UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

Case No.

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

Plaintiffs,

v.

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

Defendants.

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

INTRODUCTION

1. The National Institutes of Health ("NIH") is the world's leading funder of biomedical and behavioral research, responsible for the discovery of new ways to diagnose, prevent, and treat the most challenging diseases including cancer, strokes, diabetes, and Alzheimer's disease. Long considered "the crown jewel" of the federal government, NIH has funded research that has led to more than 100 Nobel Prizes and has supported more than 99 percent of the drugs approved by federal regulators from 2010 to 2019.¹

2. In late February 2025, Defendants upended NIH's enviable track record of rigor and excellence, launching a reckless and illegal purge to stamp out NIH-funded research that addresses topics and populations that they disfavor. Plaintiffs, who are leading health research organizations and research scientists, bring this case because they have been harmed by Defendants' unlawful grant terminations and midstream abandonment of grant application processes.

3. Congress created NIH nearly 100 years ago and funds it through annual appropriations so that it can "improve health, revolutionize science, and serve society."² Congress has provided additional directives to NIH to ensure that its research accrues to the benefit of all Americans.

4. NIH has carried out Congress's purpose and achieved its legendary successes through directing most of its budget to thousands of researchers at universities, medical schools, and other institutions in all 50 states. For decades, NIH has been guided by congressional mandate, regulatory requirements, and scientific expertise when determining what research to prioritize and fund. NIH also is subject to the Administrative Procedure Act's ("APA") requirement of reasoned decision-making, which it effectuates through rigorous grounding in scientific evidence. Pursuant to a congressional mandate, NIH develops and publishes a five-year Strategic Plan to direct its

¹ See Nobel Laureates, Nat'l Insts. of Health, (Oct. 9, 2024) <u>https://www.nih.gov/about-nih/what-we-do/nih-almanac/nobel-laureates</u>; E. Galkina 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), <u>https://jamanetwork.com/journals/jama-health-forum/fullarticle/2804378</u>.

² Impact of NIH Research, Nat'l Insts. of Health, <u>https://www.nih.gov/about-nih/what-we-do/impact-nih-research</u>.

priorities, "focused on science and good stewardship of research, guided by evidence, and informed by NIH's many stakeholders."³

5. Under this legally established framework, thousands of researchers across the country regularly apply for NIH grants to fund their research. NIH makes grant decisions following a highly competitive and rigorous process involving layers of expert scientific review over many months. Consequently, for decades, terminations of ongoing NIH grants have been exceedingly rare.

6. This all changed beginning in February of 2025, when Defendants issued a series of directives to terminate large numbers of grants and to refuse to consider certain categories of pending grant applications ("the Directives"). These Directives conflict with constitutional, statutory, and regulatory requirements. When issuing termination letters pursuant to the Directives, NIH has not referenced or met any of the standards in its governing statute or regulations. In fact, the sole legal basis that NIH cited for its authority to terminate the grants is inapplicable. It has not highlighted any genuine concerns with the rigor of projects or any underlying data; in a matter of weeks it has just declared them all "unscientific." More broadly, it has parroted the generalized and conclusory justification that the cancelled programs "no longer effectuate agency priorities." This is not a proper ground for termination under governing law.

7. As a result of the Directives, hundreds of NIH-funded research projects—many of which have been underway for years, representing millions of hours of work and hundreds of millions of dollars in investment—have been abruptly cancelled without scientifically-valid explanation or cause. Grant application processes have been abandoned midstream and funding opportunities have been removed from NIH's website.

³ NIH-Wide Strategic Plan, Fiscal Years 2021–2025, Nat'l Insts. of Health (July

^{2021),} https://www.nih.gov/sites/default/files/about-nih/strategic-plan-fy2021-2025-508.pdf at 44.

8. Defendants attempt to justify this ongoing ideological purge of hundreds of critical research projects because they assertedly have some connection to "gender identity" or "Diversity, Equity, and Inclusion" ("DEI") or other vague, now-forbidden language. Indeed, Defendants' campaign against peer-reviewed science has not stopped at topics deemed to be related to gender or DEI. Defendants' ideological purity Directives also seek to cancel research deemed related to "vaccine hesitancy," "COVID," and studies involving entities located in South Africa and China, among other things. Additionally, NIH has stopped considering submitted applications to programs designed to diversify the backgrounds of those in tenure-track positions at research universities. Defendants' actions have been taken in apparent disregard to Congress's express mandate that NIH fund research to address health equity and health disparities, include diverse populations in its studies, improve efforts to study the health of gender and sexual minorities, and enhance diversity in the biomedical research profession.

9. The new arbitrary regime is not codified in any law or policy. The operative NIH Strategic Plan, developed in furtherance of congressional mandate, has been in effect since September 2021, and remains in effect today. Defendants have failed to develop any guidelines, definitions, or explanations to avoid arbitrary and capricious decision-making in determining the parameters of the agency's prohibitions against research with some connection to DEI, gender, and other topics that fail Defendants' ideological conformity screen. Nor do Defendants' actions take into consideration the vast harms they have caused to scientific research and public health.

10. Plaintiffs are individual researchers and organizations whose members are researchers who have secured (or are in the process of securing) funding from NIH. For example, individual Plaintiffs have received NIH grants for research in the areas of Alzheimer's disease, disparities in pregnancy health, violence prevention among children, and the efficacy of

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preventative HIV medications. Plaintiffs pursue careers in medical research to help discover new treatments, cure diseases, and improve the health of people and communities across the country.

11. Plaintiffs have already suffered extensive harm from Defendants' unlawful actions, and those with grants that have yet to be cancelled wonder if they are soon to receive another vague, boilerplate termination letter. In just the past few weeks, for example, Plaintiffs and their members are facing the loss of jobs, staff, and income. Patients enrolled in NIH studies led by Plaintiffs face abrupt cancellations of treatment in which they have invested months of time with no explanation or plan for how to mitigate the harm. Over \$2.4 billion is at stake just in grants recently purged, including \$1.3 billion already spent on projects stopped midstream that is now wasted, and \$1.1 billion—that Plaintiffs and others have acted in reliance on—has been revoked. As a result of Defendants' Directives, scientific advancement will be delayed, treatments will go undiscovered, human health will be compromised, and lives will be lost.

12. Plaintiffs request that the Court declare unlawful Defendants' Directives; declare Defendants' termination of grants in this manner unlawful; order Defendants to end their arbitrary and capricious, unconstitutional, and unlawful actions; and order Defendants to restore funding to the terminated NIH grants.

JURISDICTION AND VENUE

13. This Court has subject matter jurisdiction under 28 U.S.C. § 1331 because this action arises under federal law, including the United States Constitution and the Administrative

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Procedure Act ("APA"), 5 U.S.C. §§ 551 *et seq*. This Court may grant declaratory relief, injunctive relief, and other appropriate relief pursuant to 28 U.S.C. §§ 2201–02 and 5 U.S.C. §§ 705–06.

14. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(e)(1)(C) because Defendants are officers and agencies of the United States, no real property is at issue in this case, and one or more Plaintiffs are residents of this District.

PARTIES

A. Plaintiffs

15. Plaintiff Dr. Brittany Charlton is an Associate Professor at Harvard Medical School and Harvard T.H. Chan School of Public Health. She is a resident of Massachusetts and the Founding Director of the LGBTQ Health Center of Excellence, a partnership of the Harvard Pilgrim Health Care Institute and Harvard T.H. Chan School of Public Health. Dr. Charlton is a leading scholar of LGBTQ health inequities, particularly in cancer and reproductive health, and also focuses on contraception use and family planning among people of all sexual orientations and gender identities. She has received continuous funding for her research for the last 15 years from NIH. Since February 2025, Dr. Charlton has had five grants terminated by NIH because each, allegedly, "no longer effectuates agency priorities."

16. Plaintiff Dr. Katie Edwards is a professor at the University of Michigan School of Social Work. Dr. Edwards' research focuses on preventing sexual and related forms of violence among minority communities, using evidence-based, affirming, and culturally-grounded approaches. Her current work is focused on program development and evaluation with Indigenous youth and communities, as well as LGBTQ+ youth and young people. To date, she has published more than 220 peer-reviewed articles, which were made possible, in part, through obtaining millions of dollars in research funding over her career. Since February 2025, NIH has terminated at least six grants in support of Dr. Edwards' research in projects where she is the principal investigator or co-investigator because, according to NIH, each of these grants "no longer effectuates agency priorities."

17. Plaintiff Dr. Peter Lurie is an experienced research physician and the President and Executive Director of the Center for Science in the Public Interest, a 501(c)(3) nonprofit organization based in Washington, D.C. that advocates for improving public health through science-based policies and promoting scientific integrity. From 2014–17, he was an Associate Commissioner at the Food and Drug Administration, where he worked on the regulation of over-the-counter drugs, among other projects. Additionally, for decades, Dr. Lurie has participated in biomedical research and policy focused on the treatment and prevention of HIV and AIDS. Dr. Lurie was a consultant and advisor on an NIH-funded grant studying the impact of access to preventative HIV drugs that NIH terminated because, according to NIH, it "no longer effectuates agency priorities."

18. Plaintiff Dr. Nicole Maphis is a postdoctoral fellow at the University of New Mexico's School of Medicine. Her research explores how alcohol usage affects the risk of developing Alzheimer's disease. She is the first and only person in her family to graduate college and comes from a low-income background. Dr. Maphis recently sought a grant through a program explicitly created to facilitate the transition of promising postdoctoral researchers from backgrounds underrepresented in the biomedical research workforce into independent, tenure-track or equivalent research-intensive faculty positions. Even though Dr. Maphis satisfies the eligibility criteria for the program and invested months into assembling her application, NIH is refusing to consider Dr. Maphis's grant application solely because the program is designed to help diversify the profession.

19. Founded in 1872, Plaintiff American Public Health Association ("APHA") represents about 50,000 people through organizational and individual memberships and has more than 23,000 individual public health professional members. APHA acts to build capacity in the public health community and champions optimal, equitable health and well-being for all. APHA speaks out for public health issues and policies backed by science. APHA and its members also work to ensure that health services are distributed equitably to all communities and research how disease, injury, or health related issues affect marginalized populations. APHA receives grants from NIH for its *American Journal of Public Health*. In addition, APHA members conduct research that is funded by grants from NIH. APHA has members who have had NIH grants terminated because, according to NIH, each of the grants "no longer effectuates agency priorities." APHA also has members whose grant applications NIH refuses to consider, or who are unable to submit future NIH grant applications due to the uncertainty caused by NIH's actions.

20. Founded in 2002, Plaintiff Ibis Reproductive Health ("Ibis") is a global research organization that drives change through bold, rigorous research and principled partnerships that advance sexual and reproductive autonomy, choice, and health worldwide. With offices in locations including Cambridge, Massachusetts, Ibis has a highly trained and committed staff of demographers, epidemiologists, and public health researchers leading projects with more than 100 partners in 30 countries. Research is core to the organization's work, and the organization's agenda is informed by a principled partnership approach with communities, including transgender and gender diverse community members, to identify key gaps in information and resources concerning reproductive health, autonomy, and health care access for these populations. In September 2023, Ibis was awarded a R01 grant providing about \$2.5 million over five years, to study survey design

for diverse populations, including those who identify as transgender or gender diverse. In March 2025, NIH terminated the grant on the basis that it "no longer effectuates agency priorities."

21. The International Union, United Automobile, Aerospace and Agricultural Implement Workers of America ("UAW") is one of the largest and most diverse unions in North America, with members in the United States, Canada and Puerto Rico and in virtually every sector of the economy. From its earliest days, the UAW has been a leader in the struggle to secure economic and social justice for all people. It has a rich history of supporting inclusion, equity, and diversity in the higher education sector and in all workplaces. The UAW has nearly 1,000,000 active and retired members and represents approximately 120,000 workers in higher educationgraduate students, postdoctoral scientists, researchers, university staff, and faculty-at institutions across the country including Northeastern University, Wellesley College, University of Southern California, Columbia University, Harvard University, University of Pennsylvania, Princeton University, and Worcester Polytechnic Institute, among many others. Tens of thousands of UAW members rely on NIH grant funding for their jobs and training. These members benefit from all NIH grant and fellowship types and play a variety of roles, including on NIH grant-funded projects as principal investigators. UAW has members whose grants have been cancelled because, according to NIH, each of the grants "no longer effectuates agency priorities." UAW also has members whose grant applications NIH refuses to consider, or who are unable to submit future NIH grant applications due to the uncertainty caused by NIH's actions.

B. Defendants

22. Defendant the National Institutes of Health ("NIH") is an agency of the United States, established pursuant to 42 U.S.C. § 281, and is housed within the United States Department of Health and Human Services.

23. Defendant Jay Bhattacharya is Director of NIH and is sued in his official capacity.

24. Defendant the United States Department of Health and Human Services ("HHS") is an agency of the United States that houses NIH. HHS is a department of the executive branch of the United States.

25. Defendant Robert F. Kennedy, Jr. is the Secretary of HHS and is sued in his official capacity.

FACTUAL ALLEGATIONS

A. Overview of the Structure and Priorities of NIH

<u>1. History of NIH</u>

26. In 1930, Congress enacted the Ransdell Act, establishing a "National Institute of Health" and appropriating funds to the newly-formed institute for the purpose of "ascertaining the cause, prevention, and cure of disease affecting human beings."⁴ The Ransdell Act authorized the creation of "fellowships" for "individual scientists."

27. Since then, Congress has repeatedly increased its investment in NIH, including by funding additional Institutes and Centers ("ICs") that operate within NIH.⁵

28. Over these decades of expansion, research funded through NIH has led to medical breakthroughs. For example, NIH-funded research played a critical role in developing numerous lifesaving treatments, including chemotherapy drugs, heart valve transplants, medications for

⁴ Ransdell Act, Pub. L. No. 71–251, 46 Stat. 379 (1930) (codified at 42 U.S.C. §§ 21 et seq.).

⁵ NIH Budget History, Nat'l Insts. of Health (Aug. 2024), <u>https://report.nih.gov/nihdatabook/category/1</u>.

managing type 2 diabetes, and a clot-busting medicine that is used as a first-line treatment in stroke patients.⁶

29. Today, NIH is the largest funder of biomedical research in the world, with an operating budget of \$48 billion as allocated by Congress. The vast majority—83 percent—is allocated for funding research for institutions and organizations outside of the agency. NIH provides almost 50,000 competitive grants to more than 300,000 researchers at more than 2,500 universities, medical schools, and other research institutions in every state.⁷

2. NIH Structure and Funding

30. NIH is comprised of the Office of the Director, as well as 27 ICs, which span a wide range of functions and focuses. Each of the ICs within NIH serves a particular purpose. For example, Congress established the National Cancer Institute to study and disseminate information about cancer causes, diagnosis, and treatment.

31. Twenty-four of the 27 ICs, as well as several divisions within the Office of the Director, post opportunities for funding for researchers outside of the agency. Congress has also authorized the Director to set aside a portion of NIH's allocated budget for a "Common Fund" dedicated to research that spans across ICs.

32. NIH is primarily funded through congressional appropriations, which includes both funding for agency-wide programs and dedicated budgets for each individual IC.⁸ For example, each year, Congress delegates funding directly to the National Institute on Minority Health and Health Disparities to carry out specific legislative purposes, including to "conduct and support []

⁶Impact of NIH Research: Improving Health, Nat'l Insts. of Health (Dec. 30, 2024), <u>https://www.nih.gov/about-nih/what-we-do/impact-nih-research/improving-health</u>.

⁷ *Budget*, Nat'l Insts. of Health (Oct. 3, 2024), <u>https://www.nih.gov/about-nih/what-we-</u>do/budget#:~:text=Research%20for%20the%20People,%2C%20maintenance%2C%20or%20operational%20costs.

 ⁸ See Kavya Sekar, Cong. Research Serv., NIH Funding FY1996-FY2025, (June 25, 2024), https://www.congress.gov/crs-product/.

research, training, dissemination of information, and other programs with respect to minority health conditions and other populations with health disparities."⁹

33. Congress has also defined mandates on the purposes and aims for which NIH and the ICs must fund research. Four such mandates are of particular relevance here.

34. First, Congress has long mandated that NIH must expend its funds to promote health equity and reduce health disparities across diverse populations. For instance, the Public Service Health Act requires that each IC "utilize diverse study populations, with special consideration to biological, social, and other determinants of health that contribute to health disparities."¹⁰ The Minority Health and Health Disparities Research and Education Act of 2000 recognizes the presence of continuing racial disparities "in the burden of illness and death," and obligates NIH to identify and fund health equity research and to establish a center later reclassified as the National Institute on Minority Health and Health Disparities.¹¹ And the 21st Century Cures Act mandates that NIH consider "disease burden in the United States" and "biological, social, and other determinants of health that contribute to health disparities" in identifying "strategic research priorities and objectives across biomedical research."¹² This statute expressly expands NIH's congressional mandate to study diverse populations and the issues that affect them to encompass the LGBTQ+ population, that "[t]he Director of the National Institutes of Health shall, as appropriate, encourage efforts to improve research related to the health of sexual and gender *minority populations.*"¹³

⁹ 42 U.S.C. § 285t.

¹⁰ 42 U.S.C. § 282(b)(8)(d)(ii).

¹¹ Affordable Care Act, Pub. L. No. 111-148, § 1707A(c), 124 Stat. 119, 973 (2010) (codified at 42 U.S.C. §§ 285t–285t-3). *See also* 42 U.S.C. § 285t(b) (National Institute on Minority Health and Health Disparities "shall in expending amounts appropriated under this subpart give priority to conducting and supporting minority health disparities research").

¹² *Id.* at § 282(m)(2)(b)(iii).

¹³ 42 U.S.C. § 283p (emphasis added).

35. Second, Congress has also mandated that NIH address the underrepresentation of certain groups in the medical field. For example, Congress requires that NIH "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" when "conducting and supporting programs for research, research training, recruitment, and other activities."¹⁴ Likewise, NIH must make the Ruth L. Kirschstein National Research Service Award ("Kirschstein-NRSA")—the largest congressionally-mandated NIH training program—available 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."¹⁵

36. Third, Congress has required that NIH ensure "scientifically based strategic planning . . . through the development, implementation, and updating of [a] strategic plan," and that its resources "are sufficiently allocated for research projects identified in strategic plans."¹⁶ Under this congressional mandate, NIH must develop its strategic plan no later than every six years and must submit that plan to Congress.¹⁷ Congress also mandates specific strategic plans for each IC.¹⁸ IC-specific strategic plans set forth research priorities within each institute, and by statute, each director must consider "the mission of the [IC] and . . . [its] strategic plan" "when review[ing] and mak[ing] the final decision with respect to making [a grant] award."¹⁹

37. Fourth, Congress mandates that, in creating its strategic plan for identifying its research priorities, NIH identify emerging scientific opportunities, flag near-, mid-, and long-term

¹⁴ Id. at § 282(h) (emphasis added).

¹⁵ 42 U.S.C. § 288(a)(4).

¹⁶ 42 U.S.C. § 282 (b)(5), (6).

¹⁷ *Id.* at (m)(1).

¹⁸ 42 U.S.C. § 282(m)(3).

¹⁹ 42 U.S.C. § 284(b)(3)(A)–(B).

scientific needs, assess opportunities for multi-institute research, and consider the "biological, social, and other determinants of health that contribute to health disparities."²⁰ These plans must be developed "in consultation with the directors of the national research institutes and national centers, researchers, patient advocacy groups, and industry leaders."²¹

38. Thus, Congress has long required NIH and ICs to set their priorities through science-based plans, and to study, understand, and address health equities and disparities in the field.

C. Types of NIH Grants

1. Project-Based Grants

39. Subject to the purposes and mandates articulated by Congress, NIH awards considerable funding for independent research through grants for scientific and biomedical research projects ("Project-Based Grants"), which usually are designated as part of the R-series of grants (*e.g.*, "R01," "R15," etc.). Though there are numerous categories of Project-Based Grants, the most typical designation for a Project-Based Grant is the R01, or "Research Project" grant. There are also certain grants that go to institutions that serve as coordinating centers that provide support, organize conferences, and assist researchers in applying for NIH funding in order to help advance studies in a particular field.

40. Project-Based Grants are the lifeblood of American biomedical and public health research. The billions of dollars each year in funding they provide contribute to medical and scientific breakthroughs that save lives and vitalize the economy. NIH touts, for example, that its

²⁰ 42 U.S.C. § 282(m)(2)(iii).

²¹ *Id.* at (m)(4).

funding supports scientists working on projects to develop new technologies for medical imaging, to prevent the spread of HIV/AIDS, and to understand the rising rates of colorectal cancer.²²

41. Such projects are critical to improving public health and have a demonstrable economic impact. For example, more than 30 percent of NIH-funded studies are later cited in an application for a commercial patent, demonstrating the vital role that Project-Based Grants play in fostering innovation.²³

42. The funding provided by NIH's Project-Based Grants also provides financial support for researchers and institutions who have devoted themselves to the study of important public health issues. Funding from a Project-Based Grant may cover everything from the salary and benefits paid to principal investigators and more junior researchers to the cost of the facilities in which research is conducted. As a result, the abrupt termination of Project-Based Grants can have catastrophic consequences for the individuals who rely on grant funding to make a living and the institutions where their work occurs, not to mention the participants enrolled in any study made possible by that funding.

2. Pipeline Grants

43. In addition to Project-Based Grants, NIH also makes awards to institutions or individuals for career development or training ("Pipeline Grants"). Some Pipeline Grants are congressionally mandated, such as Kirschstein-NRSAs, which have the purpose of "training individuals" to conduct "biomedical and behavioral research . . . in matters relating to the cause,

²² NIH Science Highlights, Nat'l Insts. of Health (Dec. 18, 2024), <u>https://www.nih.gov/research-training/science-highlights</u>.

²³ Elie Dolgin, NIH research grants yield economic windfall, 544 Nature 14 (2017).

diagnosis, prevention, and treatment of the diseases or other health problems to which the activities of the National Institutes of Health and Administration are directed."²⁴

44. There are numerous kinds of Pipeline Grants. For example, training awards— "institutional training grants" (T32s)—are typically applied for by the senior investigator who heads a training or research center on behalf of a larger set of researchers at an institution, and they can be used to cover the costs of predoctoral or postdoctoral students. There are also individual grants, typically classified as F-series ("Fellowship") grants, or K-series ("Career Development") grants, that can be used to provide stipends to researchers at all stages of their career, cover tuition and costs, and fund other expenses.

45. Some Pipeline Grants are designed to promote recruitment of groups that are "underrepresented in the biomedical, clinical, behavioral and social sciences." For example, consistent with their congressional mandate, NIH protocols for Kirschstein-NRSA grants state that "[w]ithin the framework of the program's longstanding commitment to excellence and projected need for investigators in particular areas of research, attention must be given to recruiting prospective trainees from diverse backgrounds."²⁵

46. Another Pipeline Grant—Maximizing Opportunities for Scientific and Academic Independent Careers ("MOSAIC") K99/R00—is designed to help promising postdoctoral researchers from diverse backgrounds transition into independent, tenure-track or equivalent

²⁴ 42 U.S.C. § 288(a)(1)(A).

²⁵ Nat'l Insts. of Health, *NIH Grants Pol'y Statement* § 11.3.3.3 (Apr. 2024). NIH identifies populations that are "underrepresented in the biomedical, clinical, behavioral and social sciences" to include racial and ethnic minorities, women, people with disabilities, and people from "disadvantaged backgrounds," determined by criteria such as current or prior homelessness, being in the foster care system, eligibility for free or reduced lunch or Pell grants, growing up in a rural area or low-income zip code, and having parents who did not complete higher education. *Id.* at § 11.3.3.4. All these categories are supported based on a reference to government data on educational or science workforce disparities. NIH's Grants Policy Statement further sets out the reasons for its policies to support the development of a diverse scientific workforce: "fostering scientific innovation, enhancing global competitiveness, contributing to robust learning environments, improving the quality of the research, advancing the likelihood that underserved or health disparity populations participate in, and benefit from health research, and enhancing public trust." *Id.*

research-intensive faculty positions. Likewise, the "F31 Diversity" grant provides a five-year fellowship to individuals from backgrounds "currently underrepresented in the biomedical, clinical, behavioral, and social sciences."²⁶ Still another is the "Faculty Institutional Recruitment for Sustainable Transformation (FIRST) initiative," which aims to transform culture at NIH-funded institutions through the recruitment of faculty cohorts who have a demonstrated commitment to diversity and inclusion.²⁷

47. Pipeline Grants are essential in shaping the careers of promising scientists, particularly those from disadvantaged backgrounds or from smaller institutions without significant private endowments. In 2022, more than 18,000 full-time graduate students received their primary federal funding support through NIH.²⁸ NIH funding programs provide essential support for promising undergraduate students at universities and colleges across the country.

48. These awards also have substantial impacts on the productivity and long-term retention of promising scientists in the field. In a 2011 study, researchers found that "receipt of an NIH postdoctoral fellowship leads to about one additional publication over the next five years, which reflects a 20 percent increase in research productivity.²⁹ A later National Bureau of Economic Review working paper found that researchers who have received fellowship awards were significantly more likely to subsequently complete an NIH-funded research project, further

²⁶ See, e.g., Nat'l Insts. of Health, *Ruth L. Kirschstein National Research Service Award (NRSA) Individual Predoctoral Fellowship to Promote Diversity in Health-Related Research (Parent F31-Diversity)* (July 6, 2020), <u>https://grants.nih.gov/grants/guide/pa-files/PA-20-251.html</u>.

²⁷ *Supra* note 4, at 17.

²⁸ Nat'l Insts. of Health, *National Statistics: Primary Source of Federal Support for Full-Time Graduate Students* (Mar. 2024), <u>https://report.nih.gov/nihdatabook/category/20</u>.

²⁹ Brian A. Jacob & Lars Lefgren, *The Impact of NIH Postdoctoral Training Grants on Scientific Productivity*, 40 Res. Policy 864 (2011).

concluding that "NRSA postdoctoral fellowship awards have the potential to promote retention of scientists in NIH-funded research and in the biomedical workforce pipeline."³⁰

D. The Grant Application Process

49. To offer funding for researchers outside of NIH, ICs post "Notices of Funding Opportunities" ("NOFOs"), alerting researchers to the availability of funds. While in some cases, grant-funded research is "investigator-initiated," meaning that the researcher comes to the funding IC with a proposed area of research, ICs "regularly identify specific research areas and program priorities to carry out their scientific missions."³¹

50. Funding awards are determined through a rigorous and competitive application process in which researchers submit their proposal and lengthy supporting documentation for review. Grant applications are substantial documents, often requiring months of effort and totaling 100 or more pages, including a detailed research plan, justifications of the proposed budget, information about facilities/locations, and letters of support from other researchers. Among other requirements, all applications must address how their research complies with NIH public policy requirements related to "inclusion of genders, members of minority groups, and individuals across the lifespan in clinical research."³²

51. Upon completion of an application, the vast majority of grants—both Project-Based and Pipeline Grants—are subjected to a two-step, highly standardized peer-review process, as set forth in the Public Health Service Act, its enacting regulations, and detailed NIH protocols. Specifically, the NIH Director must "require appropriate technical and scientific peer review" of

³⁰ Misty L. Heggeness *et al.*, *The Impact of Postdoctoral Fellowships on a Future Independent Career in Federally Funded Biomedical Research*, NBER Working Paper No. 24508 (Apr. 2018), <u>https://www.nber.org/papers/w24508</u>.

³¹ Nat'l Insts. of Health, New to NIH, (2024), <u>https://grants.nih.gov/new-to-nih</u>.

³² Nat'l Insts. of Health, NIH Grants Pol'y Statement § 2.3.6 (Apr. 2024).

"applications made for grants" for "biomedical and behavioral research."³³ NIH's stated policy is that "applications for funding submitted to NIH" will be "evaluated on the basis of a process that is fair, equitable, timely, and conducted in a manner that strives to eliminate bias."³⁴

52. In the initial phase, the Center for Scientific Review receives applications, and then assigns applications to relevant scientific review groups, where groups of approximately twenty scientific reviewers who are experts in their field analyze and score each proposal.³⁵

53. Scored applications are then moved on to IC-specific advisory councils, made up of "senior scientists with broad experience and members of the public with general knowledge of, and interest in, the IC's mission" where the IC determines which projects to move forward with funding.³⁶

54. For Pipeline Grants, reviewers also "gauge the likelihood the fellowship will enhance [the applicant's] potential for and commitment to a productive research career. For postdoctorals, they also assess whether [the applicant] has what it takes to be an independent researcher."³⁷

55. HHS regulations provide that "all" applications "shall be evaluated" and that the agency will either "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."³⁸ NIH policies

³³ 42 U.S.C. § 289a.

³⁴ Nat'l Insts. of Health, NIH Grants Pol'y Statement § 2.4 (Apr. 2024).

³⁵ See 42 C.F.R. § 52h (describing requirements for membership in scientific review groups).

³⁶ Nat'l Insts. of Health, NIH Grants Pol'y Statement § 2.4.3 (Apr. 2024).

³⁷ See, e.g., Nat'l Inst. of Allergy & Infectious Diseases, Fellowship Grants (F) (Mar. 7, 2025), https://www.niaid.nih.gov/grants-contracts/fellowship-grants.

³⁸ 42 C.F.R. § 52.5.

effectuate these regulations.³⁹ NIH policy solely contemplates the agency withdrawing an application for consideration for "non-conformity with application requirements."⁴⁰

56. There are no provisions in NIH guidelines that allow ICs to halt review of applications in specific grant lines because the agency has determined that a NOFO no longer effectuates agency priorities. Instead, NIH policy provides for the review of applications for "relevance to the IC's programs and priorities" at the IC advisory board stage of the process, which as discussed further below are set through the IC's strategic plan.⁴¹

57. After undergoing this rigorous, two-step peer review process, only a small percentage of all applications are selected to receive an award. Final authority to make an award belongs to the Director of the IC responsible for the grant.⁴²

58. Upon selection, a successful applicant receives a Notice of Award ("NOA"). The NOA identifies the institutional grantee, one or more principal investigators, and specifies the amount of the award, its duration, and all other terms and conditions with which the grantee must comply.

59. The NOA also provides the grantee and principal investigators with contact information for their program officer, who is the main point of contact throughout the lifespan of the award. Generally, program officers are trained scientists well-versed in handling the subjects covered by the grants for which they are responsible.

³⁹ See, e.g., Nat'l Insts. of Health, *NIH Grants Pol'y Statement* § 11.3.4.1 (Apr. 2024) ("*Each* initial and competing continuation application *will be* evaluated for scientific merit by an NIH peer review group. Kirschstein-NRSA institutional research training grant applications also must be reviewed by the National Advisory Council or Board of the IC") (emphases added); *see also* Nat'l Insts. of Health, *First Level: Peer Review* (Sept. 9, 2024), <u>https://grants.nih.gov/grants-process/review/first-level</u> ("Each grant application submitted to NIH is evaluated according to established review criteria that must be stated clearly in a notice of funding opportunity"). ⁴⁰ Nat'l Insts. of Health, *NIH Grants Pol'y Statement* § 2.3.9.5 (Apr. 2024).

⁴¹ *Id.* at § 2.4.3.

⁴² 42 U.S.C. § 284(b)(2).

60. Throughout the duration of the grant, grantees are required to provide annual progress reports to ensure compliance with grant terms. In response to these reports, program officers and grants management specialists conduct annual assessments to ensure that grantees are satisfying the grant's goals, terms, and conditions.

E. HHS Regulations Specify the Limited Grounds on Which Grant Terminations Must Be Based

61. The HHS regulations that are currently in effect significantly limit the termination of a grant, in whole or in part, during the duration of the award to specific circumstances: (1) if the grantee "fails to comply with the terms and conditions of the award"; (2) "for cause"; or (3) "with the consent of" the grantee.⁴³ Critically, NIH cannot terminate grants based on its determination that a grant "no longer effectuates the program goals or agency priorities." This is because the provision for terminating grants based on changes in goals or priorities appears in OMB guidance that HHS regulations did not adopt until a recent notice and comment rulemaking, and the *change to HHS regulations will not become effective until October of 2025*.

62. In 2013, OMB published the "Office of Management and Budget Guidance for Federal Financial Assistance, at 2 CFR part 200 ("OMB Uniform Guidance"). Though part of the CFR, this content, published in subtitle A, is "guidance, not regulation. Each Federal agency that awards grants has its own regulations in subtitle B. Federal agency regulations in subtitle B may

⁴³ 75 C.F.R. § 75.372. NIH written protocols are consistent with this regulatory limitation, providing for the process for termination solely on the request of a grantee or "if a recipient has failed to comply with the terms and conditions of award." Nat'l Insts. of Health, *NIH Grants Pol'y Statement* § 8.5.2 (Apr. 2024); *see also id.* at § 11.2.13.2, Termination Provision for Kirschstein-NRSA (solely provides for termination for individual awards upon awardee or trainee request or "if it determines that the recipient has materially failed to comply with the terms and conditions of the award or to carry out the purpose for which it was made."); *id.* at § 11.3.16.2 (same, for institutional Kirschstein-NRSA); *id.* at § 12.13.3 (same for Research Career Development ("K") awards).

give regulatory effect to the OMB guidance, if the agency regulations require compliance with all or portions of the OMB guidance."⁴⁴

63. The 2013 version of the OMB Uniform Guidance allowed for termination of a federal award solely under three limited conditions: (1) if the award recipient "fails to comply with the terms and conditions of a Federal award," (2) "for cause", or (3) "with the consent" of the grantee.⁴⁵

64. HHS adopted this guidance in 2014 *as a regulation* and maintained the limitation that grants could be terminated only in those three narrow circumstances.⁴⁶ HHS subsequently revised its regulations in 2016 and retained the three limited conditions for termination in 45 C.F.R. § 75.372.⁴⁷

65. In 2020, OMB made substantive amendments to the termination provision of the OMB Uniform Guidance.⁴⁸ The new termination provision—which is still only guidance without the effect of an agency regulation—continued to allow for termination for failure "to comply with the terms and conditions" of the award or upon the consent of the grantee.⁴⁹ However, OMB removed the third circumstance, which allows termination "for cause," and replaced it with language allowing for termination "to the greatest extent authorized by law, if an award no longer

⁴⁶ See Federal Awarding Agency Regulatory Implementation of Office of Management and Budget's Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, 79 Fed. Reg. 75871 (Dec. 19, 2014) ("The Federal award may be terminated in whole or in part as follows:" if the award recipient "fails to comply with the terms and conditions of a Federal award," "for cause", or "with the consent" of the award recipient.)

⁴⁴ 2 C.F.R. § 1.105 (b)–(c) (2024).

⁴⁵ See 2 C.F.R. § 200.339 (2024) (OMB Uniform Guidance, 2013 version, available with subsequent 2020 redlines at infra note 48).

⁴⁷ See Federal Awarding Agency Regulatory Implementation of Office of Management and Budget's Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards; Technical Amendments, 81 Fed. Reg. 3004 (Jan. 20, 2016).

 ⁴⁸ See Office of Mgmt. & Budget, 2 CFR Revision Redline 5 (Aug. 12, 2020), <u>https://trumpadministration.archives.performance.gov/CAP/20200812-2-CFR-Revision-Redline Final.pdf</u>.
 ⁴⁹ 2 C.F.R. §§ 200.340(a)(1), (3).

effectuates the program goals or agency priorities."⁵⁰ OMB added a fourth condition, that the agency could terminate "pursuant to termination provisions included in the Federal award," and stated that the agency "should clearly and unambiguously specify termination provisions applicable to each Federal award, in applicable regulations or in the award, consistent with this section."⁵¹

66. HHS amended its regulations in November 2020, *but did not adopt the changes that OMB made in 2020 to its termination provision*. Instead, HHS regulations continued to allow termination only under the three limited circumstances of non-compliance, for cause, or with the consent of the awardee.⁵²

67. In 2024, OMB again revised the termination provision in the OMB Uniform Guidance, effective October 1, 2025. Under the 2024 revision, agencies can terminate an award for non-compliance with the grant's terms and conditions, with the consent of the awardee, or "pursuant to the terms and conditions of the Federal award, including, to the extent authorized by law, if an award no longer effectuates the program goals or agency priorities."⁵³ The OMB Uniform Guidance also states that the agency "must clearly and unambiguously specify all termination provisions in the terms and conditions of the Federal award."⁵⁴

68. In October 2024, HHS published an interim final rule that will bring HHS regulations—*effective October 1, 2025*—into near total conformity with the OMB Uniform Guidance, including with 2 C.F.R. § 200.340. In the interim final rule, HHS stated that "HHS will forgo the separate codification, fully adopt 2 CFR part 200, reduce the total number of HHS-

⁵⁰ 2 C.F.R. § 200.340(a)(2) (2020).

⁵¹ 2 C.F.R. §§ 200.340(a)(5), (b) (2020).

⁵² See 45 C.F.R. § 75.373.

⁵³ 2 C.F.R. § 200.340(a) (1), (2), (4).

⁵⁴ 2 C.F.R. § 200.340(b).

specific changes, and codify those changes in 2 CFR part 300."⁵⁵ Therefore, beginning on October 1, 2025, *and not sooner*, HHS regulations will, for the first time, allow agencies to terminate grants "pursuant to the terms and conditions of the Federal award, including, to the extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

69. Notwithstanding the termination letters and revised NOAs described below that NIH has sent to Plaintiffs and their members citing that the grants "no longer effectuate[] agency priorities" as the authority to terminate their grants, NIH does not have such authority under current HHS regulations. Nor is there anything in the terms and conditions of the NOAs that Plaintiffs initially received when the awards were made that provide or can provide NIH with such authority. Plaintiffs' original NOA lists various terms and conditions and explicitly incorporate 45 C.F.R. Part 75. The NOAs do not list 2 C.F.R. Part 200 explicitly as an applicable term or condition.

70. The NOAs also state that they incorporate the Grants Policy Statement, which is not a formal regulation, but is instead "an aid to the interpretation of statutory and regulatory requirements."⁵⁶ In the revised NOAs that NIH sent to Plaintiffs when it terminated their grants, NIH stated that "NIH is taking this enforcement action in accordance with 2 CFR § 200.340 as implemented in NIH [Grants Policy Statement] Section 8.5.2." But this is an inaccurate statement of applicable regulations. Section 8.5.2 of the Grants Policy Statement did *not* implement the revised 2020 version of 2 C.F.R. 200.340 because HHS did not implement that revised version in its regulations. NIH Grants Policy Statement states: "These terms and conditions are intended to be compliant with governing statutes and the requirements of 2 CFR Part 200, *as modified by previously approved waivers and deviations*. However, in the case of a conflict, the statutes and

⁵⁵ Health and Human Services Adoption of the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, 89 Fed. Reg. 80,055, 80,056 (Oct. 2, 2024).

⁵⁶ Nat'l Insts. of Health, *NIH Grants Pol'y Statement* § 3 (Apr. 2024) (emphasis added).

regulations govern."⁵⁷ Because HHS's adoption of 2 C.F.R. § 200.340 is not yet in effect, HHS's current termination regulation remains a "deviation" from 2 C.F.R. § 200.340 and HHS's limited grounds for termination still apply.

71. Terminations at NIH are historically rare. In response to noncompliance, "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision. However, NIH may decide to terminate the grant if the recipient does not take appropriate corrective action during the period of suspension. NIH may immediately terminate a grant when necessary, such as to protect the public health and welfare from the effects of a serious deficiency."⁵⁸

72. As one NIH official stated, "Terminations are the *final* option." Indeed, reporting indicates that, prior to January 2025, NIH terminated around 20 grants a year on average, "and usually only because of serious problems, such as flagrant misconduct, fraud, or an ethical breach that could harm study participants." The standard approach at NIH has long been to not terminate existing grants even if they address a low programmatic or agency priority. As a former NIH official who worked at the agency for several years described, "I have been involved with legitimate grant terminations," and, "I can count them on the fingers of one hand."⁵⁹

F. NIH's Strategic Plan Guides the Review of Grants

73. The NIH-Wide Strategic Plan outlines NIH's vision for biomedical research direction, capacity, and stewardship by articulating the highest priorities of NIH for a 5-year

⁵⁷ Nat'l Insts. of Health, *NIH Grants Pol'y Statement* § 3 (Apr. 2024).

⁵⁸ Nat'l Insts. of Health, NIH Grants Pol'y Statement § 8.5.2 (Apr. 2024).

⁵⁹ Katherine J. Wu, *The NIH's Grant Terminations Are 'Utter and Complete Chaos,* 'THE ATLANTIC (Mar. 14, 2025), <u>https://www.theatlantic.com/health/archive/2025/03/nih-grant-terminations/682039/</u>.

period. The plan is designed to complement and harmonize IC strategic plans across NIH, which address their individual missions.⁶⁰

74. The current NIH-Wide Strategic Plan governs from July 2021 until September 30, 2025, but creation of the plan began well before then, in September 2019. The four-phase strategic planning process involved: (1) pre-planning, (2) gathering internal input and development of the Strategic Plan framework, (3) gathering input from external stakeholders, and (4) drafting and publishing the Strategic Plan.⁶¹

75. The NIH Strategic Plan sets forth three objectives: (1) advancing biomedical and behavioral sciences; (2) developing, maintaining, and renewing scientific research capacity; and (3) exemplifying and promoting the highest level of scientific integrity, public accountability, and social responsibility in the conduct of science—across which NIH has identified several "crosscutting themes," which include "improving minority health and reducing health disparities."⁶²

76. In line with the congressional mandate to consider health disparities, the NIH Strategic Plan "prioritizes research that addresses the needs of underserved populations to address the factors that contribute to health disparities" including by "identifying key gaps in prevention science related to health disparities and promoting targeted research on appropriately tailored public health, clinical, and community preventive services in diverse settings and contexts."⁶³

77. Similarly, the NIH Strategic Plan describes research to effectuate Congress's mandate to consider the "disease burden in the United States."⁶⁴ Suicide, for example, is

⁶⁰ *NIH-Wide Strategic Plan, supra* note 4.

⁶¹ Id.

⁶² Id. at 3.

⁶³ *Id*. at 11.

⁶⁴ 42 U.S.C. § 282 (2)(b)(iii).

disproportionately prevalent in specific populations, including sexual and gender minority populations, and NIH research into suicide prevention illustrates how improvements in care can save lives.⁶⁵

78. The NIH Strategic Plan also recognizes that the "strength of the NIH workforce depends on its sustainability and diversity."⁶⁶ Through the congressionally required "Next Generation Researchers Initiative," NIH aims to achieve sustainability by "enhanc[ing] opportunities for early-stage researchers by prioritizing funding of independent research applications" of early-stage researchers "such as policies to . . . enhance workforce diversity."⁶⁷

79. ICs also go through a strategic planning process and have plans currently in place. For example, the National Institute for Minority Health and Health Disparities' strategic plan summarizes evidence demonstrating health disparities faced by people from minority racial and ethnic backgrounds, sexual and gender minorities, rural residents, and individuals of less privileged socioeconomic status including shorter life expectancy; higher rates of cardiovascular disease, cancer, diabetes, infant mortality, stroke, cognitive impairment, asthma, sexually transmitted infections, and dental diseases; and differences in prevalence and outcomes of mental illness. That plan also sets forth "a commitment by NIH to support research aimed at addressing risk and protective factors that operate and interact on multiple levels to impact the well-being of health disparity populations."⁶⁸

⁶⁵ *NIH-Wide Strategic Plan, supra* note 4, at 9.

⁶⁶ *Id.* at 16.

^{67 42} U.S.C. § 2830; id.

⁶⁸ Nat'l Insts. of Health, *Minority Health and Health Disparities Strategic Plan 2021–2025* (2021), <u>https://nimhd.nih.gov/docs/strategic-plan/NIH-Wide MHHD Strategic Plan 2021-2025 508.pdf</u> at 4, 8. The current version of the plan available on NIH's website states that it "is being implemented through December 31, 2025," <u>https://nimhd.nih.gov/about/strategic-plan/</u>.

G. President Trump Issues Executive Orders that Ignite Chaos at NIH

80. Starting on January 20, 2025, President Donald. J. Trump issued a series of executive orders broadly seeking to end all efforts related to "equity"—including specifically with respect to any federal grants. Even after being enjoined, these executive orders nonetheless prompted Defendants to issue the unlawful Directives at NIH.

81. Executive Order No. 14151, dated January 20, 2025 and entitled "Ending Radical and Wasteful Government DEI Programs and Preferencing," instructs the Attorney General and others to "coordinate the termination of all discriminatory programs, including illegal DEI and 'diversity, equity, inclusion, and accessibility' (DEIA) mandates, policies, programs, preferences, and activities in the Federal Government, under whatever name they appear." Additionally, it directs each federal agency head to "terminate, to the maximum extent allowed by law, all... 'equity-related' grants or contracts" within 60 days.⁶⁹

82. The next day, on January 21, 2025, President Trump issued Executive Order No. 14173, entitled "Ending Illegal Discrimination and Restoring Merit-Based Opportunity." To address the purported "immoral race- and sex-based preferences under the guise of so-called [DEI] or [DEIA]," the order requires the Director of OMB to "[e]xcise references to DEI and DEIA principles, under whatever name they may appear, from Federal acquisition, contracting, grants, and financial assistance procedures" and to "[t]erminate all 'diversity,' 'equity,' 'equitable decision-making,' 'equitable deployment of financial and technical assistance,' 'advancing equity,' and like mandates, requirements, programs, or activities, as appropriate."⁷⁰ Provisions of

⁶⁹ Ending Radical and Wasteful Government DEI Programs and Preferencing, 90 Fed. Reg. 8339 (Jan. 20, 2025).

⁷⁰ Ending Illegal Discrimination and Restoring Merit-Based Opportunity, 90 Fed. Reg. 8633, 8634 (Jan. 21, 2025).

this executive order and Executive Order No. 14151 were enjoined between February 21 and March 14, 2025.⁷¹

83. On January 20, 2025, President Trump also issued Executive Order 14168, "Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government," directing that "federal funds shall not be used to promote gender ideology," instructing federal agencies to revise grant conditions accordingly, and defining "gender ideology" as a "false claim" that "replaces the biological category of sex with an ever-shifting concept of self-assessed gender identity," and that "includes the idea that there is a vast spectrum of genders that are disconnected from one's sex."⁷² Provisions of this executive order were enjoined on February 28, 2025.⁷³

84. On January 27, 2025, OMB issued a memorandum directing all federal agencies including NIH—to "temporarily pause all activities related to obligation or disbursement of all Federal financial assistance, and all other relevant agency activities that may be implicated by," among others, "[Executive Orders above], including, but not limited to, financial assistance for... DEI, woke gender ideology, and the green new deal." Provisions of this memorandum were enjoined on January 31, 2025.⁷⁴

⁷¹ See Nat'l Assn. of Diversity Officers in Higher Education v. Trump, No. 25-cv-0333-ABA (D. Md. Feb. 21, 2025) ECF No. 45 (preliminarily enjoining provisions requiring agencies to terminate equity-related grants); *Nat'l Ass'n of Diversity Officers in Higher Educ. v. Trump*, No. 25-1189 (4th Cir. Mar. 14, 2025), ECF No. 29 (staying preliminary injunction pending appeal).

⁷² Defending Women From Gender Ideology Extremism and Restoring Biological Truth to the Federal Government, 90 Fed. Reg. 8615 (Jan. 20, 2025).

⁷³ *Washington v. Trump*, No. 2:25-cv-244-LK (W.D. Wash. Feb. 28, 2025) ECF No. 50 (on February 28, 2025, preliminary enjoining sections that condition, withhold, or end federal funding in Plaintiffs states Colorado, Minnesota, Oregon, and Washington); *PFLAG, Inc. v. Donald J. Trump*, No. 8:25-cv-00337-BAH (D. Md. Mar. 4, 2025) ECF No. 116 (on March 4, 2025, preliminarily enjoining the same nationwide).

⁷⁴ New York v. Trump, No. 25-cv-39-JJM-PAS (D.R.I Jan. 31, 2025), ECF No. 50 (preliminarily enjoining federal agency defendants from "pausing, freezing, blocking, canceling, suspending, terminating, or otherwise impeding the disbursement of appropriated federal funds to the States under awarded grants, executed contracts, or other executed financial obligations," based on both the OMB directive and Executive Orders, including the DEI and Gender Ideology executive orders).

H. NIH Issues Directives to Purge Research Grants

85. Historically, the longstanding firewall between an administration's *political* choices and NIH's *scientific* peer review process ensured the agency avoided the massive waste and disruption to researcher careers, participant well-being, and public health that would accompany mid-stream research terminations. But since January 20, 2025, NIH has veered sharply from this deliberative, reasoned, and methodical approach.

86. The Executive Orders, although enjoined in part, have prompted a massive purge in NIH grants and funding streams untethered to congressional mandates, the operative NIH Strategic Plan, or any reasoned review process. As explained below, in response to the Executive Orders, NIH has issued a series of documents vaguely articulating areas of research that purportedly "no longer effectuate[] agency priorities." These documents—titled as "guidance" but including mandatory language and referred to herein as the Directives—include memoranda developed by HHS and NIH (issued on or around February 28, 2025 and on March 25, 2025) and other versions of these documents that convey the same mandate.

87. This process began on February 12, 2025, when NIH issued a memorandum stating that it "is in the process of reevaluating the agency's priorities based on the goals of the new administration."⁷⁵ That memorandum goes on to say that "NIH will effectuate the administration's goals over time, but given recent court orders, this cannot be a factor in IC funding decisions at this time." The memorandum also indicates that, "[a]dditional details on future funding actions related to the agency's goals will be provided under a separate memo."

88. NIH would provide those additional details over the next few weeks—including the very next day, when NIH issued another memorandum to IC chief grant management officers

⁷⁵ Judd Legum, *Breaking: NIH Admits Funding Freeze is Illegal*, POPULAR INFORMATION (Feb. 12, 2025), https://popular.info/p/breaking-nih-admits-funding-freeze.

("February 13 Memo"). That memo announced "hard funding restrictions" on "awards where the program promotes or takes part in diversity, equity, and includsion [sic] ('DEI') initiatives" with those restrictions applying "to new and continuation awards made on or after February 14, 2025."⁷⁶ The memorandum also states, "[i]f the sole purpose of the grant, cooperative agreement, other transaction award (including modifications), or supplement supports DEI activities, then the award must be fully restricted. The restrictions will remain in place until the agency conducts an internal review for payment integrity."

89. Soon after, NIH took steps to inventory projects for its purge of disfavored grants including the termination of Project-Based Grants and Pipeline Grants at issue here—across various ICs. As one NIH official described the agency's actions throughout this spree, "[i]t is such utter and complete chaos."⁷⁷ "In advance of the terminations… agency leadership solicited grants that might, for instance, 'promote gender ideology,' or that involved certain types of vaccinebehavior research."⁷⁸ NIH officials responded with lists of grants to terminate. One official described the lists as looking like "someone had performed a Ctrl+F search for certain terms, then copied and pasted the results" and directed the cancellation of those grants.⁷⁹

90. Directions to terminate grants came without warning to the typical NIH officials who would be involved in the process, without the usual level of rigor and deliberation that accompanies a potential termination, and without any allegations or findings of noncompliance by grantees. The directions "instructed grants-management officers to issue letters by the end of the

⁷⁶ Stephanie Mencimer, *NIH Is Defying a Federal Court and Freezing Research Funding Anyway*, MOTHER JONES (Feb. 24, 2025), <u>https://www.motherjones.com/politics/2025/02/nih-defying-federal-court-freeze-research-funding-dei-temporary-restraining-order/</u>; screenshot of February 13 Memo, MOTHER JONES (Feb. 24, 2025), <u>https://substackcdn.com/image/fetch/f_auto,q_auto:good,fl_progressive:steep/https%3A%2F%2Fsubstack-post-media.s3.amazonaws.com%2Fpublic%2Fimages%2F7e116a29-f20d-435d-a8ba-ba18cea529d8_1182x1236.png.
⁷⁷ Wu, *supra* note 59.</u>

⁷⁸ Id.

⁷⁹ Id.

day they received them . . . leaving no time to push back, or even react," eliminating any meaningful role the grants-management officers could have played in these decisions.⁸⁰ "In at least one case, . . . a program officer learned that their grantee's award had been terminated from the grantee," *not from the NIH*.⁸¹

91. Throughout February and March 2025, NIH issued Directives for assessing grant awards that expanded the scope of the purge.

92. On or around February 28, 2025, NIH issued staff "guidance" ("February 28 Guidance") that rescinded the February 13 Memo but expanded on its core anti-DEI messaging, stating: "NIH will no longer prioritize research and research training programs that focus on Diversity, Equity and Inclusion (DEI) . . . Prior to issuing all awards (competing and non-competing) or approving requests for carryover, ICs must review the specific aims[,] assess whether the proposed project contains any DEI research activities or DEI language that give the perception that NIH funds can be used to support these activities."⁸² The memorandum also instructs officials to "completely excise all DEI activities[.]"

93. The February 28 Guidance identifies four categories of awards and mandates actions for each category deemed "DEI related":

- "Category 1" the "sole purpose of the project is DEI related (e.g., diversity supplements or conference grant where the purpose of the meeting is diversity), and/or the application was received in response to a NOFO that was unpublished as outlined above." For projects construed as Category 1, "ICs must not issue the award."
- "Category 2" the project "partially supports DEI activities (i.e., the project may still be viable if those aims or activities are negotiated out, without significant changes from the original peer-reviewed scope) this [sic] means DEI activities are

⁸⁰ Id.

⁸¹ Id.

⁸² See Max Kozlov and Smriti Mallapaty, *Exclusive: NIH to terminate hundreds of active research grants*, NATURE (Mar. 6, 2025), <u>https://www.nature.com/articles/d41586-025-00703-1</u>; see also Carolyn Y. Johnson and Joel Achenbach, *NIH reels with fear, uncertainty about future of scientific research*, THE WASHINGTON POST (Mar. 5, 2025), <u>https://www.washingtonpost.com/science/2025/03/05/nih-trump-turmoil-grants/</u>.

ancillary to the purpose of the project [sic]. In some cases, not readily visible [sic]." For projects construed as Category 2, "[i]f the IC and the applicant/recipient cannot reach an agreement" to renegotiate the scope of the project, "or the project is no longer viable without the DEI related activities, the IC cannot proceed with the award." For any such ongoing project, "the IC must work...to negotiate a bilateral termination of the project," but "[w]here bilateral termination cannot be reached, the IC must unilaterally terminate the project."

- "Category 3" the project "does not support DEI activities, but may contain language related to DEI (e.g., statement regarding institutional commitment to diversity in the 'Facilities and Other Resources' attachment and terminology related to structural racism—this is not all-inclusive)." For projects construed as Category 3, ICs "must request an updated [application or progress report] with the DEI language removed," and only once the language has been removed may the IC "proceed with issuing the award."
- "Category 4" the project does "not support any DEI activities." ICs "may proceed with issuing the award."

94. The February 28 Guidance also provides "[g]uidance for staff to use when terminating awards identified by HHS or the IC." In those circumstances, NIH officials must "issue a revise[d] NOA." The February 28 Guidance also instructs NIH officials to "[u]se the following termination term" in the revised NOA: "This award related to *[select the appropriate example relevant to your project by choosing one of the highlighted examples DEI, China, or Transgender issues* (sic)*]* no longer effectuates agency priorities. It is the policy of NIH not to further prioritize these research programs. Therefore, the award is terminated [Refer to Appendix 3 for language provided to NIH by HHS.]" (emphasis added). The document also instructs NIH officials that "[t]ermination actions taken based on agency priorities do not require appeals language because the action was *not* based on administrative nor [sic] programmatic noncompliance" (emphasis added). In addition, the February 28 Guidance directs, "[i]f the grant is a no cost extension, and the HHS requests a termination, the project must be terminated."

95. Appendix 3, in turn, lists "[1]anguage provided to NIH by HHS" with "examples for research activities that NIH no longer supports," and outlines three forbidden topics:

- "China: Bolstering Chinese universities does not enhance the American people's quality of life or improve America's position in the world. On the contrary, funding research in China contravenes American national-security interests and hinders America's foreign-policy objectives."
- "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 harm the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs."
- "Transgender issues: Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs."
- 96. On March 25, 2025, as part of its Directives, NIH issued another document (the

"March 25 Guidance") with a header that warned, "INTERNAL: NOT FOR DISTRIBUTION

OUTSIDE THE GOVERNMENT."83

97. Like the February 28 Guidance, the March 25 Guidance outlines categories of

projects and mandating action for certain forbidden categories:

- Category 1 projects remain the same, and the March 25 Guidance likewise requires that NIH officials terminate all such existing projects and not issue any such awards.
- Category 2 projects are those that "partially support[] non-NIH/HHS priority/authority activities (i.e., the project may still be viable if those aims or activities are negotiated out, without significant changes from the original peer-reviewed scope). This means the non-NIH/HHS priority/authority activities are ancillary to the purpose of the project, in some cases, not readily visible [sic]." The document also notes that, "Activities required to comply with NIH inclusion policies are not considered DEI activities."

⁸³Max Kozlov, *Exclusive: NIH to cut grants for COVID research, documents reveal*, NATURE (Mar. 26, 2025), <u>https://www.nature.com/articles/d41586-025-00954-y</u>.

- Category 3 projects have a different definition and "do[] not support any DEI activities." The memo states that the "IC may proceed with issuing the award."
- Category 4 projects have a different definition and are designated "HHS Department Authority Terminations." The "Director, NIH or designee" provides a list of these projects to NIH officials, and the officials must in turn "issue termination letters" for these projects.
- Category 5 projects are those awarded "to [e]ntities in certain foreign countries." According to that part of the document, "Additional guidance on awards to foreign entities is forthcoming. At this time, ICs should hold all awards to entities located" in certain countries, including South Africa.

98. This document repeats much of the substance of the February 28 Guidance, including that "NIH will no longer prioritize research and research training programs that focus on [DEI]," but expands the topics of research NIH purports to "no longer prioritize" to include "Vaccine Hesitancy" and "COVID-related" research. It directs NIH officials to include the following language (or language substantially similar) in correspondence regarding grant reviews: "It is the policy of NIH not to prioritize [select one of the following: diversity, equity and inclusion (DEI) research programs, gender identity, vaccine hesitancy, climate change or countries of concern, e.g., China or South Africa, etc.]."

99. The March 25 Guidance also identifies—in a section labeled "Appendix 3"—a list of forbidden topics for NIH grants and prescribes language to be included in termination letters. This document is identical to the March 25 Guidance with respect to identifying "China," "DEI," and "Transgender issues" as areas of forbidden research, but it also provides required language to terminate projects in the two additional forbidden topics—"Vaccine Hesitancy" and "COVIDrelated" research:

• "Vaccine Hesitancy: It is the policy of NIH not to prioritize research activities that focuses [sic] gaining scientific knowledge on why individuals are hesitant to be vaccinated and/or explore ways to improve vaccine interest and commitment. NIH is obligated to carefully steward grant awards to ensure taxpayer dollars are used in

ways that benefit the American people and improve their quality of life. Your project does not satisfy these criteria."

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

100. Like the February 25 Guidance, the March 25 Guidance directs NIH officials to revise NOAs that are terminated pursuant to the Directives, and instructs NIH officials to include the following (or substantially similar) language in those revisions: "It is the policy of NIH not to prioritize [insert termination category language from Appendix 3, verbatim]. Therefore, this project is terminated."

101. The March 25 Guidance also has an FAQ section that includes, among other instructions: "6. When ICs issue revised NOAs to terminate awards, do they have to use the exact language provided by HHS in the termination term? Yes, ICs must use the exact language provided in Appendix 3, with no edits."

102. In addition, regarding "Notice of Funding Opportunity (NOFO) Guidance," the document has only the following text: "[pending]."

103. The Directives—comprised of the February 28 Guidance, the March 25 Guidance, and other versions of these documents that articulated areas of research that purportedly "no longer effectuate[] agency priorities"—fail to define critical terms, such as "diversity, equity, and inclusion" or "DEI"; "artificial and non-scientific categories"; "amorphous equity objectives"; "[t]ransgender issues"; "gender identity"; or "COVID-related."

104. The lack of clarity about the meaning of these and other forbidden terms has contributed to widespread confusion among NIH staff on how to implement the mandates outlined

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in the Directives.⁸⁴ For example, as one NIH official asked, "is a grant providing culturally appropriate care specifically to Hispanic and Latino population 'discrimination'?"⁸⁵

I. Pursuant to Directives, NIH Issues Boilerplate Notices to Terminate Hundreds of Grants

105. Pursuant to the Directives, NIH adopted a script for grant termination notices. It did so without regard for the limited circumstances in which terminations may be made and its legal obligation to individually and rigorously review the varied and diverse projects under consideration for termination.

106. Each termination notice begins by identifying the project number, identifying which year's Grants Policy Statement applies to the grantee's project, and stating that the letter "constitutes a notice of termination" purportedly pursuant to that Grants Policy Statement and 2 C.F.R. § 200.340(a)(2). The notice also emphasizes that "obligations generally should be determined by reference to the law in effect when the grants were made."

107. Citing the pertinent year's Grants Policy Statement, each notice states, "At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination '[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities.""

108. From there, each notice includes one of a few slightly different scripts stating, without explanation, that the grant "no longer effectuates agency priorities." The language in these notices repeats the mandatory language from the appendices, described above. Below are three examples:

• First, "This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of

⁸⁴ See Wu, supra at note 59.

⁸⁵ Kozlov et al. *supra* at note 82.

NIH not to prioritize these research programs. NIH is obligated to carefully steward grant awards to ensure taxpayer dollars are used in ways that benefit the American people and improve their quality of life. Your project does not satisfy these criteria." ("Termination Section 1"). In some notices, "DEI" is substituted for "gender identity."

- The second script is the same as the first but omits the last two sentences ("Termination Section 2").
- The third script provides, "This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ('DEI') studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs." ("Termination Section 3").
- 109. After that, the language across all notices is once again nearly identical, stating the

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

110. After this emphasis on the futility of any appeal, each notice outlines the appeals process. But as one NIH staffer stated, "the language included in the terms of the terminated grants about the appeal process is CYA [to cover their asses] and any appeal will end up in the trash."⁸⁶

111. For the vast majority, if not all, terminated grants since February 28, 2025 including all terminated Project-Based Grants and Pipeline Grants supporting the research of

⁸⁶ Max Kozlov, Bluesky (Mar. 31, 2025, 2:24 PM), https://bsky.app/profile/maxkozlov.bsky.social/post/3llp6vhkvx22t.

Individual Plaintiffs, Plaintiff Ibis, and Associational Plaintiffs' members—the notices offer no other justifications for termination.

112. The notices make no effort to explain how or why the relevant grant fails to "effectuate agency priorities" or otherwise warrant termination. The notices fail to cite any project-specific information or data, much less any reasons to disregard that information or data. Indeed, the assertions in the termination notices about the lack of scientific validity, rigor, or public health benefit of the studies contradict the conclusions of NIH and external scientists who previously reviewed these projects and helped award those grants in the first place, including the multiple panels of experts in the grantees' fields who judged the proposals on criteria such as the lead scientist's track record, the rigor of the study's design, and the project's likelihood of addressing a pressing biomedical-research issue.⁸⁷ These notices also do not address NIH's prior assessment that the projects *do* meet agency priorities and are aligned with the statutory mandate and goals of NIH and the pertinent IC.

113. The notices also demonstrate that NIH failed to consider any reliance interests at stake for ongoing grants. For example, the notices say nothing about potential job losses that would result from the termination of the grant at issue or the effect the termination would have on study participants, the data being collected, the populations served by the research, or the broader goals furthered by the study. In short, the notices say nothing about how these terminations may affect the research endeavor or public health. Indeed, as one member of senior leadership at an NIH institute stated, grants are getting killed "without any scientific input anywhere."

114. For grants that were terminated, NIH also issued revised NOAs with new end-ofproject dates that reflected immediate or near-immediate termination. These revised NOAs also

⁸⁷ See Wu, supra at note 59.

included new termination language with statements that were substantively similar to the language included in Appendix 3 of the February 28 Guidance and March 25 Guidance, and made explicit reference to "2 C.F.R. §200.340 as implemented in NIH [Grants Policy Statement] Section 8.5.2" as its statutory authority for these terminations.

115. Evidence suggests the language in the termination notices did not originate with NIH or HHS staff but was instead drafted by staff from the Department of Government Efficiency ("DOGE"). For example, metadata associated with at least one such notice shows it was authored by "JoshuaAHanley." An attorney named Joshua A. Hanley, a 2021 law school graduate, works at DOGE.⁸⁸

116. The terminations cut across diverse topics *that NIH is statutorily required to research*. At least 678 research projects have been terminated to date. These include projects on some of the most pressing public health issues of our time, including breast cancer, uterine cancer, anal cancer, stroke risk, cardiac health, Alzheimer's Disease, HIV prevention, suicide prevention, alcohol use disorder, smoking cessation, eating disorders, sexually transmitted infections, COVID-19, depression, psychopathology, pain, and many other conditions that disproportionately burden minority communities. Other terminated grants studied the harmful effects of discrimination, poverty, racism, loneliness, trans exclusionary policies, and social stress, as well as the health-protective effects of social support, education, and school-based mental health interventions. Still others have no clear or at most a tangential connection to DEI, gender identity, or the other now-disfavored topics that were the alleged basis for their termination. These terminations compromise

⁸⁸ Sara Reardon, *Trump officials will screen NIH funding opportunities*, SCIENCE (Mar. 26, 2025), https://www.science.org/content/article/trump-officials-will-screen-nih-funding-opportunities. More recently, media

reported that after a two-month freeze on posting NOFOs, NIH will resume posting NOFOs, but only after review by HHS and DOGE for consistency with administration priorities.

NIH's ability to fulfill its statutory and other obligations. They also compromise the public's health and deprive minority communities of equal access to the benefits of government research.

117. The terminations also directly conflict with NIH strategic priorities. For example, the 2021–25 Strategic Plan for the National Institute on Minority Health and Health Disparities prioritizes research, among other things, to "understand and to improve the health of racial/ethnic minority populations," to "[a]dvance scientific understanding of the causes of health disparities," and to "[d]evelop and test interventions to reduce health disparities."89 Consistent with this goal, that institute issued Grant Number 5R01MD017509 for a five-year intervention beginning May 14, 2022, to test whether directly reducing the income gap among older African American men in rural communities enhances their health and wellbeing. The grant was scheduled to last through January 2027. However, on March 14, 2025, half-way through the project, the grant was terminated. In another instance, the institute funded a proposed multi-year grant entitled, "Development of a School-Based Prevention Intervention to Promote Adolescent Mental Health Equity." The grant began on January 31, 2025, but was terminated without explanation just 40 days later. These grants exemplify a pattern, in which IC-specific directors awarded grants consistent with their IC-specific strategic plans, after which the grants were summarily terminated despite no change to IC-specific or overall NIH strategic plans.

118. The programs designed by NIH to implement Congress's statutory mandate to diversify the workforce are also being gutted. In the past four weeks, NIH has at least terminated seventeen F31 Diversity awards that support promising graduate students in their final years of dissertation research.

⁸⁹ Nat'l Insts. of Health, supra note 68 at 2.

119. Similarly, NIH has paused all work under the Undergraduate Research Training Initiative for Student Enhancement ("U-RISE"), a \$23.1 million NIH initiative launched in 2019, "to develop a diverse pool of undergraduates" who plan to pursue higher education and careers in biomedical research.⁹⁰ U-RISE is a mirror program to the Minority Access to Research Careers program ("MARC"), created in 1977.⁹¹ Universities develop, apply for, receive, and administer MARC and U-RISE grants. For nearly 50 years, these programs have operated to diversify the biomedical workforce, supporting thousands of students from underrepresented backgrounds.

120. In 2024, NIH supported 63 U-RISE and 34 MARC programs. On March 27, 2025, with no prior notice, NIH issued stop work orders for all U-RISE programs through an email stating that "NIH is currently undergoing a process to assess whether pending awards perpetuate current agency priorities." The email instructs the program directors to "cease project activities as of the current budget period end date of 3/31/25" with an additional four days to reconcile all expenditures. It appears that all U-RISE program directors have received the same communication, regardless of how many years were left on these five-year awards. MARC program officers have no idea if or when their identical programs will be paused or terminated.

121. U-RISE supports high-achieving undergraduate students, typically juniors and seniors, who have demonstrated academic promise in STEM disciplines. The program aims to increase the likelihood that these students will pursue and complete PhDs in biomedical research fields by providing tuition assistance, monthly stipends, research training, mentoring, and support

⁹⁰ Nat'l Insts. of Health, Undergraduate Research Training Initiative for Student Enhancement (expired) <u>https://grants.nih.gov/grants/guide/pa-files/par-19-218.html</u>.

⁹¹ Nat'l Ctr. for Biotechnology Information, *Meeting the Nation's Needs for Biomedical and Behavioral Scientists, Appendix A, Historical Overview*, (1994), <u>https://www.ncbi.nlm.nih.gov/books/NBK236727/</u>. The program's name has since changed to "Maximizing Access to Research Careers," but its core goal has remained the same for 48 years, i.e., "to create and sustain inclusive [undergraduate] training environments for trainees from diverse backgrounds."

for lab-related expenses. The sudden termination of funding places participating students at immediate risk of losing housing, income, and academic continuity.

122. Along with terminations, NIH is also violating its regulatory mandate to review all appropriately submitted applications.

123. In February 2025, the F31 Diversity track opportunity disappeared from NIH websites.⁹² While in the past NIH has maintained expired funding opportunities on its website with an indication that the opportunity has expired, links to the F31 Diversity track now result in a "page not found" message. NIH has not provided information on the fate of applications received for these unpublished opportunities, but the March Guidance indicates that applications "received in response to a NOFO that has been unpublished due to its focus on activities that are no longer an NIH/HHS priority/authority" will not be funded.

124. These losses will render NIH incapable of meeting its congressionally required responsibilities. And they will deeply compromise the next generation of scientists, denying the public the contributions to health their promising careers would have yielded.

J. Terminations of Plaintiffs' Grants Cause Confusion, Chaos, and Other Ongoing Harm

125. The termination of the research funding of Individual Plaintiffs, Plaintiff Ibis, and Associational Plaintiffs' members provides a window into the devastation to medical and scientific research playing out across the nation right now. Their stories—just a fraction of the chaos and harm caused by the Directives—show how large the blast radius is from these terminations. And although the subject matter of their research spans all types of subject matter and populations, each termination notice is identical except for ever-so slightly different scripts stating that the grant "no

⁹² F31 Diversity grants are far from the only programs impacted. Additional unpublished funding opportunities include the MOSAIC, U-RISE, MARC and dozens of others.

longer effectuates agency priorities" (*see* above descriptions of Termination 1, Termination 2, and Termination 3).

126. As detailed further below, across Individual Plaintiffs, Plaintiff Ibis, and Associational Plaintiffs' members, these terminations have resulted in studies being postponed or cancelled, putting at risk the health of participants. And the terminations have severely diminished—if not eviscerated—the reliability of any data or statistical analyses from those years-long research efforts, crippling scientific advancement for years to come. Whether weighing the effects on study participants or the broader field of study, the lost benefits to the populations served by their research, or even the financial consequences on themselves and their staff, each researcher has suffered severe distress because of the Directives. Science may be a collective endeavor, but the harms here have also struck Individual Plaintiffs, Plaintiff Ibis, and Associational Plaintiffs' members on a personal level.

127. What's more, based on the Directives and the conclusory nature of the termination letters, Individual Plaintiffs, Plaintiff Ibis, and Associational Plaintiffs' members do not know which of their current remaining projects—if any—are still eligible for NIH grants, and they fear that at least some of their ongoing NIH-funded projects are at risk of being terminated on similar grounds. Individual Plaintiffs, Plaintiff Ibis, and Associational Plaintiffs' members are also uncertain about how they may need to change their current and future research, what terminology they must avoid, as well as which populations their research can focus on to remain eligible for NIH funding. As such, although they intend to apply for future NIH grants, they have no idea how to propose research in their areas of expertise that would satisfy the "agency priorities."

1. Individual Plaintiffs

128. Plaintiff Charlton has received terminations for her entire portfolio of five NIH grants, including a five-year \$4.15 million R61 grant for an observational study of the mental health impact of legislative bills targeting the LGBTQ population; a five-year \$4.42 million R01 grant for a longitudinal study of worse obstetrical outcomes for LGBQ women as compared to heterosexual women to inform targeted interventions to improve their health and the health of the approximately 800,000 children born each year to this population (a project that has nothing to do with gender identity and includes no transgender study participants); and an administrative supplement of \$100,000 for the R01 grant to support an early-career trainee on the research team. These grants were terminated throughout March with notices that used Termination Section 2 (Gender Identity), Termination Section 3 (DEI), and Termination Section 2 (Gender Identity), respectively.

129. Because of these terminations, Dr. Charlton has lost nearly all of her salary as well as the money to pay the salaries of 18 people on her staff. She had to terminate the LGBTQ Health Center's director the day after the terminations. And she has had to suddenly cancel appointments with impacted youth and other research subjects and wind down her projects.

130. NIH has terminated at least six grants in support of Plaintiff Edwards' research. The total amount awarded across those grants is approximately \$11.9 million. Included in those terminations is a five-year \$3.8 million R01 grant for a longitudinal study among sexual minority men to identify factors predicting sexual assault experiences and outcomes to inform prevention and intervention efforts specific to this highly vulnerable group. Also among those cuts is a R34 research grant, titled *An Online Family-based Program to Prevent Alcohol Use and Dating and Sexual Violence among Sexual and Gender Minority Youth*, aiming to increase family support and

communication, enhance social-emotional skills, and increase awareness of accurate perceptions of alcohol and dating violence norms. Both programs were terminated in March 2025 with notices that used Termination Section 1 and 2 (Gender Identity), respectively.

131. Due to the grant terminations, Dr. Edwards has had to suddenly stop or severely curtail research projects funded through the grants, potentially halting the intervention for the 22 families that are enrolled in one of her programs and impairing her ability to analyze data and build preventative interventions through the data collected in the projects. Further, one goal of her R34 research grant is to identify ways to implement programmatic recommendations for families in places like churches, community centers, and schools; now due to the termination, she will not have the data to evaluate or propose these types of recommendations from the project. Dr. Edwards has also lost a portion of her salary because of these terminations, as well as the ability to continue to pay a number of the approximately 50 staff members who are funded through her research grants.

132. Plaintiff Lurie served as a paid consultant and advisor on a two-year \$277,552 R21 grant to evaluate the impacts of over-the counter access to pre-exposure prophylaxis ("PrEP") on reduce the risk of HIV transmission. On March 21, 2025, the grantee institution, Harvard Pilgrim Healthcare, Inc., received a termination notice from NIH using Termination Section 2 (Gender Identity).

133. As a result of the termination, the research into PrEP access being conducted under the grant has been discontinued, resulting in harms to public health in the form of reduced knowledge about how to effectively reduce the spread of HIV.

2. Plaintiff APHA Members

134. Members of Plaintiff APHA have also received letters notifying them that NIH grants supporting their research had been terminated.

135. For example, APHA Member 1 was awarded a five-year, \$4 million grant in support of their research to study time-efficient ways to measure patients' exposure to discrimination based on race, sex, gender identity, sexual orientation, age, and weight. On February 28, 2025, APHA Member 1 received a notice of grant termination from NIH informing them that NIH would be terminating the last year installment of the grant, amounting to \$650,000. That notice includes Termination Section 3 (DEI).

136. Because of the termination, the study team, who were expecting to be employed until January 2026, have lost job security, and they cannot complete analyses of the study's key outcomes—measuring and analyzing the health impacts of discrimination—or share these findings with community health centers and study participants.

137. APHA Member 2 served as principal investigator on a four-year, \$6.8 million R24 grant establishing the Coordinating Center for National Pain Scientists ("Coordinating Center") with the purpose of connecting a growing network of nearly 5,000 pain researchers across the country to support collaboration, improve networking, and centralize trainings and educational resources.

138. On March 21, 2025, APHA Member 2 received a notice of grant termination with Termination Section 3 (DEI). APHA Member 2 was alarmed and confused to see funding for the Coordinating Center cut because it does not support any study related to DEI and no hiring or scholarship decisions based on specific demographics have ever been made. To the contrary, the Coordinating Center is open to all researchers studying pain and no demographics have been

prioritized or excluded. The only reason APHA Member 2 can identify for why the grant was terminated is because the original NOFO required the Coordinating Center to include a diversity plan describing how its work would support the biomedical field broadly, including historically underrepresented researchers; however, this was ancillary to its operations and no financial resources have ever been devoted to it.

139. As a result of this termination, four staff members working on the Coordinating Center have been furloughed, APHA Member 2 has lost nearly all of their salary, and approximately \$1 million may now be wasted on pre-obligated spending toward an annual conference that can no longer occur. Without the Coordinating Center, fewer pain researchers will be trained to address chronic pain, and public health is harmed due to the reduced knowledge about how to treat and manage pain without running the risk of addiction.

140. APHA Member 3 has had one grant terminated for which they are principal investigator, and three other grants terminated for which they are a co-investigator, including an R01 grant for a longitudinal study aimed at developing interventions to reduce drug use and promote mental and physical health in Black men. On March 20, 2025, with only five weeks left to complete this multi-year project, NIH canceled the grant, effective immediately, with a termination letter that includes Termination Section 3 (DEI).

141. Due to the termination, APHA Member 3 has to wrap up a multi-year project five weeks early, and is unable to compensate three research team members who had already performed work on the project but had not yet submitted invoices for their hours worked. Collectively, these research assistants are owed compensation for their work on the grant for roughly 130 hours, an estimated \$8,560.

142. APHA Member 4 has had NIH terminate five grants that support their research, including an approximately \$4 million grant for a randomized controlled trial with 375 participants using peer intervention to encourage the use of PrEP in order to address high rates of HIV in transgender men who have sex with men. On March 21, 2025, NIH terminated the grant through a notice including Termination Section 1 (Gender Identity).

143. The impacts of the grant termination are severe. APHA Member 4 cannot pay their staff of six, has lost three months of their own salary, and will be restricted in their ability to work on a project that took years to develop and fund.

144. NIH has terminated three grants supporting APHA Member 5's research, including an R01 grant aimed to develop new or modified caregiving measures for the nearly one million sexual and gender minority adults in the U.S. who are caregivers and to ensure that they are included in future research on caregiving for those with Alzheimer's disease. On March 21, 2025, NIH terminated this grant with a notice that includes Termination Section 1 (Gender Identity).

145. The impacts of the grant termination are dire. APHA Member 5 has lost much of their salary and is in the process of laying off their staff of at least 35 people, and their coinvestigators are doing the same. Beyond that, sudden termination of the study has broken the trust of the participants in the study—all LGBTQ caregivers for people with Alzheimer's who had each spent two years answering questions about their caregiving experiences for research that will now not be completed.

146. NIH has also unlawfully terminated grants supporting the work of APHA Members 6 and 7, both principal investigators on a five-year, \$2.45 million Kirschtein-NRSA T32 grant funding recruitment and training of postdoctoral scientists. The program increases the pipeline of scientists studying addiction and related conditions and provides training in treatments that reduce

overdose deaths by 50%, work critical to HHS priorities to address the opioid crisis. Consistent with the NOFO's listed purpose to ensure a "diverse and highly trained workforce," their grant proposal prioritized recruitment of postdoctoral fellows from groups excluded based on race and ethnicity, people with a disability, people who are LGBT+, people having a disadvantaged background, and those with "diverse training backgrounds." However, despite this intention, of the four offers made to postdoctoral trainees for acceptance into the training program to date, all four were made to white candidates. On March 21, 2025, before the conclusion of the first-year budget period, the APHA members received a notice that their grant was terminated including Termination Section 3 (DEI).

147. As a result of the grant termination, APHA Members 6 and 7 have rescinded offers to postdoctoral fellows for entry into the training program. Fewer clinical researchers will be trained to address substance abuse, and trainees will not be able to pursue scientific inquiries that could have led to novel non-pharmacological approaches to reducing the risk of substance use disorders.

148. APHA Member 8 is a postdoctoral fellow who had been in the first year of the three-year training program. The sudden withdrawal of the T32 grant funding has enormous consequences for their career path. The termination, at a time when the application period for most other T32 grants has ended, means they will be without employment in academia until at least July 2026.

149. NIH has terminated at least two grants that support the research of APHA Member 9, totaling approximately \$3 million, to better understand efforts that could promote HIV prevention and treatment, and to address health inequity experienced by gay, elderly, and racial

minority populations and populations living with or without HIV. The grants were terminated in March using a notice of termination that includes Termination Section 3 (DEI).

150. Due to the grant terminations, APHA Member 9 will likely have to lay off at least three staff members, will lose approximately 20% of their annual salary, and will have to conclude the study before completing sufficient recruitment to achieve the sample size needed to conduct valid—and meaningful—statistical analyses. Cutting off these studies will prevent their contribution to the understanding of HIV and comorbidities (e.g., heart attacks, diabetes, or mental illness) across racial groups.

151. APHA Members 10 and 11 were awarded an R15 grant for over \$450,000 in support of their research on ways to improve healing for sexual and gender minority survivors of sexual violence, given the high rates of sexual violence they experience, and creating opportunities to train student researchers. In March, within the first year of the three-year grant, they received a notice of grant termination from NIH including Termination Section 1 (Gender Identity). Tied to this R15 grant was an application for a diversity supplement of approximately \$162,000 to support an early career trainee on the research team that has been in limbo for the last three months.

152. As a result of the grant termination, these APHA members will not have funds to pay their students and will lose a quarter of their own salaries. Nor will they be able to realize the project's aim of training people to better respond when a sexual or gender minority discloses that they have been a victim of sexual violence.

153. APHA Member 12 received a 4.75-year, \$3.4 million R01 Research Project Grant from NIH to fund their research on stigma around HIV testing and PrEP use among U.S. Latino men who have sex with men. On March 20, 2025, only about 40 days before the project's end date, the member received a notice that the grant was terminated. The grant termination notice includes

Termination Section 3 (DEI). Since not all participants completed interviews, it is impossible to complete the project's longitudinal analyses.

154. As a result of the grant termination, almost \$3,300,000 in sunk costs on the project have been wasted, two individuals hired to interview participants have already had their employment terminated, additional project team members may imminently lose their jobs and the 503 participants in the study will be harmed when they learn that the grant has been terminated, as it will create further stigma.

155. APHA Member 13 was awarded an almost five-year, \$1,487,916 International Research Training Grant from NIH funding the Malaysian Implementation Science Training program at the University of Malaya in collaboration with Yale University, a first of its kind initiative designed to address Malaysia's rapidly expanding HIV epidemic through training University of Malaya faculty and early career researchers.

156. On March 21, 2025, in the fifth year of a five-year grant, the lead investigator received a notice that the grant was terminated. The grant termination notice includes Termination Section 1 (Gender Identity). A renewal of the grant was recently reviewed and received a highly competitive score that should have committed five years of continued funding; this will no longer happen.

157. APHA Member 14 received a two-year, \$428,270 R25 (research training and career development) award to fund training and mentorship of early-stage investigators on measurement rigor and ethical practices. The program's goal is to narrow the gap in research on perinatal intimate partner violence, which has marked effects on maternal health outcomes. It was proposed in response to a funding call for projects addressing intimate partner violence and intended to contribute to the NIH Implementing a Maternal Health and Pregnancy Outcomes Vision for

Everyone Initiative, launched in 2019 in response to high rates of pregnancy-related complications and deaths in the United States.

158. On March 21, 2025, before the conclusion of the first-year budget period, APHA Member 14 received a notice that the award was terminated. The termination letter includes Termination Section 3 (DEI). As a result of the award termination, APHA Member 14 incurred over \$50,000 in sunk costs on the project and forfeited valuable training and research outcomes. APHA Member 14 and another APHA Member working on the project may lose their jobs, as both positions are grant-funded.

159. APHA Member 15 received a three-year, Kirschstein-NRSA fellowship aimed to develop and implement Rapid Start ART, an HIV treatment prescribed immediately after diagnosis. The fellowship's training component includes coursework, mentorship, and research on stigma, implementation science, and dyadic analysis. The fellowship bridges the gap between being a doctoral student and a professor. On March 18, 2025, only about a month after the project began, the member received a notice that the grant was terminated. The termination letter includes Termination Section 2 (DEI). Only a few hundred dollars of the grant funding had been withdrawn; the member has not yet received a paycheck. However, the member had already begun significant planning for the three-year grant, completing paperwork and meeting with the data collection team. The member had recently moved to live near the university and may lose their job.

3. Plaintiff Ibis

160. In September 2023, Plaintiff Ibis was awarded a 5-year R01 research grant, with approximately \$500,000 in funding per year for a project to study methods for improving the collection and quality of data in sexual and reproductive health research for people including those who identify as transgender and gender diverse. Plaintiff Ibis had applied for the grant two years

before that and scored in the top two percent of applications submitted. After years of developing and testing the survey methods, and on the eve of launch, Plaintiff Ibis received a termination notice from NIH in March 2025 using Termination Section 2 (Gender Identity). Even though the research supported by the grant specifically advances the priorities of NIH's National Institute of Child Health and Human Development, NIH terminated the grant for purportedly "no longer effectuat[ing] agency priorities."

161. As a result of the grant termination, Plaintiff Ibis must restructure research teams because of staffing pressures and seek additional funding to cover the salaries of four employees staffed on the project. Plaintiff Ibis has also had to pause the next phase of the study, hindering collection of crucial data on sexual and reproductive health experiences and preferences from under-studied populations.

K. NIH's Refusal to Consider Individual Plaintiffs' and Associational Members' Pending Grants, Extensions and Renewals of Existing Grants, and Stop Work Orders

162. Pursuant to the Directives, NIH is refusing to consider pending Pipeline Grant applications that it deems DEI-related.

1. Plaintiff Maphis

163. Plaintiff Maphis's MOSAIC application is one such grant. On November 12, 2024, Dr. Maphis applied for a MOSAIC grant, intended to help diversify the profession. Her proposed research would, if funded, study the link between Alcohol Use Disorder and Alzheimer's Disease. It would provide five years of funding and help her transition from her mentored postdoctoral research position at the University of New Mexico to a junior faculty member elsewhere. It would have, in short, helped launch her career as an independent researcher.

164. Dr. Maphis's application was assigned to a study group scheduled to score her proposal on March 4, 2025. The morning of March 4, however, she learned that her proposal had

been reassigned to a new generic group that was not scheduled to meet. Later that day NIH notified her that her proposal, along with others, had been pulled from its original study group. When Dr. Maphis asked whether her proposal would be reviewed, she was told "unfortunately not." Dr. Maphis was told by a member of her original study group, which had reviewed her application before March 4, that her application was highly regarded and likely would have received funding had it not been for NIH's changes. Dr. Maphis's current funding expires on September 30, 2025. Without additional funding, which the MOSAIC award would have provided, she will lose her job. She will also lose out on the training she would have received from the MOSAIC program. As a consequence, Dr. Maphis will be less competitive on the faculty job market, unlikely to secure a faculty position, and potentially forced to abandon a career in academia, which she has been training for and working towards for the last 17 years.

2. Plaintiff APHA Members

165. APHA Member 16, who researches zinc's impact on health, is the recipient of a MOSAIC grant. Member 16 has recently completed the two year (post-doctoral training) K portion of the grant and was slated to transition to the R portion of the grant, in which NIH would fund the first three years of their position as a tenure-track Assistant Professor. APHA Member 16 began their faculty position in January but never received their NOA for the R portion, which normally would have been received in January or February.

166. APHA Member 16 has not been getting responses from NIH about the status of their application, which is particularly concerning for APHA Member 16 because NIH has cancelled the MOSAIC program, removed it from the National Institute of General Medical Sciences website, and terminated the NOFO early. As a result of not receiving the NOA, APHA

Member 16 has not been able to obtain the necessary funding for completing their lab setup, hiring staff, and continuing this important research.

3. Plaintiff UAW Members

167. UAW Member 1, a PhD candidate at a private university in California, submitted an F31 dissertation proposal that, if funded, would help inform intervention efforts for suicide prevention among LGBTQ youth experiencing homelessness—the leading cause of death for this population. They received a high score (14th percentile) on the proposal. However, they learned the project would likely not be funded because of new restrictions on LGBTQ research. This will harm UAW Member 1's ability to progress through their PhD program.

168. UAW Member 2, a postdoctoral researcher at a private university in New York, has a pending application for an NIH Diversity Supplement. They research affect, sleep, and processes of embodied change (sleep health). They have received no updates from NIH on their application. Without this funding opportunity, they cannot remain at their university to complete their program. They will have to stop ongoing projects and forfeit the rest of a supplemental grant they received because they will no longer have institutional support. They will have to apply for new postdoctoral positions elsewhere that would require them to change their project and lose the research investments they have already made. This will make them less competitive for the next step of their research career and require they spend longer as a postdoctoral scholar, earning a salary as much as \$25,000 lower than they would have had they remained at their current institution.

169. As a result of NIH's refusal to consider their application, UAW Member 2 is in the position of having to choose between leaving their career as an academic researcher, for which they have trained for over 10 years, or moving to a position in a different part of the country or outside the country, away from their family, their partner, and the medical care they need as a

person with a physical disability. If they do not find an alternative position, they face a period of unemployment in one of the most expensive cities in the world.

170. UAW Member 3, a postdoctoral researcher at a private university in New York, applied to the MOSAIC K99 program through the National Institute of General Medical Sciences. This five-year career transition award of \$1 million would launch their career studying mechanisms of behavior (evolution of behavior). Their proposal received an impact score of 10 (a perfect score) last fall. NIH, however, will no longer communicate with UAW Member 3 about this award. UAW Member 3 has aged out of eligibility for the main K99, so reapplying is not an option for them. Because they thought they had secured the MOSAIC K99 award, UAW Member 3 did not apply to the Simons Foundation Fellows-to-Faculty Award. Without the K99 award, UAW Member 3 is in a strained financial position to finish their postdoctoral studies and will be much less competitive on the job market.

171. UAW Member 4 is a graduate student at a private university in New York, where they research neurophysiology, in particular, the neurobiological mechanisms underlying maternal caregiving. They were awarded a transition grant known as a D-SPAN (F99/K00) intended to support a defined pathway across career stages for outstanding graduate students from diverse backgrounds, including those from groups that are underrepresented in neuroscience research.

172. Despite having received a NOA for this program, their NIH program officer has since encouraged them to apply for other funding programs, citing uncertainty surrounding the future of the funding program. Consistent with this messaging, UAW Member 4 also noticed that language on the D-SPAN program website has changed, now referring to the D-SPAN grant in the past tense, and the pictures and bios of previous and current awardees have been removed. UAW

Member 4's potential lack of funding has created significant challenges for them in securing a postdoctoral position.

173. UAW Member 5 is a graduate student worker at a private university in California. They applied for a two-year NIH Diversity Supplement to an existing R01 grant. This supplement is intended to support underrepresented researchers, with the goal of expanding UAW Member 5's skillset and substantiating their potential to become a productive investigator. The project was part of a multi-university collaboration and would fund the bulk of UAW Member 5's dissertation research, covering direct and indirect costs, materials and supplies, travel, and other essentials.

174. UAW Member 5 completed the application process and corresponded with NIH coordinators, understanding that the supplement was officially under review. However, on the day Executive Order 14151 was announced, all communication ceased. The NIH website pages related to the diversity supplement were scrubbed, and the coordinators became unreachable. No formal notice of cancellation or termination was ever provided—only a sudden disappearance of any evidence that the supplement application existed. To date, UAW Member 5 is left to assume that the grant as a whole no longer exists, despite never receiving any official update regarding its status while under review and with no clarity on how to proceed.

175. UAW Member 6 is a postdoctoral student at a private university in New York and a MOSAIC K99/R00 scholar whose grant studies how social cues guide emotions. This study was motivated by the need to understand how social processing is impaired in several neuropsychiatric disorders. UAW Member 6 had begun the process of requesting a no-cost extension but has been unable to communicate with the NIH program officer since January 2025 to begin this process. UAW Member 6 was well-situated to receive this grant given their extensive service in mentoring and advocacy while simultaneously performing high-quality science—a feat not many scientists successfully undertake.

176. UAW Member 6 is relying on the R00 portion of their MOSAIC grant to kickstart their tenure-track faculty lab and to continue and expand on their work to develop novel treatments for psychiatric disorders. Given NIH's complete silence, UAW Member 6 fears they will not receive their R00 when they apply for it in this year's upcoming job cycle, which could potentially restrict their nation-wide job search. This has caused immense stress and has created uncertainty in their research career progression in securing a tenure-track faculty position.

177. UAW Member 7, a graduate student at a private university in New York, was preparing an F31 parent grant proposal to study the impacts of anti-transgender structural stigma (anti-transgender legislation). That funding opportunity, however, was cancelled as of March 10, 2025, depriving UAW Member 7 of the potential funding that grant would have provided.

178. UAW Member 8, a graduate student at a private university in New York, sought an F31 Diversity grant to study developmental neurobiology. This research is crucial to gain insight into early risk factors of neurodevelopmental and psychiatric disease and enable the identification of timepoints for effective prevention and treatment. UAW Member 8's proposal was highly scored (Impact score: 18, Percentile: 2.0) and, accordingly, NIH issued a notice of award in August 2024. Their supervisor, however, was notified in March 2025 that F31 had been cancelled. UAW Member 8's application status has since been changed to "pending" and the budget period has been significantly shortened from the initial accepted budget period. NIH's decision to cancel this grant will hinder development on learning the neurodevelopmental factors preceding psychiatric disease onset, which is relevant to nearly half of the U.S. population. The lack of funding will also undermine UAW Member 8's ability to progress through their PhD program. 179. UAW Pre-Member 1 is a postdoctoral fellow at a private university in Massachusetts and has been awarded a MOSAIC K99/R00 fellowship.⁹³ They are finishing the K99 phase of the award. They study how cells respond to signals outside the cell. By better understanding how this process is dysregulated, UAW Pre-Member 1 hopes to improve cancer therapeutic strategies in the future.

180. As is standard for K99/R00 fellows, UAW Pre-Member 1 has been planning to apply to activate their R00 funding this summer, once they have found an independent position as an assistant professor. They have discussed this plan with their NIH program officer. This should be a routine process, as the scientific component has already been evaluated and positively reviewed. However, the status of the MOSAIC program has become unclear—the website has been deleted, and the program is not seeking new applicants.

181. UAW Pre-Member 1 has been unable to get information from NIH about their ability to activate the R00 funding. They fear, like other MOSAIC scholars, that their grant will be terminated. These changes to NIH policy have created uncertainty in UAW Pre-Member 1's transition to an independent position. Not having this award would significantly weaken their ability to negotiate a job offer and impair their ability to begin an independent lab.

182. UAW Pre-Member 2 is a postdoctoral scholar at a private university in Pennsylvania, where they are tracking outbreaks of newly emerging multi-drug-resistant pathogens and investigating new ways to treat and prevent infections. They are funded by an NIH K12 training and career development grant awarded to their home institution which has a stated goal of improving diversity, equity, and inclusion in the biomedical sciences. As part of their

⁹³ "Pre-member" means UAW is their exclusive bargaining representative in ongoing negotiations with their employer and that they intend to become dues-paying members once a collective bargaining agreement is in place.

training under this grant, they also taught science classes at minority-serving colleges and universities in their metropolitan area.

183. When UAW Pre-Member 2 was accepted into this postdoctoral training program, they were told the tenure of the program was three years. Since January 21, 2025, however, they have been told that the status of their funding in the near future is unknown. The principal investigators of the training grant at their home institution have been unable to reach the assigned program officer, and they do not know whether the regularly anticipated non-competing renewal will be completed this summer.

184. To UAW Pre-Member 2's knowledge, there has been no communication from the federal government about the status of this entire category of training grants, nor of individual grants in this funding category. As a result, UAW Pre-Member 2 does not know whether they will lose their funding in the next few months. UAW Pre-Member 2 chose this funding path because they want to research infectious disease that directly informs clinical outcomes, and because they want to educate future generations of biomedical researchers. They had planned to spend three years developing an infectious disease research program which they could bring to a faculty position. Now, this future is uncertain as their research training time may be cut short by 30%.

185. UAW Pre-Member 3 is a third-year graduate student in the Cell and Molecular Biology Ph.D. program at a private university in Pennsylvania. They are currently performing a research project that seeks to understand how heterochromatin associated proteins impede changes to cell fate and how mutations in these proteins lead to defects in neuronal development. They applied for the F31 Diversity grant on December 8, 2024. On February 13, 2025, their proposal was assigned to the Molecular and Cellular Sciences and Technologies ZRG1 F05-A (20) study section, scheduled for review on March 26–27, 2025. However, on March 12, 2025, UAW PreMember 3 was informed that the study section information had been removed from their proposal's status. To date, the NIH has not provided any clarification or a timeline regarding when—or even if—the application will be reviewed.

186. This change is particularly perplexing given that the only difference between the standard F31 and the F31 Diversity grant is the inclusion of an additional statement recognizing that the applicant comes from an underrepresented community in the sciences. For early-career scientists, obtaining such grants does more than support a research project financially; it represents recognition of their dedication, hard work, and potential to become future primary investigators.

187. UAW Pre-Member 4 is a postdoctoral associate at a private university in New York. They applied for a diversity supplement for a project grant that seeks to improve transport of protective antibodies from mother to child during Cytomegalovirus infection. The study was motivated by the idea that Cytomegalovirus infection could prevent this transfer, leaving neonates vulnerable to a variety of congenital infections in utero.

188. UAW Pre-Member 4 met the supplement's DEI requirements as a first-generation college student and a Latina. As of January 2025, the proposal was under review. However, the funding mechanism was abruptly cancelled due to its DEI requirements. This has been a significant setback for UAW Pre-Member 4 as a first-year postdoctoral student, as the supplement would support the majority of their postdoctoral salary. The lack of funding is a barrier to the start of this project and is delaying their expected timeline for gaining independence as a scientific investigator.

189. The cancellation of this funding mechanism robs the field of study of diverse perspectives and ideas. Ultimately, restricting access to funding for researchers from diverse backgrounds will limit the impact that academic institutions can make to biomedical research.

190. UAW Pre-Member 5 is a postdoctoral research scholar at a private university in Pennsylvania. They are working on their K99/R00 "Pathway to Independence Award" from the Helping to End Addiction Long term ("HEAL") Initiative—a program co-sponsored by the National Institutes of Mental Health and the National Institute of Drug Abuse. This five-year, approximately 1 million dollar grant provides two years of advanced postdoctoral training followed by three years of start-up funds for an investigator to begin an academic lab. One of the goals of the HEAL initiative is to develop new medicines to treat pain without propensity to cause addiction, an issue of great importance to the opioid crisis.

191. On March 10, 2025, UAW Pre-Member 5 was made aware that the Request for Applications (RFA) RFA-NS-22-025 (which contained a diversity component), had been eliminated. This was not communicated by NIH. The program was designed to allow applicants from disadvantaged backgrounds to apply for evaluation in smaller study sections. UAW Pre-Member 5 was raised in an American "rust belt" city that has long struggled with the opioid epidemic. The cancellation of NIH's interest in diversity means that UAW Pre-Member 5 will be competing against a larger applicant pool, which limits their chance of success in an already competitive grant mechanism.

192. UAW Pre-Member 6, a graduate student at a private university in Pennsylvania, studies the replication mechanisms of viral diseases spread by mosquitoes to identify targets for drug therapeutics. They sought this course of study because of the lack of existing or approved vaccines and antivirals to counter viral disease in humans. A warming climate has also increased the geographic spread of these diseases as a consequence of a broader habitat for mosquitos. UAW Pre-Member 6 applied to the F31 Diversity Fellowship for the August 2024 deadline. After receiving a score and percentile well within the fundable range in December 2024, UAW Pre-

Member 6 and their principal investigator waited for a just in time request for information from NIH and notice of award. However, after NIH funding freezes were announced in January 2025, UAW Pre-Member 6's study section was canceled.

193. On March 18, 2025, UAW Pre-Member 6 reached out to their assigned NIH program officer to ask about the status of their application. The program officer then informed UAW Pre-Member 6 that their grant had been terminated. The award would have funded UAW Pre-Member 6 and their principal investigator for three years, covering stipends, conference travel, and materials for their project.

194. Completing an F31 grant application is excellent practice for the development of scientific writing and project presentation. Aside from this, the Diversity F31 is built to uplift minority researchers through financial support. Although other grant pathways exist, this grant gave UAW Pre-Member 6 the opportunity to showcase a broader part of their identity that can enhance their scientific research. Part of the F31 Diversity application process is writing about how you plan to uplift other scientists. For UAW Pre-Member 6, the cancellation of diversity fellowships feels like a devaluation of their scientific research and of their sense of self as a scientist. Funding may still be provided by their lab, but the termination of the grant has, to their knowledge, caused the principal investigator to limit expenditure of funds, including conference travel and reagent purchase, which affects UAW Pre-Member 6's ability to carry out their research, gain experience presenting their work, and network with other scientists.

CAUSES OF ACTION

195. Plaintiffs reallege and incorporate by reference all prior and subsequent paragraphs.

COUNT I Violation of the Administrative Procedure Act – Arbitrary and Capricious

196. The APA provides that courts "shall . . . hold unlawful and set aside agency action" that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

197. 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 v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

198. Defendants are acting in an arbitrary and capricious manner in violation of the APA.

A. Grant Terminations

199. Individual Plaintiffs, Plaintiff Ibis, and members of Associational Plaintiffs' members whose grants have been terminated ("Terminated Plaintiffs") assert this portion of this cause of action against all Defendants.

200. NIH's grant terminations pursuant to the Directives constitute final agency action under the APA for which there is no other adequate remedy in a court.

201. These terminations are arbitrary and capricious for at least seven reasons.

202. First, in its termination letters, NIH fails to provide adequate reasoning explaining how these studies fall below the agency's standards for scientific research. NIH's repetition of boilerplate and conclusory language across all the termination letters is not an adequate explanation as to how any specific study fails to meet agency priorities.

203. Second, NIH fails to analyze any relevant data. The termination letters show that NIH did not consider individual, or any, data from the grants at issue or from any body of research that would contradict the value or rigor of the grants at issue.

204. Third, NIH is not providing a reasoned explanation for its actions, as it is ignoring reliance interests. In the termination letters, NIH fails to mention, and does not appear to have considered, how these terminations will affect the reliance interests of researchers (including Plaintiffs), the institutions that host them, the participants in the terminated studies, and the body of research furthered by the terminated grants and the populations who would have benefitted from that research.

205. Fourth, NIH relies on assertions contrary to its prior award review and policies, including the NIH Strategic Plan and IC Strategic Plans. NIH states that its terminations are based on an alleged change in priorities, but NIH has neither adopted, described, nor explained any new priorities, and the strategic plans under which the previous awards were made remain in effect.

206. Fifth, the terminations run counter to available evidence and reflect NIH's failure to consider important aspects of the problems addressed by the terminated grants and the areas of research mandated by, among other things, Congress, NIH's Strategic Plan, and NIH's policy guidelines. As its stated change in priorities runs directly counter to congressional mandates, NIH is also relying on factors that Congress does not intend for NIH to consider.

207. Sixth, NIH reliance on mandates by individuals outside the agency (including, for example, from DOGE individuals who drafted some number of the termination letters at issue), violates NIH's requirement to appropriately reach its own decision.

208. Seventh, an agency acts arbitrarily and capriciously if it acts in a manner that is contrary to its own regulations or a congressional statute. For the reasons expressed in Counts II, III, and IV, Defendants have acted contrary to their own regulations or congressional statutes.

209. For those and other reasons consistent with the allegations herein, Defendants' grant terminations are arbitrary and capricious in violation of the APA. 5 U.S.C. § 706(2)(A).

B. Refusal to Consider Applications

210. Individual Plaintiffs, Plaintiffs Ibis, and Associational Plaintiffs' members whose grant applications NIH has refused to consider pursuant to the Directives ("Applicant Plaintiffs") assert this portion of this cause of action against all Defendants.

211. NIH's refusal to consider applications for published NOFOs that Defendants subsequently removed from publication constitutes final agency action under the APA.

212. For the same reasons described above, NIH's refusal to consider properly submitted applications is arbitrary and capricious. That is, NIH (i) failed to adequately explain its reasons for this refusal; (ii) failed to analyze any relevant data; (iii) failed to consider reliance interests; (iv) has purported to rely on a change in priorities that has not occurred and that it has not explained; (v) failed to consider important aspects of the mandated areas of research addressed by the proposed grants and considered factors that Congress did not intend for it to consider; (vi) failed to appropriately reach its own decision; and (vii) acted contrary to its own regulations or congressional statute.

C. The Directives

- 213. All Plaintiffs assert this cause of action against all Defendants.
- 214. NIH's adoption of the Directives is final agency action under the APA.

215. For the same reasons described above, NIH's adoption of the Directives is arbitrary and capricious. That is, NIH (i) failed to adequately explain its reasons for the adoption of the Directives; (ii) failed to analyze any relevant data; (iii) failed to consider reliance interests; (iv) has purported to rely on a change in priorities that has not occurred and that it has not explained; (v) failed to consider important aspects of the mandated areas of research addressed by the Directives and considered factors that Congress did not intend for it to consider; (vi) failed to appropriately reach its own decision; and (vii) acted contrary to its own regulations or congressional statute.

COUNT II Violation of the Administrative Procedure Act – Not in Accordance with Law

216. Terminated Plaintiffs assert this cause of action against all Defendants.

217. The APA directs courts to hold unlawful and set aside agency actions that are not in accordance with law. 5 U.S.C. § 706(2)(A). Defendants fail to meet this standard in at least three ways.

218. First, Defendants are purporting to terminate grants based on 2 C.F.R. § 200.340(a)(2) (2020), which allowed termination if an award "no longer effectuates the program goals or agency priorities." However, HHS did not adopt OMB guidance allowing for termination under 2 CFR Part 200.340 based on changes to agency priorities until October 2024, with an *effective date of October 1, 2025.* In the revised NOAs that NIH sent to Plaintiffs when it terminated their grants, NIH states that its action is "in accordance with 2 CFR § 200.340 as implemented in NIH GPS Section 8.5.2." But NIH Grants Policy Statement Section 8.5.2 did not implement the revised 2020 version of 2 CFR 200.340 because HHS did not implement that revised version in its regulations. This section purports "to be compliant with governing statutes

and the requirements of 2 CFR Part 200, *as modified by previously approved waivers and deviations*. However, in the case of a conflict, the statutes and regulations govern."⁹⁴

219. Second, even if 2 C.F.R. § 200.340(a)(2) (2020) applies, NIH's grant terminations are not in accordance with that regulation. 2 C.F.R. § 200.340(a)(2) (2020) provided that a federal award may be terminated in part or in its entirety "to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities." For the reasons stated in the preceding paragraph, NIH's termination was not "authorized by law." In addition, for the reasons already discussed in Count I (Arbitrary and Capricious), NIH's termination decisions were not consistent with the requirements of the APA—and therefore beyond "the extent authorized by law."⁹⁵

220. Further, the guidance accompanying the regulation indicates that any termination pursuant to 2 C.F.R. § 200.340(a)(2) must be based on the agency's consideration of evidence and in particular, "additional evidence"—indicating that the "award no longer effectuates the program goals or agency priorities." *See* Guidance for Grants and Agreements, 85 FR 49506, 49507 (2020). But as already alleged, NIH's terminations are not based on *any* evidence regarding the specific grants.

221. Moreover, 2 C.F.R. § 200.340(b) (2020) stated that the agency "should clearly and unambiguously specify termination provisions applicable to each Federal award, in applicable regulations or in the award, consistent with this section." Likewise, the OMB Uniform Guidance that NIH recently adopted to go into effect October 1, 2025 only allows for termination based on changes to agency priorities "pursuant to the terms and conditions of the Federal award," and states that the agency "must clearly and unambiguously specify all termination provisions in the terms

⁹⁴ See Nat'l Insts. of Health, NIH Grants Pol'y Statement § 3 (Apr. 2024) (emphasis added).

⁹⁵ See 2 C.F.R. § 200.340(a)(2) (2020).

and conditions of the Federal award."⁹⁶ Yet the original NOAs that Plaintiffs received did not include reference to the OMB Uniform Guidance and did not state that an award could be terminated for shifting agency priorities.

222. Third, the terminations are not in accordance with the terms of the pertinent NIH Grants Policy Statements. Section 8.5.2 allows involuntary termination solely "if a recipient has failed to comply with the terms and conditions of award." Across its termination notices, NIH has acknowledged that it "generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision," in accordance with the respective NIH Grants Policy Statement governing each award. While "NIH may immediately terminate a grant when necessary," "when necessary" is cabined by reference to circumstances "such as to protect the public health and welfare from the effects of a serious deficiency" and is only allowed under the limited circumstance where "a recipient has failed to comply with the terms and conditions of award."

223. NIH has failed to show that termination of any grants pursuant to the Directives met those circumstances. Defendants have not based termination of Plaintiffs' grants on a failure to comply with the terms and conditions of their awards. Even if termination were available to NIH where a grantee has met the terms and conditions of their award, NIH has failed to abide by its obligation under the NIH Grants Policy Statements to allow those grant recipients an opportunity to take appropriate corrective action before NIH terminated their grants.

224. Fourth, for the same reasons expressed below in Count III (APA – Exceeds Statutory Authority), Defendants' actions pursuant to the Directives—including the grant

⁹⁶ 2 CFR 200.340(a)(4),(b) (2024).

terminations and refusal to review submitted grant applications—run afoul of the mandates set forth by Congress.

225. Thus, Defendants failed to act in accordance with law in violation of the APA. 5 U.S.C. § 706(2)(A).

COUNT III

Violation of the Administrative Procedure Act – Exceeds Statutory Authority

226. All Plaintiffs assert this cause of action against all Defendants.

227. A reviewing court must hold unlawful and set aside agency actions that are found to be "in excess of statutory jurisdiction, authority, or limitations." 5 U.S.C. § 706(2)(C).

228. Through Section 301(a) of the Public Health Service Act, *see* 42 U.S.C. § 241(a), Congress delegated authority to NIH to "make grants-in-aid to universities" and other research institutions for the purpose of "promot[ing] 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." *Id*.

229. In addition, Congress has mandated the expenditure of funds by NIH and ICs to promote health equity across health disparity populations, including racial and ethnic minority populations, less privileged socioeconomic status populations, underserved rural populations, sexual and gender minorities, and any subpopulations that that can be characterized by two or more of these descriptions. Among those statutory mandates are:

> a. 42 U.S.C. § 281(b)(24), which created the National Institute on Minority Health and Health Disparities to "conduct and support…research, training, dissemination of information, and other programs with respect to minority health and conditions and other populations with health disparities." *Id.* at § 285t(a).

- b. 42 U.S.C. § 285t, which mandates that the Director of the National Institute on Minority Health and Health Disparities "shall[,] in expending amounts appropriated under this subpart give priority to conducting and supporting minority health disparities research," and "ensure that the plan and budget serve as a broad, binding statement of policies regarding minority health disparities research and other health disparities research activities..." *Id.* at § 285t(b); (f)(1)(G).
- c. 42 U.S.C. § 282(b)(8)(D)(ii), which requires the Secretary, acting through the Director of NIH, to ensure that each of the ICs within NIH "utilize diverse study populations, with specific consideration to biological, social, and other determinants of health that contribute to health disparities."
- d. 42 U.S.C. § 282(h), which mandates that "[t]he Secretary, acting through the Director of NIH..., 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."
- e. 42 U.S.C. § 282(m), which requires NIH to develop a strategic plan that, among other things, "shall...(B) consider...(iii) biological, social, and other determinants of health that contribute to health disparities..." *Id.* at § 282(m)(1),(2). The Director of NIH must "ensure that the resources of the National Institutes of Health are sufficiently allocated for research projects identified in strategic plans." *Id.* at §282(b)(6).

- f. 42 U.S.C. § 283p, which mandates that "the Director of the National Institutes of Health shall, as appropriate, encourage efforts to improve research related to the health of sexual and gender minority populations."
- g. 42 U.S.C. § 283*o*(b)(2) which requires the Director of NIH to "develop, modify, or prioritize policies, as needed, within the National Institutes of Health to promote opportunities for new researchers and earlier research independence, such as policies to...enhance workforce diversity."

230. Those mandates, and NIH's policies and regulations to effectuate them, apply to the funding and review of both Project-Based Grants and Pipeline Grants.

231. But Defendants' actions pursuant to the Directives—including the grant terminations and refusal to review submitted grant applications—run afoul of those statutory mandates.

232. Accordingly, Defendants acted "in excess of statutory jurisdiction, authority, or limitations." 5 U.S.C. § 706(2)(C).

COUNT IV

Violation of Administrative Procedure Act – Contrary to Constitutional Right

233. All Plaintiffs assert this cause of action against all Defendants.

234. A reviewing court must "hold unlawful and set aside agency action" that is "contrary to constitutional right, power, privilege, or immunity." 5 U.S.C. § 706(2)(B).

235. Defendants' grant terminations and refusal to consider grant applications constitute final agency actions under the APA.

236. For the reasons described in Count VI (Void for Vagueness), Defendants' actions are contrary to constitutional rights, and the Court must hold them unlawful and set them aside.

COUNT V

Violation of the Administrative Procedure Act – Unlawfully Withheld, Unreasonable Delay, or Failing to Conclude Matter Presented

237. Applicant Plaintiffs assert this cause of action against all Defendants.

238. An agency must "proceed to conclude a matter presented to it," 5 U.S.C. § 555(b); accordingly, a reviewing court must "compel agency action unlawfully withheld or unreasonably delayed." 5 U.S.C. § 706(1).

239. Defendants' refusal to consider submitted grant applications pursuant to the Directives constitutes final agency actions under the APA.

240. Defendants' consideration of applications for Pipeline Grants has been unlawfully withheld or unreasonably delayed for the following reasons: (i) HHS regulations require NIH to accept, disapprove, or "defer because of either lack of funds or a need for further evaluation"; (ii) NIH policy requires that it consider each application submitted to it and does not allow the agency to withhold consideration of applications based on changes in agency priorities; (iii) large numbers of current and future biomedical researchers risk unexpected job loss that will harm not only them personally but also the development of biomedical research generally; and (iv) the applications' proposed research is essential to public health, making delays in this sphere less tolerable than in other spheres such as economic regulations. Thus, the Court must compel the agency to consider these applications.

COUNT VI Violation of the Fifth Amendment – Void for Vagueness

241. Terminated Plaintiffs assert this cause of action against all Defendants.

242. Under the Fifth Amendment to the United States Constitution, a government enactment is unconstitutionally vague if it fails to provide a reasonable opportunity to know what conduct is prohibited or is so indefinite as to allow arbitrary and discriminatory enforcement.

243. Defendants' Directives are filled with vague language that do not give clear notice of what is covered: prohibiting "DEI research activities," or even "giv[ing] the perception that NIH funds can be used to support these activities" as well as research programs "based primarily on...amorphous equity objectives" or "based on gender identity" or relating to "transgender issues." Likewise, the language of the various scripts in NIH termination notices include many of these same undefined terms: "gender identity"; "so-called diversity, equity, and inclusion ('DEI') studies"; "amorphous equity objectives"; "vaccine hesitancy"; or "COVID-related" matters, for example. The language of these Directives and terminations notices is unconstitutionally vague, depriving grantees of fair notice and encouraging arbitrary and discriminatory enforcement.

244. Because of the vagueness in the language of Defendants' Directives and NIH's chaotic efforts to give effect to those Directives, Plaintiffs are unsure, for example, which areas of study they can pursue, which populations they can focus on as study subjects, what they might argue to appeal grant terminations, and what the demographics of study participants must be. This makes it impossible to determine how to reconfigure future research to stay within the bounds of NIH's newest "priorities."

245. Defendants' Directives and efforts to purge certain research thus violate the Due Process Clause because its termination notices and related documents provide inadequate notice of what types of research it purports to prohibit.

COUNT VII Violation of Separation of Powers

246. All Plaintiffs assert this cause of action against all Defendants.

247. The Constitution vests exclusive power over federal spending and lawmaking with Congress; the Constitution likewise requires the Executive branch to faithfully execute the law. These distinct roles of the co-equal branches of government are of critical importance, and "the

carefully defined limits on the power of each Branch must not be eroded." *I.N.S. v. Chadha*, 462 U.S. 919, 958 (1983).

248. The Executive Branch has no constitutional power to unilaterally amend or repeal parts of duly elected statutes.

249. Congress has exercised its Article I legislative power to mandate NIH carry out specific functions. Defendants' actions unlawfully usurp congressional legislative authority, including by ignoring and running counter to the mandates outlined in Count III (APA—Excess of Statutory Authority).

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court:

- a. Declare that the Directives—including the February 28 Guidance and March 25 Guidance—and Defendants' other actions to implement the Directives are unlawful and unconstitutional;
- b. Declare that NIH's termination of grants pursuant to the Directives, beginning on February 28, 2025, is unlawful and unconstitutional;
- c. Temporarily restrain and/or preliminarily and permanently enjoin Defendants from implementing or enforcing the Directives going forward, including from terminating any grants or withholding review of applications, based on allegedly no longer effectuating agency priorities or; in a manner that this Court has determined is unlawful;
- d. Order NIH to restore the grant awards, retroactive to the respective termination date, that NIH has terminated pursuant to the Directives or in a manner this Court has determined is unlawful or unconstitutional, including the grant terminations based on allegedly no longer effectuating agency priorities;

- e. Order NIH and all ICs to review all properly submitted applications as required by NIH policy and consistent with priorities set forth in the currently operative NIH-Wide Strategic Plan and the ICs Strategic Plans;
- f. Order Defendants to file status reports at regular intervals confirming their compliance with the Court's order(s) and judgment(s) in this case;
- g. Enjoin Defendants from imposing any negative consequences on Individual Plaintiffs,
 Plaintiff Ibis, or Associational Plaintiffs' Members and Pre-Members for involvement in
 this litigation;
- h. Award Plaintiffs' reasonable costs and attorneys' fees; and
- i. Issue such other relief as the Court deems proper.

[signatures on following page]

Dated: April 02, 2025

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