiscal Years 2010 through 2024 ranged between around 630 and 750, with an average of around 680. While almost no meetings were held during that period this fiscal year, there are still only around 540 study section meetings scheduled for April or May of this year—meaning defendants are still well behind where they need to be to catch up. In other words, defendants continue to fall short of the historical cadence for scientific peer review—even though, to make up for the previous delays and cancellations, they would have to be nearly doubling that cadence for the remainder of the fiscal year.

115. According to NIH’s contemplated schedule, some Cycle II projects were to start in April 2025. For example, multiple UMass grant applications from Cycle II—with anticipated project start dates on or around April 1, 2025—received fundable scores from their study sections and yet remain in limbo because the relevant January advisory-council meeting was canceled.

**B. Delay and Withholding of Final Disposition of Awards**

116. In addition to their frustration of the activity of study sections and advisory councils, defendants have also been systematically delaying and withholding final decisions on applications that have already received favorable scores and recommendations from the relevant study section and/or advisory council.

117. Upon information and belief, defendants maintained a total freeze on the issuance of new notices of award, including for non-competing renewals, from January 28, 2025, to February 28, 2025.

118. Defendants appear to no longer maintain a total freeze on the issuance of all new NOAs. However, upon information and belief, defendants are still delaying final decisions on applications in order to conduct a review of applications for their relation to subjects and topics disfavored by the Administration. This review process has resulted in a delay on rendering final dispositions and award decisions on pending application.

119. Upon information and belief, NIH's layoffs of the grant management, programmatic, and scientific staff that advance the grant application and peer review process have exacerbated, and will further exacerbate, these funding delays. NIHGPS §2.1.1, at I-44. The current Administration fired approximately 1,200 probationary workers at NIH, including those scientific, programmatic, and grant management staff members who worked directly on, and were in charge of, grant approvals, renewals, and disbursements. HHS has started to lay off an additional 1,200 NIH employees.<sup>28</sup> A third round of layoffs is expected by September 30, 2025.<sup>29</sup>

120. In addition, upon information and belief, the recent layoffs included the directors of individual NIH institutes and centers who are responsible for signing off on final grant funding decisions. 42 U.S.C. §284(b)(3). On April 1, 2025, the directors, including acting directors, of the National Institute of Allergy and Infectious Diseases (NIAID), the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), the National Institute on Minority Health and Health Disparities (NIMHD), the National Institute of Nursing Research (NINR), and National Human Genome Research Institute (NHGRI) either were placed on administrative leave or offered reassignment to the Indian Health Service in distant States. These

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<sup>28</sup> Liz Essley Whyte & Natalie Andrews, *RFK Jr. Plans 10,000 Job Cuts in Major Restructuring of Health Department*, Wall Street J. (Mar. 27, 2025), <https://www.wsj.com/politics/policy/rfk-jr-plans-10-000-job-cuts-in-major-restructuring-of-health-department-bdec28b0>.

<sup>29</sup> Megan Molteni et al., *Five NIH Institute Directors and Numerous Lab Heads Ousted in Unprecedented Shake-up*, STAT (Apr. 2, 2025), <https://www.statnews.com/2025/04/01/nih-rif-1200-layoffs-raise-concerns-health-medicine-biomedical-research>.

institutes' directors were responsible for at least \$9 billion in annual Congressional appropriations.<sup>30</sup> These layoffs appear targeted at institutes and centers either established by Congress for purposes that conflict with policies disfavored by the Administration, or which have conducted research on topics disfavored by the Administration.

121. As described in greater detail below (*see infra*, paragraphs 143-185), plaintiffs are awaiting a decision on hundreds of applications currently pending before the agency (“Delayed Applications”)—including many applications that received favorable reviews from the relevant study section and/or advisory council.

### **C. Delay and Withholding of Renewal of Awards**

122. On information and belief, the guidance on reconciling grant awards with the political objectives of the Administration has likewise governed NIH’s review of applications for grant renewals by current grant recipients. On information and belief, defendants have required NIH staff to review grant renewal applications to determine whether they relate to subjects that are disfavored by the Administration, which itself has resulted in substantial delays in rendering decisions on applications for grant renewals.

123. As of April 1, plaintiffs are awaiting decision on noncompetitive renewals that otherwise meet the criteria for renewal but that defendants have declined to process in the ordinary course (“Delayed Renewals”).

124. For example, as of April 1, University of Washington is experiencing delayed renewal of 73 grants totaling over \$61 million. Some of these renewals have been delayed for months, with the resulting funding disruptions undermining the University’s budgeting, forcing

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<sup>30</sup> Max Kozlov, *One of the Darkest Days’: NIH Purges Agency Leadership amid Mass Layoffs*, Nature (Apr. 1, 2025), <https://www.nature.com/articles/d41586-025-01016-z>.



pauses in research, and requiring the University to resort to furloughs, staff reductions, and planned layoffs.

### **III. Defendants' Removal of Notices of Funding Opportunities**

125. Upon information and belief, no later than January 31, NIH's institutes and centers were informed that specific Notices of Funding Opportunity were being withdrawn and cancelled. Similarly, upon information and belief, NIH only published three NOFOs between January 20 and March 26.<sup>31</sup>

126. The withdrawal of NOFOs continued on the grounds, *inter alia*, that the research opportunities involved DEI or gender.

127. The withdrawal of NOFOs occurred in the form of "unpublishing" the NOFOs, referred at times to the "disappearing" of NOFOs.

128. At least some of these NOFOs were withdrawn after grant applications had been submitted in response to them.

### **IV. Defendants' Termination of Already-Issued Grants Based on Previously Undisclosed Policy Priorities Disfavoring Particular Research Subjects**

129. Based on the categories of disfavored topics, the Administration's Executive Orders and political positions, and the guidance of HHS and NIH officers, defendants have terminated more than one hundred grants to plaintiffs' instrumentalities on the grounds that they relate to these disfavored political categories ("Terminated Grants").

130. On or about February 10, NIH provided individual institutes with a list of grants that were to be terminated. On information and belief, the decision to terminate these grants was

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<sup>31</sup> Sara Reardon, *Trump Officials Will Screen NIH Funding Opportunities*, Science (Mar. 26, 2025) (stating that "NIH only published three NOFOs between 20 January and 26 March, compared with 163 in 2023 and 147 in 2024 between the same dates"), <https://www.science.org/content/article/trump-officials-will-screen-nih-funding-opportunities>.

based on Acting Secretary Fink’s February 10 directive and on direction from the Executive Office of the President.

131. On February 28, a post on the Department of Government Efficiency’s official X account announced the cancellation of numerous NIH grants related to China, racial health disparities, and gender-affirming care:



132. The decision to terminate Diversity Supplements not only undermines NIH’s previously stated goal to promote diversity in the scientists, but it also actively harms diverse candidates. This is because, until recently, NIH has been issuing NOFOs for workforce development grants in pairs, with both a “standard” NOFO and a “diversity” NOFO, allowing individuals to self-identify as diverse. But now that Diversity Supplements are being cancelled and not funded, people who identified as diverse in their applications are not even eligible for funding, while people who did not identify as diverse remain eligible.

133. On information and belief, on or about March 4, HHS identified additional NIH grants that were to be terminated based on the topics disfavored by the Administration, which NIH's OER then communicated to the individual institutes.

134. On information and belief, on or about March 12, 2025, NIH provided staff at the individual institutes with a list of grants to be terminated, which were identified based on the factors identified in the March 4 Staff Guidance.

135. In an email dated March 13, 2025, Michelle Bulls instructed Chief Grants Management Officers on how to issue termination letters. Bulls instructed that termination letters should include the following language: "It is the policy of NIH not to prioritize [insert termination category language]. Therefore, this project is terminated." The instructions included the language that termination letters should include for the disfavored category on which the termination was based, including the following:

- DEI: Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.
- Gender: Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.
- Vaccine Hesitancy: It is the policy of NIH not to prioritize research activities that focuses gaining scientific knowledge on why individuals are hesitant to be vaccinated and/or explore ways to improve vaccine interest and commitment. NIH is obligated to carefully steward grant awards to ensure taxpayer dollars are used in ways that benefit the American people and improve their quality of life. Your project does not satisfy these criteria.

136. On information and belief, on or about March 14, Bulls met with Chief Grants Management Officers and reported approximately 945 terminated grants. Bulls forwarded the grant terminations to ICs in batches for issuance of termination letters.

137. On information and belief, NIH has terminated more than 100 grants at plaintiffs' public institutions since January 20, 2025, on the grounds that the grants' research programs relate to subject matters that the Administration does not want as the subject of scientific inquiry.

138. Plaintiffs' universities have received grant termination letters that include the boilerplate termination language provided by Bulls to the ICs.

139. These grants support a wide range of scientific inquiry, and were awarded after a thorough review process for scientific merit, consistency with agency priorities and other qualities.

140. On information and belief, the decision to terminate each of these grants was made without the input—or even knowledge—of the NIH program officers who manage the grants. In other words, NIH terminated these grants without consulting with the NIH career scientists with scientific knowledge about the research being funded.

141. On information and belief, to date, NIH has yet to identify any basis for its alleged changes in priorities, other than the Executive Orders and the Administration's political views on certain foreign countries, vaccine hesitancy, and the COVID-19 pandemic.

### **IMPACT OF THE CHALLENGED AGENCY ACTIONS**

142. Institutions in each of the plaintiff states have experienced delays and other funding disruptions as a result of the agency action.

#### **I. Harms to Massachusetts**

143. UMass has directly experienced harm as a result of defendants' treatment of the Delayed Applications.

144. As of March 31, 2025, UMass has 353 applications for NIH funding that are overdue for review based on NIH's published schedule of cycles. Of these (a) 272 are awaiting study section review; (b) 43 have received fundable scores from study section review and are awaiting advisory council review; (c) 14 have received possibly fundable scores from study section review and are awaiting advisory council review; and (d) 18 have received fundable scores and been reviewed an advisory council but have not been notified of a final determination on funding. In total, \$848,332,898 in sought funding is awaiting approval across all active applications, \$133,234,318 of which is for projects that have already been scored as fundable.

145. A project entitled, "Elucidation of the mechanisms by which Ms4a genes regulate neurodegeneration in Alzheimer's Disease and related disorders," grant number R01AG089801, is representative of the delays UMass has experienced. One major obstacle of treating Alzheimer's Disease is the paucity of genetic targets against which to direct therapeutic efforts; this project aims to investigate a recent and promising gene which could inform the development of new treatments for this and other neurodegenerative diseases. UMass researchers submitted the application for this grant on July 9, 2024, with an anticipated start date of April 1, 2025. Study section review placed it in the 13th percentile of all contemporaneous projects submitted to the IC, which has a payline of 17th percentile—thus, this was a fundable study with an overwhelming likelihood of receiving funding. This project was scheduled for advisory council review on January 28, 2025; that session was canceled, then rescheduled for April 22, 2025, three weeks after the project was intended to begin. In preparation for the start date of this grant, UMass Chan Medical School hired two postdoctoral fellows, which is standard practice and timing for this manner of research. Additionally, a significant number of genetically modified mouse cell lines had to be bred and aged so that neurogenerative phenotypes would appear. Due to the delay in

evaluating this grant, UMass must continue funding these preparatory steps well into the life of the project with the uncertainty that funding will arrive, or else scrap this promising research project entirely, foreclosing research into a promising area of new treatment for sufferers of Alzheimer's Disease and related diseases.

146. Delays in funding decisions and evaluation of applications have already caused numerous and critical harms to UMass. Due to uncertainty of the funding of multiple projects ranked as fundable, UMass schools have made dramatic cuts to the size of programs that rely significantly on NIH support. UMass Chan Medical School has rescinded acceptances to the vast majority of students admitted to its PhD program in Biomedical Sciences, reducing that program from 80 to approximately 12. UMass Amherst has reduced Fall 2025 graduate admissions to its doctoral programs from 997 admittees to 712, rescinding financial awards to many of those admitted. UMass Amherst has arranged for emergency funding to cushion the impact of interrupted federal funding and maintain salary support for affected graduate students and trainees. This relief is aimed at bridging those personnel to give them time to complete their graduate programs or to secure other funding or employment. These funds are being diverted from other important needs, such as deferred maintenance, strategic investments, and repayment of bond funds.

147. Additionally, numerous irreparable harms impend. UMass Amherst is currently considering rescinding offers of funding to some students admitted to doctoral programs. Future recruitment of doctoral students, postdoctoral researchers, faculty, and staff will be negatively impacted by diminished funding. And without incoming streams of grant funds and the attached facilities costs used to oversee the research facilities which make these projects possible and economically viable, UMass will risk a reduced ability to meet existing obligations to repay bond

funds used to construct those facilities. Any reduction in the university's bond rating will in turn increase the expense of augmenting research facilities in the future.

148. UMass has had four active grants terminated, as well as two passthrough awards, without warning or cause, all on March 21, 2025. These include a study on the effects of the quality of behavioral health care on children, "Effect of Medicaid accountable care organizations on behavioral health care quality and outcomes for children," award number 3R01MH134176-02S1, funded for \$99,974; and three studies aimed at understanding and reducing the spread of HIV amongst different vulnerable populations: "Optimizing an mHealth intervention to improve uptake and adherence of the HIV pre-exposure prophylaxis (PrEP) in vulnerable adolescents and emerging adults," award number 5R33HD107988-04, with an award of \$278,952; "Adapting mHealth interventions to improve self-management of HIV and substance use among emerging adults in Zambia," award number 5R34MH124081-02, with an award of \$671,459; and "Applying deep learning for predicting retention in PrEP care and effective PrEP use among key populations at risk for HIV in Thailand," award number 5R03MH130275-02, with an award of \$76,214. In the two other terminated grants—"Faithful response II: COVID-19 rapid test-to-treat with African American churches," award number U01MD018310, with an award of approximately \$126,000; and "Training the long-term services and supports dementia care workforce in provision of care to sexual and gender minority residents," award number 3R01AG075734-02S1, with an award of approximately \$65,000—UMass was the subawardee.

149. UMass has also had ten applications for grants summarily denied without any form of scientific review. These include grants submitted in response to subsequently withdrawn NOFOs, including PAR-23-271, PAR-21-358, and PAR-24-077.

## II. Harms to California

150. California has experienced direct and irreparable harm as a result of the grant terminations and blockage of NIH funding. Disruptions in the conduct of biomedical research and training in California directly impact the employment and economic well-being of the biotechnology and pharmaceutical industries headquartered in California. NIH grant terminations and funding delays have deterred prospective students and faculty who would have otherwise worked at universities and companies in California. Also, California has a direct interest in the health and safety of its residents, the prevention of both chronic and communicable diseases in the State, and in the State's economic wellbeing. The termination of NIH funding into research interventions to prevent or treat the spread of HIV/AIDS, sexually transmitted illnesses, COVID-19, and other virus families of pandemic concern—including diseases of emerging concern such as Dengue, Chikungunya, and Zika—and shingles, increases the risk of and incidence of these diseases in California. The terminations have specifically targeted some of the most vulnerable Californians, including women experiencing domestic violence, children at risk of suicide, and minorities at a higher risk of chronic or infectious diseases.

151. Since February 20, 2025, UC has had at least 31 NIH grants terminated, amounting to over \$37 million. Among these was a grant for a UC Davis research project investigating the biological risk factors for dementia among target populations with early signs of cognitive dysfunction, including white, Hispanic, and black participants that had already enrolled over 1,700 participants, and a grant to UCSF Professor Nisha Acharya who studied the effectiveness and potential adverse effects of a vaccine for shingles, a disease that one in three Americans are likely to develop in their lifetimes.

152. As a result, the delays in funding decisions and evaluation of applications and terminations have already caused numerous and critical harms to the UC.



153. First, the UC system has instituted a system-wide hiring freeze on new faculty and staff. Top-ranked departments across UC campuses in chemistry, biology, public health, and more may reduce their graduate student classes. UC departments have had to consider rescinding offers of funding to some students admitted to doctoral programs. To the extent possible, UC has arranged for emergency funding to cushion the impact of interrupted federal funding and maintain salary support for affected graduate students and trainees. This relief is aimed at bridging those personnel to give them time to complete their graduate programs or to secure other funding or employment.

154. These funds are being diverted from other important needs, such as deferred maintenance and strategic investments. These expected grant funds are also necessary to the research facilities that make these projects possible and economically viable.

155. Second, the delays in funding and terminations harm the UC's educational and research mission. Doctoral students, postdoctoral researchers, faculty, and staff from around the world collaborate with or come to California to join the UC research enterprise. Future recruitment of these young scientists and researchers will be negatively impacted by diminished funding and arbitrary terminations aimed at international collaboration and research projects. Further, terminations have specifically impacted the communities that come to the UC system for clinical trials and other community health interventions. Midstream terminations of long-term projects meant to reduce health disparities in projects like maternal mortality, the spread of HIV/AIDS, and services to other underserved communities directly undermines the trust necessary to convince individuals to participate in UC research projects.

156. Since February 20, 2025, the CSU has received at least 17 termination notices, including 5 where it serves as the primary awardee. They collectively amount to a loss of nearly

\$7 million in budgeted funding to the CSU, but CSU estimates the number may be much higher as grants continue to be cancelled. One of its universities, San Diego State University (SDSU) alone currently has 23 non-competing renewals pending action by the grants office to authorize the next segment of funding, 34 new proposals and competing renewals totaling approximate \$16 million awaiting NIH study section review, and 10 new proposals and competing renewals totaling approximately \$3.2 million that received fundable scores awaiting NIH advisory council and Notice of Award.

157. Over the last fifteen years, CSU campuses have made concerted investments in student training, faculty hiring, and institutional support of medical and public health research. Delays in NIH funding decisions and evaluation of applications and terminations now endanger all of those efforts. SDSU, for example, has instituted a hiring freeze on new faculty and staff, and will now defer long-term research projects. Terminations over grants studying health disparities and sexual and minority health have directly impacted the salaries of SDSU staff, faculty, and students. Without NIH funding, some students may need to discontinue their studies and in the case of international students, leave the country.

158. The damage from grant terminations to CSU campuses' relationship with the surrounding community and patients is similarly irreparable. For example, federally funded studies establish that sexual and gender minority youth are at a higher risk of suicide and suicide ideation.<sup>32</sup> Yet one of the grants terminated funded suicide prevention services to sexual and gender minority youth, and was terminated in the middle of their multi-year period without any opportunity to bridge individuals at high-risk of suicide to new services providers.

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<sup>32</sup> Jeremy W. Luk et al., *Sexual Minority Status and Age of Onset of Adolescent Suicide Ideation and Behavior*, 148 *Pediatrics*, no. 4 (2021), <https://pmc.ncbi.nlm.nih.gov/articles/PMC9446478>.

159. CSU campuses to date have received no funding or direction from NIH concerning the participants enrolled in terminated trials even where the potential for increased suicide attempts and subsequent death is high because every single participant in a study is at high risk for suicide. This is particularly damaging to CSU's relationship with the community health providers that often support enrollment in intervention studies.

160. The termination of the grants often means that researchers cannot fully evaluate whether an intervention is statistically effective—essentially wasting the valuable resources already expended and delaying scientific progress, stifling innovation, and impeding the development of new medical treatments, technologies, and public health initiatives.

161. Grant terminations, especially without warning, are also directly affecting students at the CSU. Graduate students, who are at the core of research laboratories, rely on NIH grants not only for resources to support research, but also for their own stipends, tuition support, and training programs. Sudden cuts have immediate and consequential impacts to these students, who often live paycheck to paycheck, putting their housing and basic needs at risk.

162. NIH grants also support undergraduate students at CSU. For example, the CSU U-RISE program is funded through a grant from the National Institute of General Medical Sciences and is meant to broaden perspectives in future scientific and biomedical research by identifying students' interest in pursuing research as a career and by providing training opportunities to be competitive for entering graduate programs. Students accepted into the U-RISE program receive trainee stipends to defray living expenses during research training experiences, and also support student trainee travel expenses to attend scientific meetings with their mentors and help defray university personnel expenses and supplies. At least 9 CSU universities received a notice from NIH stating that the university must "cease project activities as of the current budget period end

date of 3/31/2025,” and as a result these 9 CSU universities must immediately terminate stipends for students in the middle of the semester, causing participating students direct and significant harm, as their financial aid packages account for U-RISE stipends.

163. The impact from the termination of grants funding training programs like U-RISE is also profound. It inflicts emotional and academic distress upon students, damaging the pipeline of future researchers. The CSU, with limited resources, bears a disproportionate burden, exacerbating financial strain and competitive disadvantages.

### **III. Harms to Maryland**

164. Delays in the grant review process and terminations of existing grants have disrupted valuable research at Maryland’s research universities.

165. UMB has nearly 500 proposals totaling \$1.1 billion in the NIH review pipeline. This includes 380 proposals totaling \$1.04 billion awaiting study section review, 32 proposals totaling \$21.4 million that received fundable scores and are awaiting advisory council review, 12 proposals totaling \$37.5 million that received fundable scores and have been reviewed by NIH advisory councils, and 44 proposals totaling \$33.2 million that received possibly fundable scores and are awaiting advisory council review. UMCP has approximately 200 proposals pending with NIH, totaling about \$354 million.

166. The delays in the review process have harmed the universities in myriad ways, disrupting ongoing research, interfering with planning and budgeting, forcing the universities to divert resources from other needs, and restricting their ability to accept new graduate students and recruit and retain quality research trainees. The delays also directly harm patients and the public. Among the UMB studies that are stalled in the review process despite having already received fundable scores and undergone advisory council review are a clinical trial involving assisted living residents with Alzheimer’s disease and related dementias and another study that seeks to assist

selection of antidiabetic drugs for individual patients. One of UMCP's stalled submissions is the Bucharest Early Intervention Project, a landmark child development study that has followed a group of individuals, some of whom were raised in institutions, for more than 20 years. The study was reviewed by a study section in October 2024 and received a score of 12th percentile, but advisory council review has since been delayed three times.

167. Arbitrary grant terminations have also devastated research at UMB and UMCP. UMB has received termination notices for 11 NIH awards representing about \$15 million in lost research funding. One terminated grant funded a study at UMB involving more than 1000 human subjects who underwent diagnostic tests as part of the funded study. The human subjects consented to the study based on the understanding that they would be provided with test results that could be important to their health. The abrupt termination of the grant takes away federal funding for providing subjects with those test results. Another affected UMB project examined differences in brain and hormonal mechanisms between males and females in relation to pain conditions. The project earned the highest score in its study section. UMCP has received notice of termination of nine grants, representing about \$1 million in lost research funding. Examples of the affected studies include a study examining alcohol use among sexual orientation and gender identity minority youth and another study assessing the needs of persons who suffer biological disorders in sex development.

#### **IV. Harms to Washington**

168. The University of Washington has experienced significant harms as a result of defendants' delays and cancellations.

169. As of April 1, the University of Washington has more than 500 proposals awaiting NIH study section review. It has 54 proposals for \$138 million in total funding requested that received fundable scores, awaiting NIH advisory council and Notice of Award. And it has 76

proposals for \$260 million in total funding requested with fundable scores that for which the NIH advisory council has met or voted electronically to approve a grant for funding, but the NOA has not yet been issued.

170. Additionally, the University of Washington has 73 overdue non-competing renewals totaling over \$61 million that have yet to receive NOAs. Delays in this funding has already had potentially irreversible effects on the University of Washington. To take just one example, the University of Washington's Institute of Translational Health Sciences (ITHS) has been awaiting an overdue non-competing renewal on a \$10.5 million annual grant for over a month.

171. ITHS is a partnership between the University of Washington, Fred Hutchinson Cancer Center, Seattle Children's, and regional institutions to promote the translation of scientific discovery to clinical practice. One example of the innovative work performed at ITHS is the Gene & Cell Therapy Lab's (GCTL) accelerated development of a therapy to treat advanced ovarian cancer, called UltraCAR-T Cell therapy. Scientists in the GCTL worked with a biopharmaceutical company to transfer the technology so that the product could be made quickly and effectively. A separate unit of ITHS, the Translational Research Unit, conducted the rigorous clinical trials necessary to advance the technology towards a clinical use. But now, without funding for over thirty days, the University of Washington has been forced to institute staff reductions, furloughs, and elimination of positions at ITHS.

172. Other important research centers that are at risk because of delays in the grants review and award processes at NIH include the University of Washington's Alzheimer's Disease Research Center (ADRC), the Nathan Shock Center of Excellence (NSC) in the Basic Biology of Aging, and the joint University of Washington /Allen Center "*A multimodal brain cell atlas and*

*community resource of Alzheimer's disease and comorbid dementias.*” These Centers are funded by the National Institute on Aging (NIA) and received excellent scores during their reviews in study section in the fall. Because the NIA Council did not meet as scheduled in the January, these large grants were not approved for award. They all end in April or May and would leave large research teams without support. The work being done by these centers is longitudinal and lapse in funding will mean loss of critical cohorts that have been studied in some cases up to 40 years.

173. On top of these, University of Washington researchers have also had at least nine grants explicitly terminated by NIH, totaling over \$3 million to support innovative work in trauma research for victims of sexual assault, prevention of chlamydia infections, and the impact of air pollution on Alzheimer’s disease and related dementias, among other topics.

174. NIH’s delays and terminations have not only disrupted this critical research, they have also led to University-wide harms. The failure of NIH to communicate deviation from the normal funding application cycle for reviews and approval of funding means that research team which often plan grant applications years in advance to maintain necessary funding to support their research teams are left without consistent funding and in some cases are needing to furlough or layoff research team members. The University of Washington has paused some new hires whose research programs depend on timely NIH awards, including several where candidate interviews were already underway, and programs have been forced to reduce graduate admissions between 25 and 50%. Moreover, the terminations, delays, and unprecedented disruptions in funding have had a profoundly negative effect on morale University wide. Faculty and staff don’t know if their funding will be cut, if their research will be terminated, whether they will be able to attend conference, or even whether they will continue to have jobs. The stress of these funding disruptions is palpable and has negatively affected the University of Washington’s mission.

Research staff that are stressed about losing their jobs on a daily basis are not able to focus their full creative energy on innovation and discovery.

#### **V. Harms to the Remaining Plaintiffs**

175. In Arizona, multiple of Arizona State University's NIH-funded projects have been paused or terminated. Northern Arizona University received a termination notification of an award, "*Bridging Arizona Native American Students to Bachelor Degrees*," which funds a transfer program of students from two-year associate degree programs at Coconino Community College to four-year baccalaureate degree programs at Northern Arizona University. This program will cease for current students, jeopardizing the likelihood that they transfer to Northern Arizona University and complete a baccalaureate degree. Northern Arizona University has 34 proposals, representing approximately \$47 million, submitted to NIH for which it has not received a response.

176. CU Anschutz is Colorado's only public academic medical center. CU Anschutz has more than 500 research laboratories on campus pursuing their research mission. This work supports important basic science and clinical research, graduate students, clinical trials, and other work in a broad array of areas on the health spectrum. Currently, 479 doctoral graduate students are reliant on the grant funding of the institution to complete their education and work toward finding new discoveries. Upon information and belief, because of NIH's actions, CU Anschutz has experienced direct harm, including but not limited to: (1) A 23% decline in NIH grant awards for the period of time from January through March 2025 as compared to the period of time from January through March 2024, and (2) termination of numerous existing grant awards. CU Anschutz has received 18 NIH grant terminations to date with a total loss of funds of at least \$8,455,794.17. CU is a direct grantee of seven of those grants, totaling \$2,921,217.25 in funding loss. These grants would have funded CU Anschutz's continued work on a variety of health studies including hormones, vaccines, Alzheimer's disease and other important studies. CU is a



subgrantee on 11 additional grants terminated by NIH, totaling a funding loss of at least \$5,534,576.92. These grants would have continued to fund CU Anschutz's work and partnership with their grant sponsors on work related to antiviral measures, impact of environmental toxicants on diabetes, and adolescent medicine trials for HIV/AIDS interventions, among other studies.

177. The University of Delaware has directly experienced harm as a result of defendants' treatment of the Delayed Applications. As of March 31, 2025, the University of Delaware has: (a) 77 proposals totaling \$177 million awaiting NIH study section review; (b) at least 13 proposals totaling \$59.8 million that received fundable scores, awaiting NIH advisory council and Notice of Award; and (c) 102 proposals totaling \$234.9M that received possibly fundable scores, awaiting NIH advisory council and Notice of Award. "Since late January 2025, the University of Delaware has seen an unusual number of delays in the processing of NIH grant applications. Researchers have had their grant application study sections and advisory councils be canceled or otherwise not scheduled, and grant application scoring has been significantly delayed." The University of Delaware uses information regarding NIH grant applications and award rates to inform its graduate admissions process. Due to uncertainty of incoming grant funding related to the delays in reviewing and awarding grants by NIH, the various PhD programs at the University of Delaware that rely on NIH funding for graduate student support have reduced admission offers for their incoming class of graduate students by up to 50%. Such instability in funding "is affecting the recruitment and retention of high-caliber quality research trainees. The inability to retain quality research trainees will have ongoing effects on the research capabilities of the University of Delaware, including by limiting the individuals qualified to conduct certain research." The delays have disrupted ongoing research, as well as actively setting back the University of Delaware's ability to conduct critical research now and in the future. Funding gaps have already forced

researchers to abandon promising studies, miss key deadlines, or lose highly trained personnel. Some of these studies involve the use of animal test subjects, all of which would need to be terminated due to loss of funding. This results in not only ethical and financial losses but also wasted scientific opportunity, as experiments cannot simply be restarted once interrupted. In many cases, there is no way to recover the lost time, research continuity, or training value for graduate students and postdoctoral researchers once disrupted. Promising discoveries may be delayed indefinitely, and, in some cases, entirely lost.

178. Between March 21 and 31, 2025, the University of Hawai‘i received 2 notices of cancellation of direct NIH grants. The affected grants total approximately \$344,000. In addition, since late January of 2025, pending University of Hawai‘i grant applications have experienced unusual delays resulting in substantial uncertainty. As of March 30, 2025, the University of Hawai‘i had approximately 65 proposals awaiting NIH study section review. As of the same date, the University of Hawai‘i had 31 proposals that received fundable scores but are awaiting NIH advisory council review and a final decision whether to award the grant. These unusual delays in NIH processing are affecting University of Hawai‘i budgeting and planning for fiscal year 2025-2026, creating uncertainty around department budgets, teacher workload, and the hiring of additional faculty, teaching assistants and graduate assistants. As of March 31, 2025 the University of Hawai‘i had expended approximately \$18,000 in bridge funding to cover student payroll through the end of the current academic year.

179. As the result of three grant terminations, the University of Nevada, Las Vegas has lost \$2.4 million in research funding that supports projects focusing on, and advancing research related to, Alzheimer’s Disease. The funding losses limit access to research and findings on Alzheimer’s Disease. These grant terminations harm Nevada by defunding critical research that

advances public health and educational opportunities in Nevada. And although the University of Nevada, Reno has not reported receipt of any grant terminations, ongoing delays in review of numerous research proposals are negatively impacting the University's recruitment and retention efforts. This includes having to pause ongoing efforts to onboard new hires after the University had already provided those individuals with offer letters for positions with research programs that depend on timely NIH awards.

180. In New Jersey, Rutgers has directly experienced harm stemming from Defendants' termination of already-issued NIH grants. As of March 31, 2025, faculty and staff of Rutgers have received termination notices for at least four NIH grants. The total loss of funding to Rutgers as a result of these four NIH grant terminations is more than \$6 million. Numerous irreparable harms impend because of Defendants' terminations of these grants. Ongoing experiments have stopped, compromising components of the research. Community-based partnerships have also been stopped, including a project which would offer resources to adolescents and young adults at risk of suicide. And Rutgers may be forced to suspend hiring and reduce staff research hours.

181. In New Mexico, NIH has terminated four research training grants at UNM representing over \$9 million in lost research funding. These prestigious grants support vital biomedical workforce development programs that provide advanced training for UNM's students: (1) the Institutional Research and Academic Career Development Award (IRACDA) Post-Doctoral program trains post-doctoral fellows for research and teaching careers in academia; (2) the Leading Equity and Diversity in the Medical Scientist Training Program (LEAD MSTP) supports biomedical research training of UNM's MD/PhD students for developing the clinical research workforce, (3) the Initiative to Maximize Student Diversity at the University of New Mexico Health Sciences (IMSD) grant supports predoctoral trainees in the Biomedical Sciences

Graduate Program and (4) the Undergraduate Research Initiative for Student Enhancement (URISE) trains and prepares undergraduate students for doctoral programs and careers in biomedical research. These training grants provide structured training and mentorship programs as well as financial support, including tuition and stipends, to advance students' education and career opportunities in biomedical research; currently, UNM has approximately 50 students enrolled at different stages in these programs. Some of these programs have been at UNM for over 20 years. The aim of these training grants is to develop a group of professionals equipped with the technical, operational, and professional skills necessary for success as biomedical scientists, building capacity for groundbreaking research in New Mexico and representing our state's population in the biomedical workforce. NIH's termination of these grants harms New Mexico by threatening its future biomedical workforce in academia and industry.

182. SUNY has experienced direct harm as a result of the delays and terminations of NIH grants. For example, NIH had committed to five years of funding—a total of \$3,596,263—for a project that established a center to train and develop health equity researchers focused on health disparities in and around Buffalo. The grant had met and exceeded all of its milestones, but it was terminated on March 28, 2025. NIH also canceled grants funding research into HIV treatment and care in Ghana; the impact of peer victimization on health outcomes for LGBTQ+ youth; improving inclusivity of Alzheimer's Disease research; and cardiovascular disease risks among sexual and gender minorities.

183. In Oregon, OHSU has experienced both NIH grant notices of terminations and delays in the processing of grant applications. Since March 24, 2025, OHSU received notices of termination of one NIH grant awarded directly to OHSU and seven NIH grants awarded to other institutions that issued subawards to OHSU. These terminations will result in the loss of \$2.4

million in research funds to OHSU. OHSU has also experienced significant delay in its NIH application processing since January 2025. As of March 31, OHSU has approximately 280 proposals totaling over \$730 million awaiting NIH study section review. As of March 31, OHSU has 70 proposals that received fundable scores totaling \$172.4 million awaiting NIH advisory council meetings and notices of award. And it has 90 proposals that received possibly fundable scores totaling \$194.9 million awaiting NIH advisory council meetings and notices of award. These terminations and delays have disrupted ongoing research, graduate admissions processes, recruitment of key research personnel, and OHSU's ability to plan its operations. In many cases, once a study is disrupted, it is impossible to recover the lost time, research continuity, or training value of the study. As a result, studies with the potential to achieve breakthroughs in different disciplines and advance public health will simply not occur.

184. In Rhode Island, NIH has terminated two research grants at URI representing \$3.7 million in lost research funding. One grant funded innovative research that was aimed at advancing the public health of those living with HIV by contributing to the investigation of causal mechanisms among networks of populations at high risk for HIV infection compounded by illicit substance use. The other grant funded the University of Rhode Island's ESTEEMED Scholars Program, a program that provides students from underrepresented backgrounds with the skills and resources necessary to pursue advanced education and degree programs in bioengineering and related disciplines. The impact on student achievement and the inclusive environment at URI will be hit particularly hard. Without URI ESTEEMED, several of the current trainees would have had to drop out of URI due to the lack of academic support the program provided and the stipend that allowed them to focus on their academics and research instead of working an outside job. These grants funded research aimed at advancing public health research for some of the most vulnerable

in Rhode Island and allowing those from underrepresented backgrounds unparalleled academic opportunities. NIH's termination of these grants harms Rhode Island by defunding research that advances public health and educational opportunities.

185. In Wisconsin, as of March 31, 2025, NIH has terminated four research grants to UW-Madison. The total amount of funding anticipated under these awards is \$25,149,959, and of that amount, \$12,631,870 has not been disbursed to UW-Madison. These grants are to fund research on infectious disease, vaccine development, minority health disparities, and child health and human development. NIH has also terminated two research grants funding research at UW-Milwaukee regarding substance abuse, violence, and suicide prevention. In addition, since late January 2025, UW-Madison has seen an unusual number of delays in the processing of NIH grant applications, rendering institution-wide budgetary planning especially difficult as the budget process at UW-Madison relies upon the NIH grant application, review, and approval cycle. Delays in the review of pending grant applications creates uncertainty and disrupts the funding cycle necessary to maintain continuity of research projects and consistent staffing of trained researchers. In many cases, there is no way to recover the lost time, research continuity, or training value once research is disrupted. Some researchers at UW-Madison have already been unable to commit to bringing on graduate students or maintaining current trainees due to funding uncertainty, and if funding that historically would have been expected is not forthcoming, or funding is indeed terminated, certain research projects will need to be abandoned. For one particular award—an NIH Research Program Grant (P01) supporting three co-investigators—termination with no funding alternative would necessitate the termination of ten research staff (including a postdoctoral trainee) and interrupt the progress of forty undergraduate, graduate, and medical students towards their degrees. NIH's delays and/or cancellations of study sections and advisory council meetings

and grant terminations have thus harmed Wisconsin's universities. These actions further harm Wisconsin through the likely reduction of the future scientific workforce and by depriving Wisconsin and the broader community of critical biomedical research.

## **VI. Impact on Appropriated Funds**

186. Notwithstanding Congress's appropriation to NIH, as a result of the delays and terminations described above, NIH has not awarded billions of dollars in appropriated funding, with only a few months left of available funding.

187. Based on the publicly available NIH RePORTER database, in Weeks 4-11 of 2024 (*i.e.*, January 22, 2024, through March 15, 2024), NIH awarded a total of \$4.2 billion to 8,707 projects. By comparison, in Weeks 4-11 of 2025 (*i.e.*, January 20, 2025 through March 14, 2025), NIH awarded a total of \$2.2 billion to 4,448 projects—a reduction of approximately 50%.

188. Narrowing the focus to awards (and competing renewals) that require study section and advisory council review prior to award, in those same weeks, NIH awarded \$869 million to 2,016 projects in 2024 but only \$368 million to 772 projects in 2025. Focusing further still just on Weeks 6-11, the comparison is even more striking: 1,550 projects for \$693 million in 2024, compared with 376 projects for \$179 million in 2025, a reduction of approximately 75%.

## **CAUSES OF ACTION**

### **Count 1—Against All Defendants Administrative Procedure Act, 5 U.S.C. §706(1): Unlawful Withholding and/or Unreasonable Delay of Agency Action (As to Study Sections and Advisory Councils)**

189. Plaintiffs reallege and incorporate by reference the allegations contained in each of the preceding paragraphs as if fully set forth herein.

190. The APA authorizes a court to “compel agency action unlawfully withheld or unreasonably delayed.” 5 U.S.C. §706(1). Relief is warranted under this provision where an

agency completely fails to take, or unreasonably delays in taking, “a discrete agency action that it is required to take.” *Norton v. S. Utah Wilderness Alliance*, 542 U.S. 55, 64 (2004) (emphasis omitted); *see id.* at 63 n. 1.

191. By statute and regulation, the activities of NIH’s advisory councils—including the holding of council meetings, the review of pending grant applications by the relevant council, and the making of a final recommendation on each application by the relevant council—are discrete agency actions that NIH is required to take. The APA provides that, “within a reasonable time, each agency *shall* proceed to conclude a matter presented to it.” 5 U.S.C. §555(b) (emphasis added). And the PHSA states that each NIH institute’s advisory council “*shall* meet . . . at least three times each fiscal year,” 42 U.S.C. §284(e) (emphasis added), and that it “*shall* advise, assist, consult with, and make recommendations to the Secretary and the Director of such institute” on areas within the council’s jurisdiction, §284(a)(1) (emphasis added). The PHSA further provides that sign-off from an advisory council is a prerequisite to a final award of any grant in excess of \$50,000. 42 U.S.C. §284(b)(2); *see* 42 U.S.C. §284a(a)(3)(A)(ii). Likewise, under NIH regulations, “[a]ll applications” for NIH grants “*shall* be evaluated by the [HHS] Secretary [or his designee] through such officers and employees and such experts or consultants engaged for this purpose as the Secretary determines are specially qualified in the areas of research involved in the project, *including review by an appropriate National Advisory Council.*” 42 C.F.R. §52.5(a) (emphasis added); *see also* 42 C.F.R. §52a.5 (“NIH grants may be awarded generally only after approval recommendations from both appropriate scientific peer review groups and national advisory councils or boards.”). The regulations further provide that, “subject to approvals, recommendations or consultations by the appropriate National Advisory Council or other body as may be required by law, the Secretary *will* (1) approve, (2) defer because of either lack of funds or



a need for further evaluation, or (3) disapprove support of the proposed project in whole or in part.” *Id.* §52.5(b) (emphasis added).

192. By statute and regulation, the activities of NIH’s study sections—including the holding of section meetings, the review of pending grant applications by the relevant study section, and the making of a final recommendation on each application by the relevant study section—are likewise discrete agency actions that NIH is required to take. As discussed, the APA provides that, “within a reasonable time, each agency *shall* proceed to conclude a matter presented to it.” 5 U.S.C. §555(b) (emphasis added). The PHSA, for its part, provides that applications for NIH research grants shall undergo “technical and scientific peer review,” and that a favorable review is a prerequisite to a final award of any grant. 42 U.S.C. §§284(b)(2)(B), 289a(a). Regulations, in turn, provide for the creation of study groups and reiterate that “no awarding official shall award a grant . . . unless the application has been reviewed by a peer review group . . . and the group has made recommendations concerning the scientific merit of that application.” 42 C.F.R. §52h.7; *see generally* 42 C.F.R., pt. 52h. NIH regulations further provide that “[a]ll applications” for NIH grants “*shall* be evaluated by the [HHS] Secretary [or his designee], 42 C.F.R. §52.5(a) (emphasis added); and that that, “[o]n the basis of the Secretary [or his designee]’s evaluation of an application,” the Secretary “*will* (1) approve, (2) defer because of either lack of funds or a need for further evaluation, or (3) disapprove support of the proposed project in whole or in part,” *id.* §52.5(b) (emphasis added).

193. As discussed, defendants have cancelled and/or substantially delayed the above-described required activities of NIH’s advisory councils and study sections—a significant and unprecedented departure from the NIH’s published review process and the agency’s past practice.

194. The above-described cancellations and delays constitute unlawful withholding and/or unreasonable delay of agency action within the meaning of §706(1). *See, e.g., Rezaii v. Kennedy*, No. 1:24-cv-10838, 2025 WL 750215, at \*5 (D. Mass. Feb. 24, 2025) (holding that a plaintiff had pleaded unreasonable delay where, among other things, the agency’s delay in processing plaintiff’s application was “at the outer edge of HHS’s typical time for processing”); *Raouf v. U.S. Dep’t of State*, 702 F. Supp. 3d 19, 33 (D.N.H. 2023) (finding that a plaintiff had pleaded unreasonable delay where she alleged that the “delay [was] attributable to . . . an *ultra vires* internal policy for intentionally delaying issuance of visas”).

195. The above-described cancellations and delays have caused, are causing, and imminently threaten to cause direct, concrete, and irreparable harm to plaintiffs. As discussed above, the harms from these cancellations and delays of study section and advisory council meetings have included the reduction or rescission of graduate student admissions, the arrangement of emergency funding to cushion the impact from these interruptions, and the diversion of funding away from other important needs of plaintiffs’ universities.

196. For the foregoing reasons, plaintiffs are entitled to an order, and to a preliminary and permanent injunction, compelling defendants to undertake the activities of NIH’s advisory councils and study sections that defendants have unlawfully withheld and/or unreasonably delayed.

**Count 2—Against All Defendants**  
**Administrative Procedure Act, 5 U.S.C. §706(1):**  
**Unlawful Withholding and/or Unreasonable Delay of Agency Action**  
**(As to Delayed Applications)**

197. Plaintiffs reallege and incorporate by reference the allegations contained in each of the preceding paragraphs as if fully set forth herein.

198. As discussed, the APA authorizes a court to compel administrative agencies to undertake discrete, legally required actions that they have unlawfully withheld or unreasonably delayed. 5 U.S.C. §706(1); *see S. Utah Wilderness Alliance*, 542 U.S. at 63-64 & n. 1.

199. As discussed, NIH regulations provide that the HHS Secretary or his designee “shall” evaluate “[a]ll applications” and “will” either “approve,” formally “defer,” or “disapprove” those applications. 42 C.F.R. §52.5(a)-(b).

200. Defendants have failed to carry out those obligations with respect to the Delayed Applications. Instead, as described above, defendants have refused to process the Delayed Applications, including those of the Delayed Applications that have already received a “fundable” score from the relevant study section and/or a favorable recommendation from the relevant advisory council.

201. The above-described acts and omissions constitute unlawful withholding and/or unreasonable delay of agency action within the meaning of §706(1). *See, e.g., Rezaii*, 2025 WL 750215, at \*5; *Raouf*, 702 F. Supp. 3d at 33.

202. The above-described acts and omissions have caused, are causing, and imminently threaten to cause direct, concrete, and irreparable harm to plaintiffs. As discussed above, the harms from these delays in processing the Delayed Applications have included the reduction or rescission of graduate student admissions, the arrangement of emergency funding to cushion the impact from these interruptions, and the diversion of funding away from other important needs of plaintiffs’ universities.

203. For the foregoing reasons, plaintiffs are entitled to an order, and to a preliminary and permanent injunction, compelling defendants to undertake prompt review and issue a final decision on the Delayed Applications.

**Count 3—Against All Defendants**  
**Administrative Procedure Act, 5 U.S.C. §706(1):**  
**Unlawful Withholding and/or Unreasonable Delay of Agency Action**  
**(As to Delayed Renewals)**

204. Plaintiffs reallege and incorporate by reference the allegations contained in each of the preceding paragraphs as if fully set forth herein.

205. As discussed, the APA authorizes a court to compel administrative agencies to undertake discrete, legally required actions that they have unlawfully withheld or unreasonably delayed. 5 U.S.C. §706(1); *see S. Utah Wilderness Alliance*, 542 U.S. at 63-64 & n. 1.

206. As discussed, NIH regulations provide that the HHS Secretary or his designee “shall” evaluate “[a]ll applications” and “will” either “approve,” formally “defer,” or “disapprove” those applications. 42 C.F.R. §52.5(a)-(b); *see also* 45 C.F.R. §52.6(c) (allowing HHS to notice a grant award for a “project period,” during which HHS intends to support the project “without requiring the project to recompete for funds”).

207. Defendants have failed to carry out those obligations with respect to the Delayed Renewals, refusing to process those renewals even though they meet the requirement for renewal.

208. The above-described acts and omissions constitute unlawful withholding and/or unreasonable delay of agency action within the meaning of §706(1). *See, e.g., Rezaii*, 2025 WL 750215, at \*5; *Raouf*, 702 F. Supp. 3d at 33.

209. The above-described acts and omissions have caused, are causing, and imminently threaten to cause direct, concrete, and irreparable harm to plaintiffs. As discussed above, the harms from these delayed renewals have included the reduction or rescission of graduate student admissions, the arrangement of emergency funding to cushion the impact from these interruptions, and the diversion of funding away from other important needs of the plaintiffs’ universities.

210. For the foregoing reasons, plaintiffs are entitled to an order, and to a preliminary and permanent injunction, compelling defendants to undertake prompt review and issue a final decision on the Delayed Renewals.

**Count 4—Against All Defendants**  
**Administrative Procedure Act, 5 U.S.C. §706(2):**  
**Agency Action Contrary to Regulation**  
**(As to Terminated Grants)**

211. Plaintiffs reallege and incorporate by reference the allegations contained in each of the preceding paragraphs as if fully set forth herein.

212. The APA authorizes a court to “hold unlawful and set aside agency action, findings, and conclusions found to be “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law” and/or “without observance of procedure required by law.” 5 U.S.C. §706(2).

213. As discussed, defendants have invoked 2 CFR §200.340(a)(2) (2020) in canceling the Terminated Grants. However, that regulation does not apply here and does not authorize the cancellation of the Terminated Grants because (1) HHS-specific regulations, not §200.340, govern the termination of NIH awards, (2) even by its own terms, §200.340 does not empower an awarding agency to terminate a grant based on purported change in priorities that occurs after the grant is awarded, and (3) an agency may not invoke its “priorities” to cancel a grant under §200.340 unless the notice of award expressly included “priorities” as a possible basis for termination—something that did not happen with respect to the Terminated Grants.

214. Accordingly, plaintiffs are entitled to an order and judgment, and a preliminary and permanent injunction, holding unlawful and setting aside defendants’ termination of the Terminated Grants and the staff directives to and within NIH underlying the terminations.

**Count 5—Against All Defendants**  
**Administrative Procedure Act, 5 U.S.C. §706(2):**  
**Agency Action Contrary to Statute**  
**(As to Terminated Grants)**

215. Plaintiffs reallege and incorporate by reference the allegations contained in each of the preceding paragraphs as if fully set forth herein.

216. The APA requires a court to “hold unlawful and set aside agency action, findings, and conclusions found to be . . . in excess of statutory jurisdiction, authority, or limitations, or short of statutory right,” 5 U.S.C. §706(2)(C), or “otherwise not in accordance with law,” *id.* §706(2)(A).

217. In reviewing agency action, a court cannot accept “the agency’s policy judgments . . . if they conflict with the policy judgments that undergird the statutory scheme.” *Health Ins. Ass’n of Am., Inc. v. Shalala*, 23 F.3d 412, 416 (D.C. Cir. 1994); *see Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155, 176 (4th Cir. 1998), *aff’d*, 529 U.S. 120 (2000) (explaining that “federal agencies” cannot “substitute their policy judgments for those of Congress”).

218. Defendants have terminated certain of the Terminated Grants on the ground that they “no longer effectuate[] agency priorities” because, according to defendants, those grants support, or relate to, “DEI.”

219. These terminations are contrary to law and beyond statutory authority because they defy Congress’s statutory directives to NIH to support research through publicly promulgated priorities—including those directed to “DEI.”

220. Specifically, the mass terminations defy statutory directives which require that NIH and its respective ICs “shall” encourage and support research and are authorized to make grants to institutions and researchers for that purpose, *see* 42 U.S.C. §284(b)(1) (A), (b)(2)(A), and that the

NIH Director “shall,” for example, “encourage efforts to improve research related to the health of sexual and gender minority populations,” in conducting and supporting research. 42 U.S.C. §283p.

221. The mass terminations also defy statutory directives which require that NIH articulate its priorities via the NIH Strategic Plan, which NIH must develop, submit to the appropriate Committees of Congress, and post publicly, *see* 42 U.S.C. §282(m)(1), including the 2020 Strategic Plan’s policy stating that NIH would prioritize “improving minority health and reducing health disparities; enhancing women’s health; addressing public health challenges across the lifespan; promoting collaborative science; and leveraging data science for biomedical discovery,” as well as vaccine development.

222. Defendants’ mass terminations are also contrary to law because they likewise defy Congress’s consistent appropriation of funding to NIH’s Institutes and Centers to carry out their respective statutory purposes and public priorities.

223. NIH is flouting its statutory responsibilities by terminating so many grants with a dwindling opportunity to reallocate them, which will result in a substantial portion of Congress’s appropriation going unspent.

224. The terminations therefore are contrary to the statutes authorizing and appropriating funds for NIH research, and beyond Defendants’ statutory authority, and must be set aside.

225. Accordingly, plaintiffs are entitled to an order and judgment, and a preliminary and permanent injunction, holding unlawful and setting aside defendants’ termination of the Terminated Grants and the staff directives to and within NIH underlying the terminations.

**Count 6—Against All Defendants**  
**Administrative Procedure Act, 5 U.S.C. §706(2):**  
**Arbitrary and Capricious Agency Action**  
**(As to Terminated Grants)**

226. Plaintiffs reallege and incorporate by reference the allegations contained in each of the preceding paragraphs as if fully set forth herein.

227. The APA requires a court to “hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. §706(2)(A).

228. An agency action is arbitrary and capricious if the agency has “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). An agency action is also arbitrary and capricious if, when departing from a prior policy, an agency does not “display awareness that it *is* changing position” or does not “show that there are good reasons for the new policy.” *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009).

229. As described above, defendants have terminated the Terminated Grants on the ground that they “no longer effectuate[] agency priorities.” Defendants have communicated these termination decisions through boilerplate letters, using stock language, that state that each Terminated Grant “no longer effectuates agency priorities” given its perceived connection with certain subject matters (*e.g.*, “DEI” or “gender identity”).

230. Defendants’ termination decisions are arbitrary and capricious because their boilerplate letters do not acknowledge—let alone provide “good reasons for”—any official change



in agency policy. *Fox Television Stations*, 556 U.S. at 515. Indeed, this boilerplate language obfuscates the obvious, actual reason for the terminations: implementation of the President's Executive Orders and other policies. Such a patently false explanation does not satisfy the requirement to provide a reasoned basis for agency decisionmaking.

231. Defendants' termination decisions are arbitrary and capricious for the additional reason that they have not engaged in reasoned consideration of any individual project before terminating a grant.

232. Defendants' termination decisions are arbitrary and capricious for the additional reason that, in purporting to terminate the Terminated Grants, defendants failed to consider several important aspects of the issues before them, including, at a minimum (1) plaintiffs' reliance interests in the terminated projects, (2) whether those projects could be adjusted, rather than terminated, to comply with defendants' new "priorities" (assuming those new "priorities" were otherwise lawful), (3) whether defendants could have adopted a measure other than across-the-board termination of entire categories of grants to effectuate their new "priorities" (assuming those new "priorities" were otherwise lawful); (4) the harm that terminating the studies would inflict on human test subjects participating in the studies.

233. Defendants' termination decisions are arbitrary and capricious for the additional reason that, they have relied on factors which Congress has not intended them to consider, including considerations in conflict with the PHSA's directives in favor of diversity, equity, and inclusion.

234. Accordingly, plaintiffs are entitled to an order and judgment, and a preliminary and permanent injunction, holding unlawful and setting aside defendants' termination of the Terminated Grants and the staff directives to and within NIH underlying the terminations.

**Count 7—Against All Defendants**  
**Separation of Powers**  
**(As to Delayed Applications, Delayed Renewals, and Terminated Grants)**

235. Plaintiffs reallege and incorporate by reference the allegations contained in each of the preceding paragraphs as if fully set forth herein.

236. Federal courts possess the power in equity to grant injunctive relief “with respect to violations of federal law by federal officials.” *Armstrong v. Exceptional Child Ctr., Inc.*, 575 U.S. 320, 326-327 (2015).

237. The Constitution “grants the power of the purse to Congress, not the President.” *City & Cnty. of San Francisco v. Trump*, 897 F.3d 1225, 1231 (9th Cir. 2018); see U.S. Const. art. I, §9, cl. 7 (Appropriations Clause); U.S. Const. art. I, §8, cl. 1 (Spending Clause). “Among Congress’s most important authorities is its control of the purse.” *Biden v. Nebraska*, 143 S. Ct. 2355, 2375 (2023). “The Appropriations Clause is thus a bulwark of the Constitution’s separation of powers among the three branches of the National Government.” *U.S. Dep’t of Navy v. Fed. Lab. Rels. Auth.*, 665 F.3d 1339, 1347 (D.C. Cir. 2012) (Kavanaugh, J.). If not for the Appropriations Clause, “the executive would possess an unbounded power over the public purse of the nation.” *Id.* (internal citations omitted).

238. Congress also possesses exclusive power to legislate. Article I, Section 1 of the Constitution states that “[a]ll legislative Powers herein granted shall be vested in a Congress of the United States, which shall consist of a Senate and a House of Representatives.” U.S. Const. art. I, §1; see *Clinton v. City of New York*, 524 U.S. 417, 438 (1998) (“There is no provision in the Constitution that authorizes the President to enact, to amend, or to repeal statutes.”).

239. The Constitution further provides that the executive must “take Care that the Laws be faithfully executed.” U.S. Const. Art. II, Sec. 3; see *Util. Air Reg. Grp. v. EPA*, 573 U.S. 302,

327 (2014) (“Under our system of government, Congress makes the laws and the President . . . faithfully executes them.” (brackets and quotation marks omitted)).

240. The Executive Branch violates the Take Care Clause where it declines to execute or otherwise undermines statutes enacted by Congress and signed into law or duly promulgated regulations implementing such statutes. *See In re United Mine Workers of Am. Int’l Union*, 190 F.3d 545, 551 (D.C. Cir. 1999) (“[T]he President is without authority to set aside congressional legislation by executive order . . . .”); *Kendall v. United States*, 37 U.S. 524, 613 (1838) (rejecting argument that by charging the President with faithful execution of the laws, the Take Care clause “implies a power to forbid their execution”); *see also Util. Air. Reg. Grp.*, 573 U.S. at 327 (noting that the President “act[s] at time through agencies”).

241. Nor does any statute authorize the Executive’s action here. Congress consistently has appropriated funds to NIH’s ICs to further their statutory purposes of advancing and promoting medical research and has not authorized the Executive to decline to spend vast swaths of funds. Further, Congress has provided for a procedure by which the Executive may propose to Congress to either rescind or cancel funds. Congressional Budget and Impoundment Control Act of 1974, 2 U.S.C. §§682 *et seq.* That statute likewise does not permit the Executive to take unilateral action, instead requiring the President must “propose[]” any rescission to Congress (which Congress must then affirmatively approve) and may not defer funding for the policy reasons Defendants explicitly invoke here. 2 U.S.C. §§683, 684(a).

242. Accordingly, consistent with these principles, the Executive’s authority is at its “lowest ebb” because he is acting without constitutional authority and contrary to the will of Congress by attempting to unilaterally decline to spend appropriated funds. *See Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579, 637-638 (1952) (Jackson, J., concurring).

243. Defendants' pattern and policy of systematic delays and terminations—as reflected in their treatment of the Delayed Applications, Delayed Renewals, and Terminated Grants—therefore violates the separation-of-powers constraints described above. Through these actions, defendants have overridden the careful judgments of Congress by refusing to disburse duly appropriated funding.

244. The delays and terminations are also contrary to the principle that funding restrictions can only impose conditions that are reasonably related to the federal interest in the project and the project's objectives. *S. Dakota v. Dole*, 483 U.S. 203, 207, 208 (1987). Here, the delays and terminations are not related to the federal interest in NIH research—to support and encourage scientific research—and instead are related to policies and political factors. Indeed, the effect of these delays and terminations is to chill scientific research as they have subjected researchers and the administrators who support them to the fear that their ongoing research activities can and will be suspended based on shifting political objectives of the current Administration.

245. For the foregoing reasons, plaintiffs are entitled to a preliminary and permanent injunction barring defendants from maintaining their pattern and policy of systematic delays and terminations—as reflected in their treatment of the Delayed Applications, Delayed Renewals, and Terminated Grants. For the same reasons, plaintiffs are entitled, pursuant to 28 U.S.C. §2201, to a declaration that the defendants' pattern and policy of systematic delays and terminations—as reflected in their treatment of the Delayed Applications, Delayed Renewals, and Terminated Grants—violates the Constitution's guarantee of separation of powers.

**Count 8—Against All Defendants**  
**Spending Clause**  
**(As to Terminated Grants)**

246. Plaintiffs reallege and incorporate by reference the allegations contained in each of the preceding paragraphs as if fully set forth herein.

247. Federal courts possess the power in equity to grant injunctive relief “with respect to violations of federal law by federal officials.” *Armstrong*, 575 U.S. at 326-327.

248. The Spending Clause of the U.S. Constitution, art. I, §8, cl. 1, provides that Congress—not the Executive—“shall have Power to lay and collect Taxes, Duties, Imposts and Excises, to pay the Debts and provide for the common Defence and general Welfare of the United States.”

249. The Spending Clause requires States to have fair notice of the terms that apply to the disbursement of funds to them. *See Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17, 25 (1981); *NFIB v. Sebelius*, 567 U.S. 519, 583-584 (2012). The funding conditions must be set out “unambiguously.” *Arlington Cent. Sch. Dist. Bd. of Educ. v. Murphy*, 548 U.S. 291, 296 (2006). And the federal statute must be viewed “from the perspective of a state official who is engaged in the process of deciding whether the State should accept [federal statute] funds and the obligations that go with those funds.” *Id.*

250. The delays and terminations are also contrary to the principle that funding restrictions can only impose conditions that are reasonably related to the federal interest in the project and the project’s objectives. *S. Dakota v. Dole*, 483 U.S. 203, 207, 208 (1987). Here, the delays and terminations are not related to the federal interest in NIH research—to support and encourage scientific research—and instead are related to policies and political factors. Indeed, the effect of these delays and terminations is to chill scientific research as they have subjected researchers and the administrators who support them to the fear that their ongoing research

activities can and will be suspended based on shifting political objectives of the current Administration.

251. Defendants' pattern and policy of systematic and retroactive terminations, as reflected in their treatment of the Terminated Grants, has altered the terms upon which grants were obligated and disbursed to plaintiffs, contrary to Congressional authority. These alterations are coercive, retroactive, ambiguous, and unrelated to the purpose of the myriad grants affected.

252. For the foregoing reasons, plaintiffs are entitled to a preliminary and permanent injunction barring defendants from maintaining their pattern and policy of systematic terminations, as reflected in their treatment of the Terminated Grants. For the same reasons, plaintiffs are entitled, pursuant to 28 U.S.C. §2201, to a declaration that the defendants' pattern and policy of systematic delays and terminations, as reflected, inter alia, in their treatment of the Terminated Grants, violates the Constitution's guarantee of separation of powers.

### **PRAYER FOR RELIEF**

Wherefore, plaintiffs pray that the Court:

I. Enter an order pursuant to 5 U.S.C. §706(1), and a preliminary and permanent injunction, compelling defendants to undertake (1) the activities of NIH's advisory councils and study sections that defendants have unlawfully withheld and/or unreasonably delayed with respect to the Delayed Applications; (2) prompt review of, and issue a final decision on, the Delayed Applications; (3) prompt review of, and issue a final decision on, the Delayed Renewals;

II. Enter an order pursuant to 5 U.S.C. §706(2) holding unlawful and setting aside, and a preliminary and permanent injunction barring defendants from carrying out, their withdrawal of Notices of Funding Opportunity: based on 2 C.F.R. §200.340(a)(2) (2020) or 2 C.F.R. §200.340(a)(4) (2024); or on the grounds that the Notice of Funding Opportunity relates to issues that do not comport with agency priorities or the priorities of the defendants, including, but not

limited to, on the grounds that the Notice of Funding Opportunity related to diversity, DEI (diversity, equity and inclusion), gender, transgender issues, vaccine hesitancy, COVID-19, science disinformation, or foreign countries.

III. Enter an order pursuant to 5 U.S.C. §706(2) holding unlawful and setting aside, and a preliminary and permanent injunction barring defendants from carrying out, their purported terminations of the Terminated Grants: based on 2 C.F.R. §200.340(a)(2) (2020) or 2 C.F.R. §200.340(a)(4) (2024); or on the grounds that the grants purportedly no longer effectuates agency priorities or the priorities of the defendants, including, but not limited to, on the grounds that the grants related to diversity, DEI (diversity, equity and inclusion), gender, transgender issues, vaccine hesitancy, COVID-19, science disinformation, or foreign countries.

IV. Issue a declaration pursuant to 28 U.S.C. §2201 that defendants' treatment of the Delayed Applications, Delayed Renewals, Notices of Funding Opportunity and Terminated Grants is unconstitutional; and

V. Award such additional relief as the interests of justice may require.

April 4, 2025

Respectfully submitted.

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CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

I. (a) PLAINTIFFS
Commonwealth of Massachusetts et al. (see attached)
(b) County of Residence of First Listed Plaintiff n/a
(c) Attorneys (Firm Name, Address, and Telephone Number) (see attached)

DEFENDANTS
Robert F. Kennedy, Jr., et al. (see attached)
County of Residence of First Listed Defendant n/a
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.
Attorneys (If Known)
U.S. Department of Justice, 950 Pennsylvania Ave. NW
Washington, DC 20530 202-514-2000

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)
1 U.S. Government Plaintiff
2 U.S. Government Defendant
3 Federal Question (U.S. Government Not a Party)
4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)
PTF DEF
Citizen of This State 1 1
Citizen of Another State 2 2
Citizen or Subject of a Foreign Country 3 3
Incorporated or Principal Place of Business In This State 4 4
Incorporated and Principal Place of Business In Another State 5 5
Foreign Nation 6 6

IV. NATURE OF SUIT (Place an "X" in One Box Only) Click here for: Nature of Suit Code Descriptions.

Table with columns: CONTRACT, REAL PROPERTY, CIVIL RIGHTS, TORTS, PRISONER PETITIONS, FORFEITURE/PENALTY, LABOR, IMMIGRATION, BANKRUPTCY, SOCIAL SECURITY, FEDERAL TAX SUITS, OTHER STATUTES. Includes codes for various legal actions like 110 Insurance, 310 Airplane, 365 Personal Injury, etc.

V. ORIGIN (Place an "X" in One Box Only)
1 Original Proceeding
2 Removed from State Court
3 Remanded from Appellate Court
4 Reinstated or Reopened
5 Transferred from Another District (specify)
6 Multidistrict Litigation - Transfer
8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION
Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):
Administrative Procedure Act, 5 U.S.C. §702; U.S. Constitution
Brief description of cause:
Judicial review of agency action

VII. REQUESTED IN COMPLAINT:
CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P. DEMAND \$
CHECK YES only if demanded in complaint:
JURY DEMAND: Yes No

VIII. RELATED CASE(S) IF ANY (See instructions):
JUDGE Hon. Brian E. Murphy DOCKET NUMBER 1:25-cv-10787

DATE 04/04/2025 SIGNATURE OF ATTORNEY OF RECORD /s/ Gerard J. Cedrone

FOR OFFICE USE ONLY
RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

**Plaintiffs, continued:**

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State of Maryland  
State of Washington  
State of Arizona  
State of Colorado  
State of Delaware  
State of Hawai'i  
State of Minnesota  
State of Nevada  
State of New Jersey  
State of New Mexico  
State of New York  
State of Oregon  
State of Rhode Island  
State of Wisconsin

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**Defendants, continued:**

Robert F. Kennedy, Jr., in his official capacity as Secretary of Health and Human Services  
United States Department of Health and Human Services  
Jayanta Bhattacharya, in his official capacity as Director of the National Institutes of Health  
National Institutes of Health  
National Cancer Institute  
National Eye Institute  
National Heart, Lung, and Blood Institute  
National Human Genome Research Institute  
National Institute on Aging  
National Institute on Alcohol Abuse and Alcoholism  
National Institute of Allergy and Infectious Diseases  
National Institute of Arthritis and Musculoskeletal and Skin Diseases  
National Institute of Biomedical Imaging and Bioengineering  
Eunice Kennedy Shriver National Institute of Child Health and Human Development  
National Institute on Deafness and Other Communication Disorders  
National Institute of Dental and Craniofacial Research  
National Institute of Diabetes and Digestive and Kidney Diseases  
National Institute on Drug Abuse  
National Institute of Environmental Health Sciences  
National Institute of General Medical Sciences  
National Institute of Mental Health  
National Institute on Minority Health and Health Disparities  
National Institute of Neurological Disorders and Stroke  
National Institute of Nursing Research  
National Library of Medicine  
National Center for Advancing Translational Sciences  
John E. Fogarty International Center for Advanced Study in the Health Sciences  
National Center for Complementary and Integrative Health  
NIH Center for Scientific Review

**Description of Related Cases:**

Under Local Rule 40.1(g)(1), civil cases “shall be deemed related to one another” if (A) “some or all of the parties are the same,” and (B) the cases “involve the same or substantially similar issues of fact” or “arise out of the same occurrence, transaction or property.” This case is related to No. 1:25-cv-10787, *American Public Health Association v. National Institutes of Health* within the meaning of that rule.

First, the defendants in the two cases are effectively the same. Plaintiffs in this case have named the same defendants as the plaintiffs in *American Public Health Association* did, plus 25 individual institutes and centers that make up the NIH.

Second, the two cases are factually intertwined. To take just one example, both cases involve the termination of grants to researchers at the University of New Mexico. An individual UNM researcher is a plaintiff in *American Public Health Association*, whereas the State of New Mexico (which operates UNM) is a plaintiff in this case. More generally, both cases will involve common factual inquiries into defendants’ conduct and the equitable factors governing injunctive relief, risking inconsistent judgments if the cases are heard separately. Under the local rule, two civil cases “shall not be deemed related to each other *solely* on the ground that they” challenge the same government action or involve common questions of law. L.R. 40.1(g)(3) (emphasis added). For the foregoing reasons, this case involves more than just a parallel challenge to the same action or common issues of law.

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

1. Title of case (name of first party on each side only) Commonwealth of Massachusetts v. Robert F. Kennedy, Jr.

2. Category in which the case belongs based upon the numbered nature of suit code listed on the civil cover sheet. (See local rule 40.1(a)(1)).

- I. 160, 400, 410, 441, 535, 830\*, 835\*, 850, 880, 891, 893, R.23, REGARDLESS OF NATURE OF SUIT.
- II. 110, 130, 190, 196, 370, 375, 376, 440, 442, 443, 445, 446, 448, 470, 751, 820\*, 840\*, 895, 896, 899.
- III. 120, 140, 150, 151, 152, 153, 195, 210, 220, 230, 240, 245, 290, 310, 315, 320, 330, 340, 345, 350, 355, 360, 362, 365, 367, 368, 371, 380, 385, 422, 423, 430, 450, 460, 462, 463, 465, 480, 485, 490, 510, 530, 540, 550, 555, 560, 625, 690, 710, 720, 740, 790, 791, 861-865, 870, 871, 890, 950.

\*Also complete AO 120 or AO 121. for patent, trademark or copyright cases.

3. Title and number, if any, of related cases. (See local rule 40.1(g)). If more than one prior related case has been filed in this district please indicate the title and number of the first filed case in this court.

No. 1:25-cv-10787, American Public Health Association v. National Institutes of Health

4. Has a prior action between the same parties and based on the same claim ever been filed in this court?

YES  NO

5. Does the complaint in this case question the constitutionality of an act of congress affecting the public interest? (See 28 USC §2403)

YES  NO

If so, is the U.S.A. or an officer, agent or employee of the U.S. a party?

YES  NO

6. Is this case required to be heard and determined by a district court of three judges pursuant to title 28 USC §2284?

YES  NO

7. Do all of the parties in this action, excluding governmental agencies of the United States and the Commonwealth of Massachusetts ("governmental agencies"), residing in Massachusetts reside in the same division? - (See Local Rule 40.1(d)).

YES  NO

A. If yes, in which division do all of the non-governmental parties reside?

Eastern Division  Central Division  Western Division

B. If no, in which division do the majority of the plaintiffs or the only parties, excluding governmental agencies, residing in Massachusetts reside?

Eastern Division  Central Division  Western Division

8. If filing a Notice of Removal - are there any motions pending in the state court requiring the attention of this Court? (If yes, submit a separate sheet identifying the motions)

YES  NO

(PLEASE TYPE OR PRINT)

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