# UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

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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.

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

CIVIL ACTION NO. 25-10787-WGY

Plaintiffs, CIVIL ACTION NO. v. 25-10814-WGY ROBERT F. KENNEDY, JR., in his official capacity as Secretary of Health and Human Services; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; JAYANTA BHATTACHARYA, in his official capacity as Director of the National Institutes of Health; ) NATIONAL INSTITUTES OF HEALTH; NATIONAL CANCER INSTITUTE; NATIONAL EYE INSTITUTE; NATIONAL HEART, LUNG, AND BLOOD INSTITUTE; NATIONAL HUMAN GENOME RESEARCH INSTITUTE; NATIONAL INSTITUTE ON AGING; NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM; NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES; NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES; NATIONAL INSTITUTE OF BIOMEDICAL IMAGING AND BIOENGINEERING; EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT; NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION DISORDERS; NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH; NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES; NATIONAL INSTITUTE ON DRUG ABUSE; NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES; NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES; NATIONAL INSTITUTE OF MENTAL HEALTH; NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES; NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND

STROKE; NATIONAL INSTITUTE OF

NURSING RESEARCH; NATIONAL LIBRARY )

OF MEDICINE; NATIONAL CENTER FOR )

ADVANCING TRANSLATIONAL SCIENCES; )

JOHN E. FOGARTY INTERNATIONAL )

CENTER FOR ADVANCED STUDY )

IN THE HEALTH SCIENCES; NATIONAL )

CENTER FOR COMPLEMENTARY AND )

INTEGRATIVE HEALTH; and CENTER )

FOR SCIENTIFIC REVIEW, )

Defendants. )

YOUNG, D.J. July 2, 2025

# FINDINGS OF FACT, RULINGS OF LAW, AND ORDER FOR PARTIAL SEPARATE AND FINAL JUDGMENT

#### I. INTRODUCTION

These consolidated actions are two of many in this district, and across the Nation, claiming that current Executive Branch policies, mostly through Executive Orders, have been implemented by various agencies in violation of the Administrative Procedure Act, statutory law, and the Constitution. Based upon the evidence presented at the hearing on the APA claims and bench trial of the remainder, this Court concludes what has been occurring at the Department of Health and Human Services ("HHS") and the National Institutes of Health ("NIH") with respect to its disruption of grants, the grant making process and the pipeline of future scientists by

forbidding by fiat certain topics, is on this Administrative Record, illegal under the Administrative Procedure Act ("APA").

After this Court collapsed the separate motions for preliminary injunctions into a single consolidated trial pursuant to Rule 65(a), and after hearing on the Administrative Procedure Act claims and a bench trial on the Constitutional claims (Phase One), in both actions save -- for the APA delay claims (Phase Two), the Court provides its findings of fact and rulings of law pursuant to Rule 52(a) of the Federal Rules of Civil Procedure as to Phase One.

#### II. PROCEDURAL HISTORY

In American Public Health Association et al. v. the

National Institutes of Health et al., Civ No. 25-10787 ("the

'10787 Action"), the American Public Health Association

("APHA"), Ibis Reproductive Health, the International Union,

United Automobile, Aerospace, and Agricultural Implement

Workers, Dr. Brittany Charlton, Dr. Katie Edwards, Dr. Peter

Lurie, and Dr. Nicole Maphis (collectively, "the APHA

Plaintiffs") seek declaratory and injunctive relief against the

National Institutes of Health ("the NIH"), NIH Director Jay

Bhattacharya in his official capacity, and Secretary of Health

and Human Services Robert F. Kennedy, Jr. in his official

capacity.

Similarly, in Commonwealth of Massachusetts et al. v.

Kennedy et. al., Civ No. 25-10814 ("the '10814 Action"), the

Commonwealth of Massachusetts along with 15 other States¹

(referred to collectively as "the State Plaintiffs"), sue

Secretary Kennedy, the Director Bhattacharya, and the federal institutes and centers² (in both actions the defendants are referred here collectively as "the Public Officials" and the

APHA Plaintiffs and State Plaintiffs referred to collectively as

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In addition to the Commonwealth of Massachusetts, the State of California, the State of Maryland, the State of Washington, the State of Arizona, the State of Colorado, the State of Delaware, the State of Hawai'i, the State of Minnesota, the State of Nevada, the State of New Jersey; the State of New Mexico; the State of New York, the State of Oregon, the State of Rhode Island; and the State of Wisconsin join as plaintiffs.

<sup>&</sup>lt;sup>2</sup> Those ICs are: the National Cancer Institute, the National Eye Institute, the National Heart, Lung, and Blood Institute, the National Human Genome Research Institute, the National Institute on Aging, the National Institute on Alcohol Abuse and Alcoholism, the National Institute of Allergy and Infectious Diseases, the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the National Institute of Biomedical Imaging and Bioengineering, the Eunice Kennedy Shriver National Institute of Child Health and Human Development, the National Institute on Deafness and Other Communication Disorders, the National Institute of Dental and Craniofacial Research, the National Institute of Diabetes and Digestive and Kidney Diseases, the National Institute on Drug Abuse; the National Institute of Environmental Health Sciences, the National Institute of General Medical Sciences, the National Institute of Mental Health, the National Institute on Minority Health and Health Disparities, the National Institute of Neurological Disorders and Stroke, the National Institute of Nursing Research, the National Library of Medicine, the National Center for Advancing Translational Sciences, the John E. Fogarty International Center for Advanced Study in the Health Sciences, the National Center for Complementary and Integrative Health, and the Center for Scientific Review.

"the Plaintiffs"). Both actions arise from the NIH's newly-minted war against undefined concepts of diversity, equity and inclusion and gender identity, that has expanded to include vaccine hesitancy, COVID, influencing public opinion and climate change.

The actions were randomly reassigned to this Court on May 1, 2025. Elec. Notice Reassignment, ECF No. 99. The Court collapsed the motions into a trial on the merits pursuant to Rule 65(a) of the Federal Rules of Civil Procedure.<sup>3</sup> The Court has ruled on jurisdictional issues and a broader motion to dismiss. See Mem. & Order, '10787 Action, ECF No. 84; Mem. & Order, '10817 Action, ECF No. 105.

The trial was divided into two phases largely based on the APA claims, but each phase including other claims: Phase One, APA Section 706(2) (primarily arbitrary and capricious claims) and concomitant statutory and constitutional claims), and Phase Two, Section 706(1) (primarily the delay claims).

The Court held a full hearing and bench trial as to Phase One. At the conclusion of the trial of Phase One, the Court

<sup>&</sup>lt;sup>3</sup> The Court acknowledges that its usual process is expeditious, it observes that while this matter has proceeded to trial, injunctive relief has recently issued as to other actions relating to HHS's and the NIH's actions. See New York v.

Kennedy, No. 25-CV-196-MRD-PAS, 2025 WL 1803260, at \*13 (D.R.I. July 1, 2025); Massachusetts v. Nat'l Institutes of Health, 770 F. Supp. 3d 277 (D. Mass. 2025) (Kelley, J.), judgment entered, No. 1:25-CV-10338, 2025 WL 1063760 (D. Mass. Apr. 4, 2025).

ruled from the bench that the Challenged Directives taken as a whole, were arbitrary and capricious final agency action, as well as were the terminations of the grants in accordance therewith; the Court took the rest of the matter under advisement. The Court now provides its complete findings of fact and rulings of law as to so much of Phase One as pertains to the APA claims raised therein and addressed from the bench<sup>4</sup> as

On the ground, while the HHS continues to repeat its now-familiar dirge of empty triumphalism, <u>see</u> https://www.reuters.com/business/healthcare-pharmaceuticals/federal-judge-says-trump-cuts-nih-grants-are-illegal-politico-reports-2025-06-16/, the NIH appears to be working in good faith to reassemble its grant-making machinery. <u>See e.g.</u>, https://www.nytimes.com/2025/06/25/science/nih-grant-terminations-halted.html;

https://www.science.org/content/article/nih-will-reinstate-900-grants-response-court-order;

https://www.masslive.com/news/2025/06/20-nih-grants-restored-to-umass-system-after-judge-rules-against-trump-admin.html

More is required to be done on Phase One. In addition to ruling on Constitutional law questions, the Court must address:

# Racial Discrimination - Constitutionally Prohibited

The Court has found as fact that there was pervasive racial discrimination in selecting grants for termination. It needs to

<sup>&</sup>lt;sup>4</sup> Time is of the essence in this equity case. For that reason, the Court entered a partial judgment under Fed. R. Civ. P. 54(b) to allow for a prompt appeal of a "clean" decision on the APA claims. Partial Final Judgment, '10787 Action, ECF No. 138; Partial Judgment, '10814 Action, ECF No. 151. Quite properly, the Public Officials have promptly appealed. Notice of Appeal, '10787 Action, ECF No. 139; Notice of Appeal '10814 Action, ECF No. 152. The Public Officials sought a stay pending the appeal, which this Court denied. See Order, '10787 Action, ECF No. 147; Order, '10814 Action, ECF No. 160.

fashion a permanent injunction to prevent any continuation of this practice.

# Gender Discrimination - Statutorily Prohibited

Speaking from the bench following closing arguments, the Court had not sufficient time to analyze and reflect on the administrative record such that it could make a finding of gender discrimination. Now it has.

The Court finds by a fair preponderance of the evidence that the grant terminations here at issue demonstrate an unmistakable pattern of discrimination against women's health issues. The Court thus needs to afford the parties a chance to present evidence of the harm resulting from such terminations and, in the absence of such evidence, whether this is one of those cases "likely of repetition but evading review."

## LGBTQ+ Discrimination - No Federal Remedy

This Court's factual finding that there has been extensive discrimination against everyone whose lived experience of their sexuality is in any way different from the executive orthodoxy expressed in the President's fiat, see Exec. Order 14168, 90 Fed. Reg. 8615 (Jan. 20, 2025), is fully affirmed. What changed in the days following this Court's finding is the Supreme Court's teaching concerning these matters. I had thought the factual finding warranted a more complete equal protection analysis. The decision in United States v. Skrmetti, 145 S. Ct. 1816, 1832 (2025) quite clearly forecloses such analysis. Justice Barrett's concern about imprecision in language addressing these matters, and the skepticism of Justices Thomas and Alito about the role of science, Id. at 1851 (Barrett, J., concurring); 1852 (Thomas, J., concurring), 1867 (Alito, J., concurring) leads this Court to conclude that, while here there is federal government discrimination based on a person's status, not all discrimination is pejorative. After all, setting the voting age, excluding felons from the franchise, and regulating a young person's access to obscene material, see Free Speech Coal., Inc. v. Paxton, No. 23-1122, 2025 WL 1773625, at \*9 (U.S. June 27, 2025); Simmons v. Galvin, 575 F.3d 24, 42 (1st Cir. 2009), all "discriminate" based upon an individual's status. They all fall within the state's police powers. This Court is thus not warranted in considering injunctive relief as to an officer of the United States on this ground (despite the fact that these grant determinations were here arbitrary and

required under Rule 52(a) of the Federal Rules of Civil Procedure.

#### III. FINDINGS OF FACT

# A. The National Institutes of Health -- The World Standard of Research

The HHS is an Executive Agency of the United States. <u>See</u> generally, 42 U.S.C. § 3501a et seq. The National Institutes of Health is an agency of the HHS, and is comprised of 27 separate institutes and centers ("ICs") that focus on certain diseases or human body systems.

The NIH is run by its Director. Under the Director, there are five deputy directors: (1) Principal Deputy Director; (2)

Deputy Director for Intramural Research; (3) Deputy Director of Extramural Research; (4) Deputy Director for Management; and (5)

Deputy Director for Program Coordination, Planning, and Strategic Initiatives. See https://www.nih.gov/about-nih/organization/nih-leadership.

Congress, through the Public Health Service Act ("the PHSA"), 42 U.S.C. § 201 et seq., mandates that the Secretary of HHS promote research "relating to the causes, diagnosis,

capricious under the APA) because, at least as to puberty blockers, what is a denial of equal protection of the laws in some states is sound public policy in Tennessee.

This Court regrets serving up matters for appeal on a piecemeal basis but the exigencies of an equitable action and unfolding reality require it.

treatment, control, and prevention of physical and mental diseases and impairments," including by, among other things and relevant here, offering "grants-in-aid to universities, hospitals, laboratories, and other public or private institutions, and to individuals." 42 U.S.C. §241(a)(3). The NIH has similar statutory mandates. 42 U.S.C. §§ 282(b), 284(b).

Congress requires the NIH operate predictably and with stability, not just for its understanding of how the NIH is fulfilling its duties to the American people, but also to provide a predictable path for researchers. Specifically, Congress by statute requires the NIH to provide a "National Institutes of Health Strategic Plan" (the "Strategic Plan") every six years in order "to provide direction to [the NIH's] biomedical research investments." Id. §282(m)(1).

The Strategic Plan's purpose is manifold: providing direction to NIH's research investment, increasing efficiencies across the ICs, leveraging scientific opportunity, and advancing biomedicine. Id. 5

 $<sup>^{5}</sup>$  Section 282(m)(1) provides:

<sup>[</sup>A]t least every 6 years . . . the Director of the National Institutes of Health shall develop and submit to the appropriate committees of Congress and post on the Internet website of the National Institutes of Health, a coordinated strategy (to be known as the "National Institutes of Health Strategic Plan") to

The Strategic Plan forms the foundation of the NIH's work. Indeed, NIH is mandated to "ensure that scientifically based strategic planning is implemented in support of research priorities as determined by the agencies of the National Institutes of Health, and through the development, implementation, and updating of" the Strategic Plan. 42 U.S.C. § 282(b)(5) (emphasis added).

The Strategic Plan is required to "identify strategic priorities and objectives in biomedical research" of areas such as assessment of the "state of biomedical and behavioral research" and opportunities therein, "priorities and objectives to advance the treatment, cure and prevention of health conditions," "emerging scientific opportunities," "health challenges" and "scientific knowledge gaps." 42 U.S.C. § 282(m)(2)(A). The Strategic Plan is also required to identify "near-.mid-, and long term scientific needs." Id.

The Strategic Plan is a statutorily imposed collaboration, requiring the NIH to consult "with the directors of the national

<sup>[(1)]</sup> provide direction to the biomedical research investments made by the National Institutes of Health, [(2)] to facilitate collaboration across the institutes and centers, [(3)] to leverage scientific opportunity, and [(4)] to advance biomedicine.

<sup>42</sup> U.S.C. § 282(m) (emphasis added).

research institutes and national centers, researchers, patient advocacy groups, and industry leaders." 42 U.S.C. § 282(m)(4)

Congress historically has paid close attention to its tax-dollar investments in medical, health and behavioral research.

In some cases, it has expressed its research priorities directly in the PHSA, see e.g. Section 283(p). For example, Congress has by statute created ICs dedicated to certain systems, and minority populations.

The NIH is the primary source of federal funding for biomedical research in the United States, and is the largest public funder of biomedical research in the world. Due to its operations, NIH has contributed to profound medical breakthroughs and through its funding trains future generations of scientists. It is tax-payer investment in the health and welfare not just of Americans, but humanity. Broadly, the NIH performs research within federal facilities, also called "intramural" research. It also supports research through funding of competitive grants to researchers and institutions outside the federal system. This is known as "extramural" research, and is what is at issue in these consolidated actions.

The NIH's process to allocate funding from Congress for extramural research is covered by several statutes and regulations. See 42 C.F.R. § 52 et seq.; . The Court presumes the parties' familiarity with the process, but broadly, with

respect to extramural research, researchers must apply to the NIH for funding. The NIH, in line with its priorities, invites proposals for grants through what is known as "Notice of Funding Opportunity" ("NOFO"). In simple terms, the applications go through a three-step process: a scientific review group, and if successful, then to the advisory council. If the application is approved by the advisory council, their recommendation proceeds to the IC's director who makes the ultimate funding decision.

Grants are, understandably, oftentimes not a one-time event. Research takes time, often requiring continuation grants or multiple grants. The NIH's framework of stability and predictability has proven itself time and again over the past several decades over multiple administrations. It is one reason the United States, through the support of the hard-working government workers at HHS and the NIH, in partnership with the scientific research community, has been unsurpassed in its contributions to breakthroughs in science that have enhanced our lives. To be sure, there are priorities, as funding is not unlimited, and administrations each have differing views on what those priorities ought be, but the NIH's priority changes have been predictable. What is clear is that Congress intends for the NIH to operate with Congressional oversight and certainly some statutory direction, but by and large leaves the science to the scientists. Indeed, the American people have enjoyed a

historical norm of a largely apolitical scientific research agency supporting research in an elegant, merit-based approach that benefits everyone.

That historical norm changed on January 20, 2025. The new Administration began weaponizing what should not be weaponized — the health of all Americans through its abuse of HHS and the NIH systems, creating chaos and promoting an unreasonable and unreasoned agenda of blacklisting certain topics, that on this Administrative Record, has absolutely nothing to do with the promotion of science or research.

#### B. Timeline of Events

1. January 20, 2025 - January 21, 2025 -- Executive Orders 14151, 14168, and 14173 are issued.

The Executive Branch decided early on, through Executive Orders, to focus on eradicating anything that it labels as Diversity, Equity and Inclusion ("DEI"), an undefined enemy. No one has ever defined it to this Court — and this Court has asked multiple times. Indeed, as will be demonstrated, while the Executive, HHS, and the NIH certainly identify the acronym DEI and its component words, it's definition is purely circular reasoning: DEI is DEI. It also is focused on gender identity as a priority, proclaiming through Executive Orders its concerns. The Executive Branch, of course, has every right to espouse its views, and this Court opines on neither their veracity nor

wisdom. Nevertheless, the Executive Orders lay the groundwork for what occurred at HHS and the NIH.

### a. Executive Order 14151

On January 20, 2025, the President issued Executive Order No. 14151, entitled "Ending Radical and Wasteful Government DEI Programs and Preferencing." Exec. Order 14151, 90 Fed. Reg. 8339 (Jan. 20, 2025) ("EO 14151"). EO 14151 focuses on ending what the Executive views as a perceived "infiltration" of the federal government of "illegal and immoral discrimination programs of the Biden Administration going by the name 'Diversity, Equity and Inclusion'". Id. EO 14151 posits that DEI is mutually exclusive to "serving every person with equal dignity and respect." Id. Under the guise of "making America great," EO 14151 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." Id. EO 14151 does not define DEI. Additionally, and pertinent here, E014151 directs each federal agency head to "terminate, to the maximum extent allowed by law, all 'equityrelated' grants or contracts" within 60 days. Id. This too has broad, undefined contours. As one Court recently noted, "'[t]he vagueness of the term 'equity-related' grants or contracts

invites arbitrary and discriminatory enforcement and does not provide sufficient notice to grantees as to what types of speech or activity they must avoid to prevent termination of their grants or contracts -- compelling grantees and grant applicants to steer far too clear of the forbidden area of anything related to the broad and undefined term of equity.'" <a href="San Francisco">San Francisco</a>
A.I.D.S. Found. v. <a href="Trump">Trump</a>, No. 25-CV-01824-JST, 2025 WL 1621636, at \*21 (N.D. Cal. June 9, 2025) (cleaned up).

#### b. Executive Order 14168

On January 20, 2025, the President also issued Executive
Order 14168, "Defending Women from Gender Ideology Extremism and
Restoring Biological Truth to the Federal Government." The
President claims that women need protection from transgender
persons:

Efforts to eradicate the biological reality of sex fundamentally attack women by depriving them of their dignity, safety, and well-being. The erasure of sex in language and policy has a corrosive impact not just on women but on the validity of the entire American system. Basing Federal policy on truth is critical to scientific inquiry, public safety, morale, and trust in government itself.

Exec. Order 14168, 90 Fed. Reg. 8615 (Jan. 20, 2025) ("EO 14168"). The EO goes on to proclaim that "gender ideology" somehow "replaces the biological category of sex with an evershifting concept of self-assessed gender identity," that it is a "false claim," and that "includes the idea that there is a vast

spectrum of genders that are disconnected from one's sex." Id. \$2(f). Pertinent here, the Executive seeks to stamp "gender ideology" out: "Federal funds shall not be used to promote gender ideology. Each agency shall assess grant conditions and grantee preferences and ensure grant funds do not promote gender ideology." Id. \$3(f).

### c. Executive Order 14173

On January 21, 2025, President issued Executive Order No. 14173, entitled "Ending Illegal Discrimination and Restoring Merit-Based Opportunity." Exec. Order 14173, 90 Fed. Reg. 8633 (Jan. 21, 2025) ("EO 14173"). Similar to EO 14151, EO 14173 purportedly seeks to end "immoral race- and sex-based preferences under the guise of so-called [DEI] or [DEIA]," and the order requires the Director of the 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." Id. There is, conspicuously, no definition of DEI.

# 2. January 21, 2021, The Pause Directive.

On January 21, 2025, HHS Acting Secretary Dorothy Fink ("Acting Secretary Fink"), appointed January 20, 2025, ordered an immediate communication pause until February 1, 2025. R. 1. ("the Pause Directive").



#### DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

TO: Heads of Operating Divisions Head

Heads of Staff Divisions

THROUGH: Wilma M. Robinson, Ph.D., Deputy Executive Secretary

FROM: Dorothy A. Fink, MD, Acting Secretary

**DATE:** January 21, 2025

SUBJECT: Immediate Pause on Issuing Documents and Public Communications - ACTION

As the new Administration considers its plan for managing the federal policy and public communications processes, it is important that the President's appointees and designees have the opportunity to review and approve any regulations, guidance documents, and other public documents and communications (including social media). Therefore, at the direction of the new Administration and consistent with precedent, I am directing that you immediately take the following steps through February 1, 2025:

- Refrain from sending any document intended for publication to the Office of the Federal Register until it has been reviewed and approved by a Presidential appointee. Please note that the Office of the Executive Secretary (Exec Sec) withdrew from OFR all documents that had not been published in the Federal Register to allow for such review and approval.
- Refrain from publicly issuing any document (e.g., regulation, guidance, notice, grant announcement) or communication (e.g., social media, websites, press releases, and communication using listservs) until it has been reviewed and approved by a Presidential appointee.
- Refrain from participating in any public speaking engagement until the event and material have been reviewed and approved by a Presidential appointee.
- 4. Coordinate with Presidential appointees prior to issuing official correspondence to public officials (e.g., members of Congress, governors) or containing interpretations or statements of Department regulations or policy. Nothing in this guidance is intended to limit an employee's personal correspondence with members of Congress or other third parties, including an employee's whistleblower protected communications.
- 5. Notify Exec Sec promptly of any documents or communications that you believe should not be subject to the directives in paragraphs 1-4 because they are required by statute or litigation; affect critical health, safety, environmental, financial, or national security functions of the Department; or for some other reason. Please provide the title, a brief summary, the target release date, and the rationale for expedited release to your Exec Sec Policy Coordinator.

The President's appointees intend to review documents and communications expeditiously and return to a more regular process as soon as possible.

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NIH GRANTS 000001

If you identify any actions taken inconsistent with these requests, please know they shall not be considered impliedly ratified. These items should be immediately withdrawn or rescinded to deem them as void and without effect.

Thank you for your assistance in ensuring a smooth transition consistent with our nation's democratic principles.

Dorothy A. Fink, MD, Acting Secretary

R. 1-2.6 Although referenced for completeness, this Challenged Directive relates to Phase 2 of this Action, so will not be discussed further at this time.

# 3. February 10, 2025 -- The Secretarial Directive -- Challenged Directive 2

On February 10, 2025, Acting Secretary Fink, issued the following "Secretarial Directive on DEI-Related Funding" ("the Secretarial Directive"):

<sup>&</sup>lt;sup>6</sup> Stylistically, this Court usually avoids inserting full documents in its opinions lest bulk substitute for analysis. Here, however, no paraphrasing can replace the originals and convey what was actually going on.



#### DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

#### SECRETARIAL DIRECTIVE ON DEI-RELATED FUNDING

February 10, 2025

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

These contracts and grants can cause serious programmatic failures and yet it is currently impossible to access sufficient information from a centralized source within the Department of Health and Human Services to assess them. Specifically, there is no one method to determine whether payments the agency is making to contractors, vendors, and grantees for functions related to DEI and similar programs are contributing to the serious problems and acute harms DEI initiatives may pose to the Department's compliance with Federal civil rights law as well as the Department's policy of improving the health and well-being of all Americans. It is also currently impossible to assess whether payments the Department is making are free from fraud, abuse, and duplication, as well as to assess whether current contractual arrangements, vendor agreements, and grant awards related to these functions are in the best interests of the United States. See FAR 12.403(b), 49.101; 45 C.F.R. § 75.371-372. Finally, it is also impossible to determine with current systems whether current contracts and grant awards are tailored to ameliorate these specific problems and the broader problem of DEI and similar programs rather than exacerbate them. The Department has an obligation to ensure that no taxpayer dollars are lost to abuse or expended on anything other than advancing the best interests of the nation.

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

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

This Directive shall be implemented through the Department's contracts and payment management systems by personnel with responsibility for such systems who shall, in doing so, comply with all notice and procedural requirements in each affected award, agreement, or other instrument. Whenever a DEI or similar contract or grant is paused for review, Department personnel shall immediately send such payment to Scott Rowell, Deputy Chief of Staff for Operations, for prompt review to determine whether or not the payment is appropriate and should be made. Payments on paused contracts shall remain paused and already terminated contracts shall remain terminated pending completion of that review to the maximum extent permitted by law and all applicable notice and procedural requirements in the affected award, agreement, or other instrument.

I thank you for your attention to this matter, as well as your efforts to ensure that no taxpayer dollars are misspent.

Dorothy A. Fink, M.D., Acting Secretary

R. 4-5. In what will be a common theme throughout the agency action, Dr. Fink chose not to define DEI at all, but merely echoed the EOs, lumping DEI -- whatever DEI is -- as somehow "discriminatory" in nature. <u>Id.</u> Presumably, Dr. Fink, a highly educated physician and acclaimed researcher, understood the downstream effects of the absence of definition. There is conspicuously nothing else in the Administrative Record concerning the Secretarial Directive.

<sup>&</sup>lt;sup>7</sup> Dr. Fink is currently Deputy Assistant Secretary for Women's Health and Director of the Office of Women's Health in the Office of the Assistant Secretary for Health at HHS. Her biography is located https://womenshealth.gov/about-us/who-we-are/leadership/dr-dorothy-fink.

## 4. February 12, 2025 -- The Lauer Memoranda

In the ensuing days, federal courts issued temporary restraining orders against, among others, the NIH. In response, on February 12, 2025, Dr. Michael S. Lauer ("Dr. Lauer"), then-Deputy Director for Extramural Research at the NIH and Michelle G. Bulls, NIH Chief Grants Management Officer ("CGMO Bulls"), issued to the ICs a memorandum stating that NIH "is in the process of reevaluating the agency's priorities based on the goals of the new administration." R. 9. That memorandum states that the "NIH will effectuate the administration's goals over time, but given recent court orders, this cannot be a factor in [Institutions and Centers'] funding decisions at this time."

Id. The memorandum also promised "[a]dditional details on future funding actions related to the agency's goals will be provided under a separate memo."

Id. The memorandum in full:



Date: February 12, 2025

To: Institute and Center Chief Grants Management Officers (IC CGMOs)

Michael S. Lauer, MD Michael S. Lauer - S Date: 2025.02.12 09:26:33 -05'00' From:

Deputy Director for Extramural Research, National Institutes of Health (NIH)

Michelle G. Bulls

NIH Chief Grants Management Officer

Subject: NIH Review of Agency Priorities Based on the New Administration's Goals

NIH is in the process of reevaluating the agency's priorities based on the goals of the new administration. 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. In consultation with NIH leadership and with the Office of General Counsel (OGC), we recognize that NIH programs fall under recently issued Temporary Restraining Orders (New York et al. v. U.S. Office of Management and Budget and Commonwealth of Massachusetts et al. v. National Institutes of Health et al see attached). Therefore, with this memo, IC CGMOs are authorized, along with their respective grants management staff, to proceed with issuing awards for all competing, non-competing continuation, and administrative supplements (previously cleared through Office of Extramural Research) grants. Until further notice, as awards are issued, ICs must follow their existing FY25 IC funding policies and use the previously approved negotiated indirect cost rates. Additional details on future funding actions related to the agency's goals will be provided under a separate memo.

#### Attachments

- 1. Temporary Restraining Order, New York et al. v. U.S. Office of Management and Budget (Jan. 31, 2025)
- 2. Court Order Questions HHS OGC Responses (February 4, 2025)
- 3. Temporary Restraining Order, Commonwealth of Massachusetts et al. v. National Institutes of Health et al., (February 10, 2025)
- 4. Order Enforcing TRO, New York et al. v. U.S. Office of Management and Budget (February 10, 2025)
- 5. Office of General Counsel Note, New York et al. v. U.S. Office of Management and Budget (February 10, 2025)
- R.9. The Court views this memorandum as hardly a ringing endorsement of HHS's Secretarial Directive of the Executive Orders.

Nevertheless, that new guidance came the next day. On February 13, 2025, Dr. Lauer and CGMO Bulls issued another memorandum to ICs Chief Grant Management Officers, that announced "hard funding restrictions" on "awards where the program promotes or takes part in diversity, equity, and includsion [sic] ('DEI') initiatives" with restrictions applying "to new and continuation awards made on or after February 14, 2025." R. 16. The memorandum also states that, "[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." Id. The February 13, 2025 Memorandum is set forth in full:



Date: February 13, 2025

To: Institute and Center Chief Grants Management Officers (IC CGMOs)

Michael S. Lauer, MD Michael S. Lauer - S Digitally signed by Michael S. Lauer - S Date: 2025.02.13 15:06:52 -05'00' From:

Deputy Director for Extramural Research, National Institutes of Health (NIH)

Michelle G. Bulls

NIH Chief Grants Management Officer

Subject: Supplemental Guidance to Memo Entitled- NIH Review of Agency Priorities Based on

the New Administration's Goals

The Office of Extramural Research is issuing supplemental guidance to the memo, dated February 12, 2025, to Institute and Center (IC) Chief Grants Management Officers (CGMOs) and their respective staff to issue hard funding restrictions on awards and within the Payment Management System (PMS)/Program Support Center (PSC) on awards where the program promotes or takes part in diversity, equity, and includsion ("DEI") initiatives or any other initiatives that discriminate on the basis of race, color, religion, sex, national origin, or any other protected characteristics. The restriction requirement applies to new and continuation awards made on or after February 14, 2025. If 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. Such review shall include, but not be limited to a review for fraud, waste, abuse, of all grants, cooperative agreements, and Other Transactions that determines the funding of the activities/program are in the best interest of the government and consistent with current policy priorities.

### Attachments

- Memo NIH Review of Agency Priorities Based on the New Administration's Goals, February 12, 2025
- 2. UPDATE Temporary Restraining Order in State of New York et al. v. Trump et al., 1:25-cv-00039 (D.R.I.), February 12, 2025
- Secretarial Directive on DEI Related Funding, February 10, 2025

R. 16. It is unclear how the NIH could use this document to determine the contours of DEI, where it does not define the term, nor how to determine whether something "promotes or takes part in diversity equity and inclusion . . . initiatives." <u>Id.</u>8

Further, it apparently relies upon the Secretarial Directive.

<u>Id.</u>

- A It's the supplemental -- it's the beginning of the guidance providing agency - I mean
  ICs with guidance on how to unpause funding.
- $\mathbf{Q}\cdot$  And it does say that there is a Restriction. What's the restriction that it gives guidance about?
- A· · On spending funding related to DEI activities on grants.
- Q Was there a definition of DEI activities provided with this memo?
- MS. ANDRAPALLIYAL: Objection. To the extent the information sought is deliberative and not final, I'm instructing the witness not to answer.

#### BY MR. McGINTY:

<sup>8</sup> Consistent with the Administrative Record, NIH Chief Grants Management Officer Michelle Bulls testified in another federal action that she drafted the February 13, 2025 memorandum with Dr. Lauer and acknowledged that the ICs would determine for themselves what in fact DEI meant:

Q · · Do you recognize this document?

A· · Yes.

Q · · And you wrote this document, right?

A · · I wrote it with Dr. Lauer, yes.

Q · · Okay. · And what is it?

Q. How are ICs supposed to determine if something fell within DEI activities?

A· They have scientific, the scientific background and they know their programs, so the Grants Management

5. February 13, 2025 -- Deputy Director of Extramural Research, Dr. Lauer Resigns and Liza Bundensen is promoted as Acting Extramural Research Director.

Deputy Director Lauer resigned that same day, effective

February 14, 2025. See Second top NIH official, who oversaw

awarding of research grants, departs abruptly, Stat+ https:/,

/www.statnews.com/2025/02/13/nih-michael-lauer-deputy-directordeparts/. Liza Bundesen ("Dr. Bundesen") became acting director

of Extramural Research of the NIH after Dr. Lauer resigned.

That promotion was short-lived, as she resigned less three weeks

later on March 5, 2025. April 3, 2025 Depo. Liza Bundesen 5,

State of Washington et al. v. Trump et al., Civ No. 25-cv
00244, ECF No. 276-8.

6. February 21, 2025 -- The Memoli Directive - Challenged Directive 5

On February 21, 2025, Dr. Matthew Memoli ("Acting Director Memoli"), Acting Director of NIH, appointed by Dr. Fink, from January 22, 2025 through March 31, 2025, see

https://www.nih.gov/about-nih/nih-almanac/leadership/nih-

officials work with the program officials to identify DEI activities where it's not clear in the statute.

Dep. Michelle Bulls 99-100, Decl. Chris Pappavaselio, Ex. 41, ECF No. 77-41. When asked about what statute, she assumed that Minority Health Disparity Institute had some language, but ultimately testified she did not know if "it ties directly, but I think that is being used. And that's an assumption, that's not facts." <a href="Id.">Id.</a>

directors/matthew-j-memoli-md-ms, and currently Principal Deputy

Director of the NIH, sent an email to Nina Schor, Deputy

Director for Intramural Research, Alfred Johnson, Deputy

Director for Management, and Dr. Bundesen, Deputy Director of

Extramural Research:

From: Memoli, Matthew (NIH/OD) [E]

To: Bundesen, Liza (NIH/OD) [E]; Johnson, Alfred (NIH/OD) [E]; Schor, Nina (NIH/OD) [E]

Subject: Memo on NIH priorities

Date: Friday, February 21, 2025 2:54:40 PM

Attachments: 2695\_001.pdf

Hello,

After working with OGC we determined it was possible to set priorities at an NIH level, which now allows us to proceed with the process of making sure our programs are meeting these goals. I will talk with you individually about the plan of action.

Thanks,

Matt

---

Matthew J. Memoli, MD, MS
Acting Director, National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892
matthew.memoli@nih.gov

R. 2929. It is unclear what Dr. Memoli told the recipients of his email about the supposed "plan of action," but on that same date Dr. Memoli issued a Directive entitled "Restoring Scientific Integrity and Protecting Public Investment in NIH

Awards" ("the Memoli Directive"), which was sent out by Deputy Dr. Bundesen:

From: Bundesen, Liza (NIH/OD) [E]

To: Kosub, David (NIH/OD) [E]; Roman, Laurie (NIH/OD) [E]; Bulls, Michelle G. (NIH/OD) [E]; Ta, Kristin (NIH/OD)

[E]; Faenson, Inna (NIH/OD) [E]; Corbett, Dawn (NIH/OD) [E]; Boone, Ericka (NIH/OD) [E]

Cc: Jacobs, Anna (NIH/OD) [E]; Bundesen, Liza (NIH/OD) [E]; Schwetz, Tara (NIH/OD) [E]; Joshi, Pritty (NIH/OD)

[E]

Subject: URGENT - FW: Memo on NIH priorities
Date: Friday, February 21, 2025 4:19:52 PM

Attachments: 2695 001.pdf

Hi all,

I'm very sorry to once again be sharing an urgent task on a Friday afternoon (I've already talked to David), but **today**, we have to pull down all of the NOFOs that we previously pulled down and put back up (DEI, gender ideology, environmental justice, etc). The attached memo from the Acting NIH Director provides this directive. I understand that Matt Memoli discussed this with OGC.

There are other actions that we will need to take to address this memo, but we can discuss those at a calmer pace on Monday.

I have confirmation that this memo can be shared with other OER staff, and I'm sending to this group now because I think you have the most immediate need to know. Please note that the memo is not to be distributed outside of OER at this time. I will think through how to notify the ICs.

I appreciate you all.

Liza

R. 3823. The memorandum was attached:

### Directive on NIH Priorities

Agency: National Institutes of Health

Office of the Director

Action: Directive

## FOR FURTHER INFORMATION CONTACT:

National Institutes of Health

Office of the Director

EFFECTIVE DATE: February 21, 2025

# Restoring Scientific Integrity and Protecting the Public Investment in NIH Awards

The National Institutes of Health (NIH) is the largest public funder of biomedical and behavioral research in the world. The public trusts NIH with substantial funds to foster creative discoveries that will improve health and prevent disease in this Country. Accordingly, NIH is committed to promoting only the highest level of scientific integrity, public accountability, and social responsibility in the programs it funds. And NIH promises to prioritize the funding of projects that will generate a high return on the public's investment, so that taxpayer dollars are not going to waste. Every dollar should be used to make Americans live longer, healthier lives.

This mission requires NIH to ensure that it is not supporting low-value and off-mission research programs, including but not limited to studies based on diversity, equity, and inclusion (DEI) and gender identity. While this description of NIH's mission is consistent with recent Executive Orders issued by the President, I issue this directive based on my expertise and experience; consistent with NIH's own obligation to pursue effective, fiscally prudent research; and pursuant to NIH authorities that exist independently of, and precede, those Executive Orders.

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, 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.

Likewise, 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 either.

For these reasons and pursuant to, among other authorities, 42 U.S.C. § 282(b) and 45 C.F.R. Part 75 (45 C.F.R. §§ 75.207, 75.210, 75.371–373), the Director of NIH hereby directs:

NIH personnel shall conduct an internal review of all contract solicitations and notices of funding opportunities; applications pending Type 1 and Type 2 awards; existing awards; cooperative agreements; and other transactions. Such review shall be aimed at ensuring NIH grants, contracts, cooperative agreements, and other transactions do not fund or support low-value and off-mission research activities or projects – including DEI and gender identity research activities and programs. NIH personnel should also ensure grants, contracts, cooperative agreements, and other transactions are free from fraud, abuse, and duplication, and are being implemented consistent with federal law.

This Directive shall be implemented by all relevant NIH personnel, including but not limited to those in the Office of Extramural Research, Office of Intramural Research, and the Division of Program Coordination, Planning, and Strategic Initiatives. Grants, contracts, cooperative agreements, and other transactions deemed inconsistent with NIH's mission may, where permitted by applicable law, be subject to funding restrictions, terminated or partially terminated, paused, and/or not continued or renewed, in compliance with all procedural requirements.

Notwithstanding this Directive, and consistent with any court orders that may apply, no open award disbursements may be paused in reliance upon Office of Management and Budget Memorandum M-25-13 or any Executive Order underlying that Memorandum. Previous instructions ordering the immediate release of such funds remain in effect. Also, consistent with any court orders that may apply, this Directive does not instruct personnel to condition or withhold federal funding pursuant to Section 4 of Executive Order 14,187 (Protecting Children from Chemical and Surgical Mutilation) based on the fact that a healthcare entity or health professional provides care or treatment.

Dated: February 21, 2025

Matthew J. Memoli, M.D.

Acting Director of NIH

R. 3821 - 3822. The Memoli Directive notably picks up gender identity language for the first time.

While Dr. Memoli claimed that this Directive is based upon his "expertise and experience" and attempts to make it appear the NIH was acting "independently" it is obvious that much, if not all, of the content was provided to him by HHS. Indeed, the record reflects that HHS spoon-fed Dr. Memoli exactly what to say in his Directive as later drafts of guidance confirm that certain specific language was provided by HHS, even going so far as to putting it in quotations:

- 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 ICO's, which harms the health of Americans. Therefore, it is the policy
  of NIH not to prioritize such research programs."
- Gender-Affirming Care: "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." Reminder: At this time, do not
  terminate any grants related to gender identify/transgender without clearance from OER. All
  such actions must be approved before any terminations.

R. 3280. There is evidence in the record that on that same date, Dr. Memoli was taking advice as to NOFOs that purportedly did not align with the new objectives from Brian M. Smith, an official in the so-called Department of Government Efficiency ("DOGE"). R. 3752-3753.

# 7. February 22, 2025 -- NOFOs Taken Down

On Saturday, February 22, 2025, Brad Smith of DOGE sent a list to Dr. Memoli of NOFOs that in their view did not fall within the Memoli Directive:

From: Smith, Brad M. EOP/DOGE < Brad.M.Smith@doge.eop.gov >

Date: Saturday, February 22, 2025 at 11:36 AM

To: Memoli, Matthew (NIH/OD) [E] < matthew.memoli@nih.gov>

Subject: [EXTERNAL] NOFOs

Matt,

Thanks so much for your time yesterday. Per our conversation, below are a number of NOFOs that it may be worth your team reviewing to make sure they align with your directive and priorities. We 100% defer to your team on whether each of these align with your directive, but I thought you might find this list helpful as you consider where to focus your review:

https://grants.nih.gov/grants/guide/pa-files/PAR-23-112.html https://grants.nih.gov/grants/guide/pa-files/PAR-22-145.html https://grants.nih.gov/grants/guide/pa-files/PAR-23-309.html https://grants.nih.gov/grants/guide/pa-files/PAR-23-292.html https://grants.nih.gov/grants/guide/pa-files/PAR-24-077.html https://grants.nih.gov/grants/guide/pa-files/PAR-24-109.html https://grants.nih.gov/grants/guide/pa-files/PAR-24-157.html https://grants.nih.gov/grants/guide/pa-files/PAR-24-158.html https://grants.nih.gov/grants/guide/pa-files/PAR-25-098.html https://grants.nih.gov/grants/guide/pa-files/PAR-25-201.html https://grants.nih.gov/grants/guide/pa-files/PAR-25-237.html

https://grants.nih.gov/grants/guide/pa-files/PAR-25-240.html https://grants.nih.gov/grants/guide/pa-files/PAR-25-241.html https://grants.nih.gov/grants/guide/pa-files/PAR-25-317.html

https://grants.nih.gov/grants/guide/pa-files/PAR-26-001.html

https://grants.nih.gov/grants/guide/rfa-files/RFA-MD-24-003.html https://grants.nih.gov/grants/guide/rfa-files/RFA-NR-25-004.html https://grants.nih.gov/grants/guide/rfa-files/RFA-MD-24-005.html

Best, Brad

Dutifully, Dr. Memoli instructed Director Bundesen to remove published NOFOs because of a lack of alignment:

From: Memoli, Matthew (NIH/OD) [E] Bundesen, Liza (NIH/OD) [E] To: Cc: Burklow, John (NIH/OD) [E] Subject: NOFOS that need to come down Saturday, February 22, 2025 12:01:32 PM Date:

#### Hi Liza,

I was sent a list of NOFOs to review that are still up. After my review I have determined these NOFOs in their current form have issues that cause them to not be properly directed at current NIH priorities. Please take these NOFOs down. Some of the projects my be reconsidered after they are modified to address current priorities and definitions.

https://grants.nih.gov/grants/guide/pa-files/PAR-23-112.html https://grants.nih.gov/grants/guide/pa-files/PAR-22-145.html https://grants.nih.gov/grants/guide/pa-files/PAR-23-309.html https://grants.nih.gov/grants/guide/pa-files/PAR-23-292.html https://grants.nih.gov/grants/guide/pa-files/PAR-24-077.html https://grants.nih.gov/grants/guide/pa-files/PAR-24-109.html https://grants.nih.gov/grants/guide/pa-files/PAR-24-157.html https://grants.nih.gov/grants/guide/pa-files/PAR-24-158.html

https://grants.nih.gov/grants/guide/pa-files/PAR-25-098.html https://grants.nih.gov/grants/guide/pa-files/PAR-25-201.html https://grants.nih.gov/grants/guide/pa-files/PAR-25-237.html https://grants.nih.gov/grants/guide/pa-files/PAR-25-240.html https://grants.nih.gov/grants/guide/pa-files/PAR-25-241.html https://grants.nih.gov/grants/guide/pa-files/PAR-25-317.html https://grants.nih.gov/grants/guide/pa-files/PAR-26-001.html https://grants.nih.gov/grants/guide/rfa-files/RFA-MD-24-003.html https://grants.nih.gov/grants/guide/rfa-files/RFA-NR-25-004.html https://grants.nih.gov/grants/guide/rfa-files/RFA-MD-24-005.html

Thank you, Matt

Matthew J. Memoli, MD, MS Acting Director, NIH

Dr. Memoli then, equally dutifully, reported back to R. 3810. DOGE:

From: Memoli, Matthew (NIH/OD) [E] <matthew.memoli@nih.gov>

Sent: Saturday, February 22, 2025 12:05 PM

To: Smith, Brad M. EOP/DOGE <Brad.M.Smith@doge.eop.gov>

Subject: Re: NOFOs

Hi Brad,

After my review these all need to come down. Some of the projects may be able to be modified to properly address our current priorities, but in their current form they are not in line with what NIH would like to be doing right now. I have instructed OER to take them all down.

Thanks,

Matt

R. 3751. DOGE acknowledged the response, providing what this Court finds to be false deference by DOGE:

 From:
 Smith, Brad M. EOP/DOGE

 To:
 Memoli, Matthew (NIH/OD) [E]

 Subject:
 [EXTERNAL] RE: NOFOs

Date: Saturday, February 22, 2025 4:34:04 PM

Matt,

Thanks for the update. We are all very grateful for your leadership.

Best, Brad

R. 3752.

8. February 28, 2025 - The Grant Terminations Begin

On February 28, 2025, the first batch-terminations

occurred. R. 1403. Dr. Memoli forwarded a spreadsheet to Dr. Bundesen, who forwarded it to CMGO Bulls. 9

<sup>&</sup>lt;sup>9</sup> Consistent with the Administrative Record, Dr. Bundesen testified that as for decisions on terminations, that DOGE was involved in selecting the grants to be terminated, apparently out of the blue:

Q How did you first learn that grants were going to be terminated on February 28th?

A I received a text message over Microsoft Teams from James McElroy. He said, Liza - - something to the effect of: Liza, can you please get in touch with Rachel Riley ASAP, she's been trying to reach you.

I'm paraphrasing.

I said, James, I'm sorry, I do not know who Rachel Riley is. And then shortly thereafter, James called me over a Microsoft Teams video call, and so he was there and Rachel Riley was there. She - introduced herself as being part of DOGE, who was working with HHS.

And she informed me that a number of grants will need to be terminated and that Matt Memoli will be sending me an e-mail, a list of grants in an e-mail shortly thereafter.

Q Did she explain why the grants were being terminated?

A No.

Q Did you ask?

A She explained that -- excuse me, let me clarify.

She said that the current administration's OGC has a different opinion from the previous administration's OGC on grant termination and, therefore, we will need to terminate grants by the end of the day.

That email and spreadsheet is part of the record:

From: Bundesen, Liza (NIH/OD) [E]

To: Bulls, Michelle G. (NIH/OD) [E]; Jacobs, Anna (NIH/OD) [E]

Subject: FW: Grants for immediate termination today

Date: Friday, February 28, 2025 2:35:58 PM

Attachments: 28 FEB Grants for Cancellation.xlsx

NIH Termination Letter 022625[42].docx

From: Memoli, Matthew (NIH/OD) [E]
Sent: Friday, February 28, 2025 2:34 PM

To: Bundesen, Liza (NIH/OD) [E]

Cc: Smith, Brad M. EOP/DOGE; Rachel.Riley@hhs.gov; Keveney, Sean (HHS/OGC)

Subject: Grants for immediate termination today

Liza.

Please terminate the grants on the attached spreadsheet by COB today. Attached is an OGC cleared termination letter.

Thank you,

Matt

--

Matthew J. Memoli, MD, MS Acting Director, National Institutes of Health

9000 Rockville Pike Bethesda, MD 20892

matthew.memoli@nih.gov

I did not ask what, you know, what grants because I just literally was a little bit confused and caught off guard. And so I waited to see what I would receive by e-mail.

Q: And then what did you receive by e-mail?

A: I received an e-mail from Matt Memoli that said something to the effect of: Liza, the attached list of grants need to be terminated by COB today. And there was an Excel file attached to the e-mail.

R. 2295 - 2302. Recall that Dr. Bundesen oversaw extramural research. There is no evidence of any discussion, rather, the evidence in the Administrative Record that Dr. Bundesen followed orders that apparently went from Riley to Dr. Memoli to Dr. Bundesen and on down the chain. Smith is copied on this email.

CGMO Bulls's testimony in another case confirms what the Administrative Record reveals:

- Q· This is one of those letters that you've been asked to send that you were just talking about?
  - A· · Yes.
  - Q · · And you signed this letter, right?
  - A· · Yes.
  - Q · · Okay. · And why did you send this letter?
  - A· · I was asked to send it.
  - Q · · Who asked you to send it?
  - A My supervisor.
  - Q · · Okay. · And who is that?
  - A · · At the time, Liza Bundesen.
    - \* \* \*
  - Q. Did she tell you why she was asking you to send it?
  - A· · Yes.
  - Q · · Okay. · And what did she say?
  - A. . That we were asked to terminate grants.
  - $Q \cdot$  Did she tell you why you were asked to

terminate grants?

A · · She did not.

Q· · Okay.

A·· Can I correct the statement? The e-mail that I received from Liza Bundesen indicated that we needed to terminate the grants, and the language in the letters were provided so I didn't question, I just followed the directive.

Q· · Okay.

A·· She didn't say: Terminate the grant because of. She said: The list below. So I just wanted to be clear about that.

\* \* \*

Q. Okay. And is that the same list that you were talking about earlier that came from Rachel Riley?

A · · That was on the same e-mail, yes.

Depo. Bulls 66-68. CGMO Bulls describes the letters, accurately, as "template letters" <u>Id.</u> She also testified that but for her signature on the letters, she did not create any of the language, which was provided by Rachel Riley, and that she is unaware whether the NIH undertook any assessment at all as to whether a particular grant met the criteria being espoused in the letters. <u>Id.</u> The testimony concerning the February 28, 2025 letters comports with the Administrative Record, though the grant described is not one before this Court:

Q · · So it says here -- actually, can you read

the fourth paragraph, the one that starts with, "This award no longer effectuates."

A· "This award no longer effectuates agency priorities. 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. 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."

 $Q \cdot \cdot O$  okay. And this was part of the template letter that Rachel Riley provided?

A· · Yes.

\* \* \*

 $Q \cdot \cdot$  Was this edited in any way from the template letter that Rachel Riley provided?

A· · No.

Q· · Okay. · It says, "Your project does not satisfy these criteria." · Do you see that there?

A· · Yeah.

 $Q \cdot$  Are you aware of any assessment of Dr. Ahrens' grant in particular that was made to see if her grant satisfied the criteria?

A· · No.

 $\mathbf{Q}\cdot$  Would you have been aware of such assessment if one had been made?

A· · I don't know.

Q· · Okay. · Would you have been aware of such an assessment if one had been made by NIH? A· · Yes.

- Q. And it says, "Research programs based on gender identity are often unscientific with little identifiable return on investment, and do nothing to enhance the health of many Americans." Did NIH do any assessment of this particular grant to see if it was unscientific?
- A· I don't know. The letter was provided and it was sent. I don't know what happened before ·8 · ·that.
- Q · · Well, did NIH do any assessment?
- A · · I don't know.
- Q· You don't know if NIH did an assessment to see if Dr. Ahrens' grant was scientific or not?
- ${\tt A}\cdot\,\,\cdot\,\,{\tt Are}$  you talking about -- I don't understand your question, sorry.
- Q· · Well, it says in this letter, and I understand you didn't write it, but you signed it, "Research programs based on gender identity are often unscientific." And that was the reason this particular grant was terminated. :Is that right?
- A · · That's what the letter says.
- $Q \cdot$  That's what the letter says. So I'm trying to figure out whether or not there was any basis to think that Dr. Ahrens' grant was unscientific.
- A · · I don't know.
- Q. Okay. And do you know if there was any assessment to see if it had an identifiable return on investment?
- A · · No, I don't know.
- Q · · Do you know if NIH did one?
- A · · I don't know.

- · Q· · Okay. · Would you have been aware if NIH did one?
  - A · · I'm not sure.
  - Q. Okay. And it also says, "and do nothing to enhance the health of many Americans." Do you know if NIH did any assessment to see if Dr. Ahrens' grant would enhance the health of many Americans?
  - A · · I don't know.
  - \* \* \*
  - Q Did Rachel Riley provide any other template letters that were sent?
  - A· Yes.
  - Q · · Okay. · What were those template letters about?
  - A· · In that [February 28, 2025] list, I don't recall.
  - Q. . How about any list for letters that had been sent?
  - A· · DEI activities, this language. · I think one on China. · I don't know. · That's it that I can recall, and I'm sure I'm blanking right now.
  - Q. So what you remember is the gender identity language, the DEI language, and the China. Was there language on vaccine hesitancy that was used?
  - A · · In that batch, no.

Bulls Depo. 72 - 74. CMGO Bulls later testified, again, consistent with the Administrative Record, that Rachel Riley provided the following DEI language in template letters:

And then it says, "DEI: Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to scientific inquiry, do nothing to expand our knowledge of living systems, provides 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." That language also was provided by Rachel Riley?

A Yes.

Id. 90 - 91. Consistent with the Administrative Record, CMGO
Bulls testified that she was provided lists with the categorical
reasons for termination, and she executed based on those lists.
She had no input into which grants were terminated or for what
reasons:

- Q. Okay. But it's your testimony that the reason that the grant is going to be terminated is provided to you. Is that right?
- A · · That's right.
- Q · · And you don't have any input into that?
- A· · I don't.
- Q · · Okay. · And you're testifying that the template letter for each reason is provided to you. Is that right?
- A· Yes.
- $Q \cdot$  And you don't have any input into that either?
- A· · I don't.
- Id. 97 98. From January 20, 2025 through April 2025, CMGO
  Bulls had received "more than five lists" of grants to
  terminate, and she estimated that at that time between 500 and
  1,000 grants had been terminated. Id. 98 99. While there

had been a "handful" of noncompliance terminations of which the NIH had undertaken between 2012 through January 20, 2025, Bulls Depo. 46 ("My testimony is that it doesn't happen often, more than one and probably less than five."), the current type of terminations that were dictated from HHS had occurred only once before during the prior Trump Administration. Id. 47 -48. The Administrative Record is replete with a large number of these new, dictated terminations.

The templates for these letters are all variations on a theme, and has been dictated onto the NIH by Riley as a reason-for-termination menu. A good example is provided in full, but the record is replete with examples of the templates being used:

## PRIVILEGED, CONFIDENTIAL, PRE-DECISIONAL

#### FOR GRANTS ISSUED DECEMBER 2022-MARCH 2024 (TO BE DELTED)

[Address block & date]

## [Grant recipient]:

Funding for Project Number [INSERT] is hereby terminated pursuant to the 2022 National Institutes of Health ("NIH") Grants Policy Statement, 13 and 2 C.F.R. § 200.340(a)(2) (2023). This letter constitutes a notice of termination. 14

The 2022 Policy Statement applies to your project because NIH approved your grant on [INSERT DATE], and "obligations generally should be determined by reference to the law in effect when the grants were made."15

The 2022 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards."16 According to the Policy Statement, "NIH may ... terminate the grant in whole or in part as outlined in 2 CFR Part 200.340."17 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."

This award no longer effectuates agency priorities. 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. [INSERT] EXPLANATION—EXAMPLES BELOW

- 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 harms the

<sup>&</sup>lt;sup>13</sup> https://grants.nih.gov/grants/policy/nihgps/nihgps\_2022.pdf.

<sup>14 2</sup> C.F.R. § 200.341(a); 45 C.F.R. § 75.373

<sup>15</sup> Bennett v. New Jersey, 470 U.S. 632, 638 (1985).

<sup>16 2022</sup> Policy Statement at IIA-1.

<sup>17</sup> Id. at IIA-153.

## PRIVILEGED, CONFIDENTIAL, PRE-DECISIONAL

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.].

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 Project Number [INSERT] is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable. 19 Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to USAspending.gov. 20

## Administrative Appeal

You may object and provide information and documentation challenging this termination. <sup>21</sup> NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board. <sup>22</sup>

You must submit a request for such review to [the NIH Director or his designee] no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, [the NIH Director or his designee] may grant an extension of time.<sup>23</sup>

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.<sup>24</sup>

#### Sincerely,

18 2022 Policy Statement at IIA-154.

<sup>19</sup> See 2 C.F.R. § 200.343 (2023).

<sup>&</sup>lt;sup>20</sup> 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)

<sup>21</sup> See 45 C.F.R. § 75.374.

<sup>22</sup> See 42 C.F.R. Part 50, Subpart D.

<sup>23</sup> Id. § 50.406(a).

<sup>24</sup> Id. § 50.406(b).

R. 2482 - 2483.

# 9. March 2025 -- The NIH Priorities Directives Emerge

Between March 4, 2025, and March 25, 2025 internal staff guidance was issued. See March 4, 2025 email from CMGO Bulls to Chief GMOs, R. 345.

From: Bulls, Michelle (NIH/OD) [E]

To: Chief GMOs

Cc: Bulls, Michelle (NIH/OD) [E]; Ta, Kristin (NIH/OD) [E]; Sass-Hurst, Brian (NIH/OD) [E]

Subject: DEI Staff Guidance - Final - March 4 2025

Date: Tuesday, March 04, 2025 11:02:00 AM

Attachments: DEI Staff Guidance - Final 3.4,25,pdf

#### Good morning,

Attached is staff guidance that includes the DEI term along with details on when the term must be applied. Let's plan to talk through this guidance and note Dr. Memoli has **approved** the DEI term for immediate use. I have also added the process for terminating awards based in DEI as provided to us by HHS. I will follow up with a few of you to pull out the details needed to address terminations that were made yesterday—just to pull the information out and to address specific questions. Finishing up meetings and then, I will that information out to all that were impacted by yesterday's termination list provided to us by HHS/ASA.

Thanks,

Michelle

The guidance is provided in full:

## Staff Guidance -Award Assessments for Alignment with Agency Priorities - March 2025

#### Background

This staff guidance rescinds the guidance provided in the February 13, 2025, memo to IC Chief Grants Management Officers entitled Supplemental Guidance – NIH Review of Agency Priorities Based on the New Administration's Goals. In accordance with the Secretarial Directive on DEI Related Funding (Appendix 1), NIH will no longer prioritize research and research training programs that focus on Diversity, Equity and Inclusion (DEI). Terminations that result from science that no longer effectuates NIH's priorities must follow the appeals guidance below. All other terminations for noncompliance require, always, appeal language.

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. To avoid issuing awards, in error, that support DEI activities ICs must take care to completely excise all DEI activities using the following categories.

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.

Action: ICs must not issue the award.

Category 2: 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 means DEI activities are ancillary to the purpose of the project. In some cases, not readily visible. This category requires a scientific assessment and requires the GM to use the DEI Restriction Term of Award in Section IV of the Notice of Award, no exceptions will be allowed without a deviation from the Office of Policy for Extramural Research Administration (OPERA)/Office of Extramural Research (OER).

- Action 1: Funding IC must negotiate with the applicant/recipient to address the activities that are non-compliant, along with the associated funds that support those activities, obtain revised aims and budgets, and document the changes in the
- o Action 2: Once the IC and the applicant/recipient have reached an agreement, issue the award and include the DEI Term and Condition of Award in Section IV of the Notice of Award. Hard funds restrictions are not required.
  - Note: If the IC and the applicant/recipient cannot reach an agreement, or the project is no longer viable without the DEI related activities, the IC cannot proceed with the award. For ongoing projects, the IC must work with OPERA to negotiate a bilateral termination of the project. Where bilateral termination cannot be reached, the IC must unilaterally terminate the project. Terminated awards (bilaterally or unilaterally) should follow the process identified in Appendix 2.

Category 3: Project does not support DEI activities, but may contain language related to DEI (e.g., statement regarding institutional commitment to diversity in the 'Facilities & Other Resources' attachment and terminology related to structural racism—this is not allinclusive).

- Action 1: Funding IC must request an updated application/RPPR with the DEI language removed.
- Action 2: Once the language has been removed, the IC may proceed with issuing the award.

Category 4: Project does not support any DEI activities

o Action: IC may proceed with issuing the award.

R. 2152 -2153. Again, no definition is provided for DEI.

Multiple appendices are provided, simply stating that it is "in accordance with the Secretarial Directive," which is included as an appendix. R. 2154 - 2155. It also includes the boilerplate language regarding DEI, "transgender issues," and China:

## Appendix 3 – Language provided to NIH by HHS providing examples for research activities that NIH no longer supports.

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

Appendix 4 - Approved Term - Use for all Category 2 awards, i.e., renegotiated aims and associated budgets. Approval embedded below. ICs should use this term in the IC specific award conditions

#### Term and Condition of Award

NIH and the recipient have renegotiated the scope of this award. Pursuant to the revised scope, NIH funds may only be used to support activities within the revised scope of the award. NIH funds may not be used to support activities that are outside the revised scope of the award, including Diversity Equity and Inclusion (DEI) research or DEI-related research training activities or programs. Any funds used to support activities outside the scope will result in a disallowance of costs, and funds will be recovered.

This term is consistent with NIH's ongoing internal review of NIH's priorities and the alignment of awards with those priorities as well as a review of program integrity of awards. Such review includes, but is not limited to, a review for fraud, waste and abuse, and a review of the NIH portfolio to determine whether awards are in the best interests of the government and consistent with policy priorities. If recipients are unclear on whether a specific activity constitutes DEI or has questions regarding other activities that could be considered outside the scope of the award, refrain from drawing down funds and consult with the funding IC, particularly where the activity may impact the specific aims, goals, and objectives of the project.

Approval email from Dr. Memoli (Acting Director, NIH) on Friday, February 28, 2025.

Notably, Appendix 4 delves into renegotiated awards R. 2157. concerning DEI activities. Anticipating questions about an

undefined DEI, the NIH invites recipients to inquire before drawing down funds. <u>Id.</u> Throughout March 2025, the Priorities directive was modified for certain procedures, but the boilerplate language of the reasons for termination did not substantially vary.

10. Friday, March 7, 2025 -- Deputy Director Bundesen Resigns and Acting Director Memoli Appoints Himself Acting Deputy Director of Extramural Research

On Friday, March 7, 2025, a mere three weeks after appointment as Acting Deputy Director of Extramural Research, Director Bundesen resigned from the NIH.

## 11. March 10, 2025

Dr. Memoli was in the thick of it, and he sent an email to his Deputies and general counsel, expressing that week was going to be busy:

Lorsch, Jon (NIH/NIGMS) [E] From: Bulls, Michelle G. (NIH/OD) [E] To:

Subject: FW: OER

Monday, March 10, 2025 9:15:25 AM Date: 1VH Termination 3-10-25.xlsx Attachments:

Importance:

Do you want to send this out or do you want me to? I assume it should go to GMAC with CC to

Let me know how you would like to proceed.

Thanks.

Jon

From: "Memoli, Matthew (NIH/OD) [E]" Date: Monday, March 10, 2025 at 8:37 AM

To: "Lorsch, Jon (NIH/NIGMS) [E]", "Jacobson, Ray (NIH/CSR) [E]", "Schwetz, Tara

(NIH/OD) [E]"

Cc: "McElroy, James (NIH/OD) [E]", "Burklow, John (NIH/OD) [E]", "Lankford, David

(NIH/OD) [E]" Subject: OER Good morning,

This is going to be a busy week for OER. There will be many actions this week similar to this. Two things this morning:

- 1. I would like an updated list of all grants terminated so far.
- 2. I attached all ist of 43 grants, OTA, and NOFOs that need to be terminated/taken down, preferably by COB today if possible. These are on the first tab of the spreadsheet. These no longer align with HHS priorities so we can use the termination letters we have been using regarding HHS priorities.

Please have someone confirm with me when this is complete.

Thank you all again for your efforts and taking OER on.

Matt

Matthew J. Memoli, MD, MS Acting Director, National Institutes of Health 9000 Rockville Pike Bethesda, MD 20892 matthew.memoli@nih.gov

R. 2352. He wasn't wrong.

## a. The Columbia University Bulk Terminations --Another Example of the Weaponization of the NIH

Separate to the categorized grant terminations, there is a curious exchange in the Administrative Record concerning the NIH weighing in on the Columbia University campus unrest. As best the Court can discern, the NIH was being required to come down hard on Columbia University and cancel their grants on the basis of campus unrest. There is no evidence in the record that this had ever been done before. Deputy Director Lorsch, perhaps understanding the implications of cancelling all grants to a research university, appeared to be trying to soften the blow recommending to Dr. Memoli to fire a warning shot across Columbia University's bow -- that Columbia be put on notice that NIH "intended" to terminate a list of grants. Dr. Memoli provided that same recommendation to David Lankford, the NIH's General Counsel:

From: Memoli, Matthew (NIH/OD) [E]
Lorsch, Jon (NIH/NIGMS) [E]; Lankford, David (NIH/OD) [E] To:

Subject: Re: One more thought... Monday, March 10, 2025 1:15:45 PM Date:

NIH Termination Letter\_Columbia (2024 Statement)\_v3 (s Attachments

Columbia Grants for Suspension or Termination.xlsx

Jon.

Attached is a termination letter that was drafted. I think the last paragraph is the relevant part we may need to use, but I defer to David and OGC.

David, we would like to send a single letter to the University telling them we intend to terminate the grants listed in the attached spreadsheet. We will the proceed with orderly terminations through our normal process.

We would like an approved letter sent by close of business today.

Thanks,

Matt

Matthew J. Memoli, MD, MS Acting Director, National Institutes of Health 9000 Rockville Pike Bethesda, MD 20892

matthew.memoli@nih.gov

From: Lorsch, Jon (NIH/NIGMS) [E] <jon.lorsch@nih.gov>

Date: Monday, March 10, 2025 at 1:03 PM

To: Memoli, Matthew (NIH/OD) [E] <matthew.memoli@nih.gov>

Subject: One more thought...

What if we issued a letter to the VPR at the university saying we "intend to terminate the following awards..." with a list of the awards. That would make the point and then we could follow an orderly procedure for doing it. Perhaps there would be a resolution before that process finished?

R. 3462. The email attached a list of Columbia's grants and a draft letter, dated March 7, 2025.10 The draft without the list is set forth in full here:

<sup>10</sup> This draft letter date coincides with a March 7, 2025 Department of Justice/HHS, Department of Education and General Services Administration Press Release which stated "GSA will assist HHS and ED in issuing stop-work orders on grants and contracts that Columbia holds with those agencies. These stop-



#### DEPARTMENT OF HEALTH & HUMAN SERVICES

**Public Health Service** 

National Institutes of Health Bethesda, Maryland 20892 www.nih.gov

March 7, 2025

President Katrina Armstrong The Trustees of Columbia University in the City of New York 202 Low Library 535 W. 116 St. New York, NY 10027

Dear President Armstrong:

Funding for Project Number [INSERT] is hereby terminated pursuant to the 2024 National Institutes of Health ("NIH") Grants Policy Statement, 1 and 2 C.F.R. § 200.340(a)(2) (2024). This letter constitutes a notice of termination.2

The 2024 Policy Statement applies to your project because NIH approved your grant on [INSERT DATE], and "obligations generally should be determined by reference to the law in effect when the grants were made."3

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards."4 According to the Policy Statement, "NIH may ... terminate the grant in whole or in part as outlined in 2 CFR Part 200.340." 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."

This award no longer effectuates agency priorities. 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.

NIH is responsible for ensuring that its limited resources are appropriately allocated. NIH policy is that grant dollars should support institutions that foster safe, equal, and healthy working and learning conditions conducive to high-quality research and free inquiry-and should not subsidize institutions that are not built on American values of free speech, mutual respect, and open debate. 6 In this vein, NIH is aware of recent events at Columbia University involving antisemitic action that suggest the institution has a disturbing lack of concern for the safety and wellbeing of Jewish students. Columbia's ongoing inaction in the face of repeated and severe harassment and targeting of Jewish students has ground day-to-day campus operations to a halt, deprived Jewish students of learning and research opportunities to which they are entitled, and brought shame upon the University and our nation as a whole. Supporting research in such an

work orders will immediately freeze the university's access to these funds. Additionally, GSA will be assisting all agencies in issuing stop work orders and terminations for contracts held by Columbia University." Mar. 7, 2025 Press Release, https://www.hhs.gov/press-room/task-force-cancels-columbiauniversity-grants.html

<sup>1</sup> https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

<sup>&</sup>lt;sup>2</sup> 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373

<sup>3</sup> Bennett v. New Jersey, 470 U.S. 632, 638 (1985).

<sup>4 2024</sup> Policy Statement at IIA-1.

<sup>5</sup> Id. at IIA-155.

<sup>6 2024</sup> Policy Statement, Section 4.

environment is plainly inconsistent with NIH's priorities and raison d'etre of funding and championing the very best American research and educational institutions.

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 Project Number [INSERT] is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.8 Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to USAspending.gov.9

#### Administrative Appeal

You may object and provide information and documentation challenging this termination. 10 NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board. 11

You must submit a request for such review to Director Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time. 12

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim. 13

Sincerely,

Monemoli-Matthew J. Memoli, M.D., M.S. Acting Director, NIH

7 2024 Policy Statement at IIA-156.

R. 3503-3504.

Drs. Lorsch' s and Memoli's softer approach was apparently wholly rejected; the Administrative Record reflects a full termination:

<sup>8</sup> See 2 C.F.R. § 200.343 (2024).

<sup>9 2</sup> C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)

<sup>10</sup> See 45 C.F.R. § 75.374.

<sup>11</sup> See 42 C.F.R. Part 50, Subpart D.

<sup>12</sup> Id. § 50.406(a).

<sup>13</sup> Id. § 50.406(b).





March 10, 2025

Angela V. Olinto, Ph.D. Provost, Columbia University Email: provost@columbia.edu

Dear Dr. Olinto:

NIH is hereby providing notice that funding for the projects in the attached spreadsheet will be terminated pursuant to the National Institutes of Health ("NIH") Grants Policy Statement (GPS), and 2 C.F.R. § 200.340(a)(4).

As reflected in the Notices of Award for the most recent budget period of these projects, the NIH Grants Policy Statement is incorporated as a term and condition of award. The GPS "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards." According to the GPS, "NIH may ... terminate the grant in whole or in part as outlined in 2 CFR Part 200.340." At the time the Notices of Award were issued for the most recent budget period, 2 C.F.R. § 200.340(a)(4) 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."

These awards no longer effectuate agency priorities. 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.

NIH is responsible for ensuring that its limited resources are appropriately allocated. NIH policy is that grant dollars should support institutions that foster safe, equal, and healthy working and learning conditions conducive to high-quality research and free inquiry<sup>4</sup>—and should not subsidize institutions that are not built on American values of free speech, mutual respect, and open debate. In this vein, NIH is aware of recent events at Columbia University involving antisemitic action that suggest the institution has a disturbing lack of concern for the safety and wellbeing of Jewish students. Columbia's ongoing inaction in the face of repeated and severe harassment and targeting of Jewish students has ground day-to-day campus operations to a halt, deprived Jewish students of learning and research opportunities to which they are entitled, and brought shame upon the University and our nation as a whole. Supporting research in such an

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https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

<sup>&</sup>lt;sup>2</sup> NIH GPS, Section 3.

<sup>3</sup> Id. at Section 8.5.2.

<sup>&</sup>lt;sup>4</sup> NIH GPS, Section 4.

environment is plainly inconsistent with NIH's priorities and raison d'etre of funding and championing the very best American research and educational institutions.

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,"5 no corrective action is possible here. The actions described above are incompatible with agency priorities, and no modification of the projects could align the projects with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.<sup>6</sup> Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 200.344. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to USAspending.gov.7

#### Administrative Appeal

You may object and provide information and documentation challenging these terminations. NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.8

You must submit a request for such review to Director Memoli no later than 30 days after this letter is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.9

The request for review must include a copy of this decision, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim. 10

Sincerely,

Michelle G. Bulls Director, Office Policy for Extramural Administration Chief Grants Management Officer - National Institutes of Health Email: michelle.bulls@nih.gov

William Berger, Assistant Vice President for Sponsored Projects Administration, Columbia University

R. 3805 - 3806. While the parties do not appear to assert claims based directly upon this letter, it was included in the Administrative Record, and in the Court's view is further

<sup>5</sup> NIH GPS, Section 8.5.2.

<sup>6</sup> See 2 C.F.R. § 200.343.

<sup>7 2</sup> C.F.R. § 200.341(c).

<sup>8</sup> See 42 C.F.R. Part 50, Subpart D.

<sup>9</sup> Id. § 50.406(a).

<sup>10</sup> Id. § 50.406(b).

evidence of the NIH's grant process being abused as a bludgeon, this time to sanction Columbia University for the Administration's perception of inaction by Columbia with respect to campus unrest. While the Court takes no position as to the merits of the Executive's perception or of the legality of its action, it is clear that Drs. Memoli and Lorsch at least had some pause as to a wholesale termination of Columbia's grants, numbering in the hundreds. R. 3807 - 3809. Indeed, how the scientific and research activities had any connection with unrest issues on Columbia's campus is conspicuously never explained. The record evidence certainly reveals none.

## 12. March 10, 2025 Further Terminations

The record is replete with termination activity. On March 10, 2025, grants were terminated. See e.g. R. 794 - 795; 1326 - 1333; 1357 -1363. On March 11, 2025, Riley sent Dr. Memoli a list of grants to terminate, that were approved by Dr. Memoli within 2 minutes of the email having been sent:

From: Memoli, Matthew (NIH/OD) [E]

To: Riley, Rachel (OS/ASA); Bulls, Michelle G. (NIH/OD) [E]

Subject: Re: Shortlist of SGM for Tonight
Date: Tuesday, March 11, 2025 9:49:35 PM

All of these grants can be terminated for being unaligned with current NIH /HHS priorities.

Matt

Get Outlook for Mac

From: Riley, Rachel (OS/ASA) < Rachel. Riley@hhs.gov>

Date: Tuesday, March 11, 2025 at 9:43 PM

**To:** Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>, Memoli, Matthew

(NIH/OD) [E] <matthew.memoli@nih.gov> Subject: Shortlist of SGM for Tonight

Dr. Memoli -

Please see a short list below/attached; I have sent you 6 in case you find an issue with any one. If you are comfortable, the wonderful <u>@Bulls, Michelle G. (NIH/OD) [E]</u> will work to action tonight:

I will then get you an updated combined list for tomorrow!

Thanks, Rachel

R. 3820. There is record evidence of template letters being sent on that date. R. 297 - 298; 653 -654 711- 712; 3508 - 3509; 3585 - 3586.

## 13. March 12, 2025 -- Further Terminations

On March 12, 2025, Dr. Memoli sent an email to Deputy

Director Lorsch and Bulls with a list of grants to terminate.

R. 3631 - 3635. Brad Smith of DOGE is copied on the email. Id.

From: Memoli, Matthew (NIH/OD) [E]

To: Lorsch, Jon (NIH/NIGMS) [E]; Bulls, Michelle G. (NIH/OD) [E]
Cc: Smith, Brad M. EOP/DOGE; McElroy, James (NIH/OD) [E]

Subject: Terminations

Date: Wednesday, March 12, 2025 2:00:56 PM

Attachments: Terminated Grants 3-12.xlsx

#### Good afternoon.

Attached is a list of grants that should be terminated for not being aligned with current HHS/NIH priorities. If possible, please terminate by COB today.

Thank you,

Matt

--

Matthew J. Memoli, MD, MS

Acting Director, National Institutes of Health

9000 Rockville Pike

Bethesda, MD 20892

matthew.memoli@nih.gov

R. 2932-2933; 3631. Terminations were issued on that date. <u>See</u>
<u>e.g.</u> R. 651 - 652 709 - 710.

On March 13, 2025, Dr. Memoli sent an email to Deputy Director Lorsch and Bulls, directing them to terminate an additional 530 grants. Brad Smith of DOGE is copied on the email, which is provided in full:

 From:
 Memoli, Matthew (NIH/OD) [E]

 To:
 Lorsch, Jon (NIH/NIGMS) [E]

Cc: Cutler, Diane (HHS/IOS); Smith, Brad M. EOP/DOGE; Bulls, Michelle G. (NIH/OD) [E]

Subject: New list for termination

 Date:
 Thursday, March 13, 2025 9:03:01 AM

 Attachments:
 Grants for Termination 3-13 to 3-24-25.xlsx

#### Jon.

Here is an additional list of grants for termination There are 530 grants here. I do not expect these to get done today. Please complete these by COB next Friday if possible. A daily evening update on how many were terminated would be appreciated. I want to thank you and Michelle for your diligent work getting this done. Michelle has been doing a lot of heavy lifting and it has not gone unnoticed.

Thank you,

Matt

--

Matthew J. Memoli, MD, MS
Acting Director, National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892
matthew.memoli@nih.gov

R. 3122 - 3191. There is record evidence of multiple terminations of grants. See e.g., R. 3593 - 3630; March 14, 2025 (R. 289 - 290); March 18, 2025 (R. 440- 441; 601 - 602); March 19, 2025 (R. 391 - 392); March 20, 2025 (R. 158 - 159; 449- 450; 745 -746; 1348 -1349; 1371- 1375; 1392 - 1392; 1397- 1398); March 21, 2025 (R. 114 - 116; 152 - 153; 187 - 189; 757 - 759; 771- 773; 782 - 784; 810-814; 859 - 861; 871 - 873; 877 - 878; 995-996; 1195 -1197; 1237 -1242; 1268-1273; 1284 - 1292; 1380 - 1384; 1399 - 1401; 1416- 1421; 1483 - 1484; 1492 -1493; 1668 - 1670; 1689 -1694; 2415 - 2468); March 24, 2025 (R. 689-

691; 747 - 749; 844 - 846; 1218 - 1220; 1299 - 1301; 1309 - 1310; 2257 - 2258).

# 14. March 25, 2025 - Staff Guidance (Priorities Directive)

On March 25, 2025, the NIH issued further guidance ("the March 25 Guidance"). R 3216 -3230. This is a continuation of the Priorities Directive, which was changing on the fly over March, though it is not clear whether any grants were terminated based upon this guidance.

NIH Grants Management Staff Guidance – Award Assessments for Alignment with Agency Priorities- March 2025

Issue Date: March 25, 2025

#### Background

This staff guidance rescinds the guidance provided in the February 13, 2025, memo to IC Chief Grants Management Officers entitled Supplemental Guidance - NIH Review of Agency Priorities Based on the New Administration's Goals. In accordance with the Secretarial Directive on DEI Related Funding (Appendix 1), NIH will no longer prioritize research and research training programs that focus on Diversity, Equity and Inclusion (DEI). Terminations that result from science that no longer effectuates NIH's priorities related to DEI, gender identity and other scientific areas must follow the appeals guidance below. All other terminations for noncompliance require, always, appeal language.

Prior to issuing all awards (competing and non-competing) or approving requests for carryover, ICs must review the specific aims/major goals of the project to assess whether the proposed project contains any DEI, gender identity or other research activities that are not an NIH/HHS priority/authority. To avoid issuing awards, in error, that support these activities ICs must take care to completely excise all nonpriority activities using the following categories.

ICs should review the current application/RPPR under consideration, only. ICs should not request retroactive changes to previous RPPRs and competitive applications to modify language related to research that has already been conducted. Categories 1-3 are IC determinations not those ordered by HHS.

Category 1: The sole purpose of the project is related to an area that is no longer an NIH/HHS priority/authority (e.g., diversity supplements, diversity fellowships, or conference grant where the purpose of the meeting is diversity), and/or the application was 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. This applies to all projects, including phased awards, etc.

- Action: ICs must not issue the award (competing or non-competing).
- For ongoing projects where NIH will not issue the next Type 5 (IC determination not HHS list), the IC must:
  - Issue a revised award to remove all outyears.
  - Add the action to the master spreadsheet located at: OD OPERA Grant Action Tracking (access limited to CGMOs).
  - Include the following term in the revised NOA:

#### Term of Award:

It is the policy of NIH not to prioritize research programs related to [insert category from Appendix 3, verbatim]. Therefore, no additional funding will be awarded for this project, and all future years have been removed. [RECIPIENT NAME] may request funds to support patient safety and orderly closeout of the project, and remaining funds will be deobligated. Funds used to support any

other research activities will be disallowed and recovered. Please be advised that your organization, as part of the orderly closeout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), as applicable) within 120 days of the end of this grant.

NIH is taking this enforcement action in accordance with 2 C.F.R. § 200.340 as implemented in NIH GPS Section 8.5.2. This revised award represents the final decision of the NIH. It shall be the final decision of the Department of Health and Human Services (HHS) unless within 30 days after receiving this decision you mail or email a written notice of appeal to Dr. Matthew Memoli. Please include a copy of this decision, your appeal justification, total amount in dispute, and any material or documentation that will support your position. Finally, the appeal must be signed by the institutional official authorized to sign award applications and must be dated no later than 30 days after the date of this notice.

- Check PMS to determine amount of funds remaining, and if funds are available request a hard funds restriction of all funds except \$1 in PMS.
- No cost extension requests: For second and third NCE's, ICs must determine if the sole purpose of the grant was to support research activities that are no longer an NIH/HHS priority/authority and, if so, issue an award to end the grant project (use disapproved extension term below). If the non-NIH/HHS priority/authority research activities are ancillary to the project, approve the extension (use approved extension term below). Reminder - even if a grant project is in an NCE, IC staff must still determine if non-NIH/HHS priority/authority activities are proposed during the extension period. Extensions may only be approved for orderly closeout, and funds may not be used to support any non-NIH/HHS priority/authority research activities.
  - ICs may use the following term of award when approving/disapproving NCEs:
    - Term of Award (approved extension): The no-cost extension has been approved for this project to support orderly closeout of the project, only. NIH grants funds must not be used to support [insert category e.g., Diversity, Equity and Inclusion (DEI), gender identity, etc.] research or research training activities or programs. Any funds used to support such activities will result in a disallowance of costs, and funds will be recovered.
    - Term of Award (disapproved extension): The no cost extension request for this project has been denied. Please proceed with orderly closeout of the project. NIH grant funds must not be used to support [insert category – e.g., Diversity, Equity and Inclusion (DEI), gender identity, etc.] research or research training activities or programs.

Category 2: Project partially supports 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. This category requires a scientific assessment and requires the GM to use the Restriction Term of Award in Section IV of the Notice of Award. No exceptions will be allowed without a deviation from the Office of Policy for Extramural Research Administration (OPERA)/Office of Extramural Research (OER).

- Note: Activities required to comply with NIH inclusion policies are not considered DEI activities.
- Action 1: Funding IC must negotiate with the applicant/recipient to address the activities that are non-compliant, along with the associated funds that support those activities, obtain revised aims and budgets, and document the changes in the grant file. The recipient/awardee cannot rebudget these funds, they must be recovered by the IC. OPERA is consulting with eRA on options to collect these application updates in a structured format.
  - Sample language for requesting application updates from the AOR: 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.] [Funding IC] has identified [insert appropriate activity taken from the list above] activities within section [XXXX] of your application. Please work with the PD/PI to update the application sections and adjust the budget as appropriate to remove all [insert appropriate activity] activities and submit these updates to the Program Official and Grants Management Specialist for review and approval.
- Action 2: Once the IC and the applicant/recipient have reached an agreement, issue the award and include the following Term and Condition of Award in Section IV of the Notice of Award. Hard funds restrictions are not required.

## Term of Award (Approved 2/28/2025 - Refer to Appendix 4 for the approval from Dr. Memoli):

NIH and the recipient have renegotiated the scope of this award. Pursuant to the revised scope, NIH funds may only be used to support activities within the revised scope of the award. NIH funds may not be used to support activities that are outside the revised scope of the award, including [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.] research or related research training activities or programs. Any funds used to support activities outside the scope will result in a disallowance of costs, and funds will be recovered.

This term is consistent with NIH's ongoing internal review of NIH's priorities and the alignment of awards with those priorities as well as a review of program integrity of awards. Such review includes, but is not limited to, a review for fraud, waste and abuse, and a review of the NIH portfolio to determine whether awards are in the best interests of the government and consistent with policy priorities. If recipients are unclear on whether a specific activity constitutes

[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.] or has questions regarding other activities that could be considered outside the scope of the award, refrain from drawing down funds and consult with the funding IC, particularly where the activity may impact the specific aims, goals, and objectives of the project.

- Unable to remove activities that are not an NIH/HHS priority/authority: If the IC and the applicant/recipient cannot reach an agreement, or the project is no longer viable without the non-compliant activities, the IC cannot proceed with the award. For ongoing projects, the IC must work with OPERA to negotiate a bilateral termination of the project. Where bilateral termination cannot be reached, the IC must unilaterally terminate the project. Terminated awards (bilaterally or unilaterally) should follow the process identified in Category 4.
- Diversity Supplements: Type 5 Diversity supplements may no longer be awarded. For ongoing awards, ICs must remove the diversity supplement activities prior to issuing the next Type 5 for the parent award and include the DEI Term and Condition of Award in Section IV of the NOA of the parent grant. The IC must revise the Diversity Supplement award to remove all outyears. If diversity supplement outyears were included in the previous NOA, the IC must revise the prior year award to remove references to those outyear commitments.
- Conference Grants: If a conference supported by an NIH grant focuses on scientific topics that are unrelated to DEI, but the conference itself is targeted at a specific population (e.g., underrepresented groups), the IC must work with the applicant/recipient to open the conference up to all populations. If a negotiation to broaden the target audience is not feasible, or the conference is no longer viable, then the IC must terminate the award following the process in Category 4.
- Diversity Reports (e.g., Ts, R25, K12, and any others): NIH is modifying the application instructions and RPPR instructions to remove requirements for diversity reports (e.g., Trainee Diversity Report). If ICs receive these reports in applications or RPPRs, the IC should not review the report. These reports provide diversity related information, but do not involve specific DEI activities. ICs must use the following term: "NIH no longer requires the [name of diversity table/plans]. Therefore, NIH did not review the [name of diversity table/plans] provided. NIH funding may not be used to support any diversity, equity or inclusion (DEI) activities". Note: this section applies to diversity related reports, only. Other areas that are no longer NIH/HHS priorities/authority must be addressed under category 2 negotiations.
- Administrative Supplement Requests: Administrative supplement applications should be reviewed for any activities that are no longer NIH/HHS priorities/authority and modified as needed. ICs do not need to retroactively review the competitive parent grant application- only the supplement application requires review.

#### Category 2B:

Prospective reviews by GM where the DEI language in certain sections of the application has to be removed even though the project itself is not focused on DEI but may have language or have been awarded from a DEI NOFO that is expired/taken down for revision to go back up once the language is appropriately excised.

Examples below, and in these cases, IC should consider using the Category 2 term of award but remove the negotiation language from the term:

- Resource Section
- Biosketch
- **RPPRs**

#### Category 2C:

Subprojects terminated by HHS.

OPERA will restrict the funds associated with the project. No action required from the IC.

#### Category 3: Project does not support any DEI activities

Action: IC may proceed with issuing the award.

## Category 4/HHS Departmental Authority Terminations:

- OPERA receives a list from the Director, NIH or designee.
- OPERA will issue termination letters on behalf of the IC Chief Grants Management Officers. The IC CGMO will be copied on the email with the termination letter.
  - Supplements Parent Award Terminated: If a terminated award has active supplement(s), all supplement awards must be terminated along with the parent.
  - Supplement Terminated Only: If a termination letter references a supplement only, and not the parent award, then the supplement alone must be terminated following the instructions below.
  - Linked (or equivalent) Awards: If one linked (or equivalent) award is terminated, the IC is only required to terminate the specific award noted in the letter. The IC must conduct a separate review to determine whether terminating that award will have a structural impact on the scientific design along with associated outcomes and act, as appropriate, to early terminate or allow the remaining awards to continue. Feel free to discuss with OPERA, as needed.
- When a termination letter is received, the IC must:
  - Issue a revised NOA within 3 business days of the date the termination letter was issued to the recipient.
    - Change the budget and project period end dates to match the date of the termination letter.

- OPERA will place a hard funds restriction on all PMS subaccounts as termination letters are issued. OPERAs Federal Financial Report Center (FFR-C) will deobligate the remaining funds after the Final FFRs are submitted. There is no deobligation action required from the ICs.
- Remove all future years from the project, where applicable. If the grant is in a no cost extension, and HHS requests a termination, the project must be terminated even in a no cost extension. If the grant is in a no cost extension, and HHS did not request a termination, follow the NCE guidance above.
- Include the following Termination Term in the revised NOA:

It is the policy of NIH not to prioritize [insert termination category language from Appendix 3, verbatim]. Therefore, this project is terminated. [RECIPIENT NAME] may request funds to support patient safety and orderly closeout of the project. Funds used to support any other research activities will be disallowed and recovered. Please be advised that your organization, as part of the orderly closeout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), as applicable) within 120 days of the end of this grant.

NIH is taking this enforcement action in accordance with 2 C.F.R. § 200.340 as implemented in NIH GPS Section 8.5.2. This revised award represents the final decision of the NIH. It shall be the final decision of the Department of Health and Human Services (HHS) unless within 30 days after receiving this decision you mail or email a written notice of appeal to Dr. Matthew Memoli. Please include a copy of this decision, your appeal justification, total amount in dispute, and any material or documentation that will support your position. Finally, the appeal must be signed by the institutional official authorized to sign award applications and must be dated no later than 30 days after the date of this notice.

- Note: Appeals language must be included prior to October 1, 2025. After October 1, 2025, when HHS will fully adopt 2 CFR 200, per 2 CFR 200.340, termination actions taken based on agency priorities are not appealable. This is different from terminations based on noncompliance (administrative and programmatic).
- o eRA provides OPERA with daily reports on NOAs issued, so ICs do not need to report to OPERA on each action completed.

#### Category 5: Awards to Entities in certain foreign countries

- o Additional guidance on awards to foreign entities is forthcoming. At this time, ICs should hold all awards to entities located in South Africa or countries identified on any of the following lists.
  - State Department Countries of Particular Concern
  - State Sponsors of Terrorism
  - Final Rule Restricting Transfer of Personal U.S. Data to Countries of Concern

Office of Foreign Assets Control Sanctions List

## Separation of Duties Guidance:

OPERA has issued a Separation of Duties (SOD) waiver for all CGMOs, specific to the HHS Departmental Authorities termination actions, to allow IC CGMOs to work up and issue termination actions. Copy available in <a href="Teams">Teams</a>.

The March 25 Guidance settles on an examples list of: "China," "DEI," "Transgender issues," "Vaccine Hesitancy", "COVID-related" research:

# Appendix 3 - Language provided to NIH by HHS providing examples for research activities that NIH no longer supports. Use this language for HHS terminations only.

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

### R. 3226.

The March 25 Guidance also features 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.

R. 3229. In addition, "Notice of Funding Opportunity (NOFO)
Guidance," was listed as "[pending]." R. 3228.

On May 15, 2025, it appears that Dr. Memoli was provided an expanded list from the Office of General Counsel

## Appendix 3 - Language provided to NIH by HHS providing examples for research activities that NIH no longer supports.

- 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 ICO's, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs."
- Gender-Affirming Care: "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." Reminder: At this time, do not terminate any grants related to gender identify/transgender without clearance from OER. All such actions must be approved before any terminations.
- Vaccine Hesitancy: "It is the policy of NIH not to prioritize research activities that focuses gaining scientific knowledge on why individuals are hesitant to be vaccinated and/or explore ways to improve vaccine interest and commitment. NIH is obligated to carefully steward grant awards to ensure taxpayer dollars are used in ways that benefit the American people and improve their quality of life. Your project does not satisfy these criteria."
- COVID (to be used for HHS/NIH OD directed terminations only): "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." Note: ICO's may continue to support projects that funds general biology of coronavirus not linked to COVID-19. As ICO's conduct in-house analysis of project portfolios related to COVID the term may change. Please work with OPERA to develop standard terms based on the outcome of the analysis.
- Climate Change: "Not consistent with HHS/NIH priorities particularly in the area of health effects of climate change."
- Influencing Public Opinion: "This project is terminated because it does not effectuate the NIH/HHS' priorities; specifically, research related to attempts to influence the public's opinion."

R. 3536. Again, usage of this list was mandatory:

7. When ICO's issue revised NOAs to terminate awards, do they have to use the exact language provided by HHS in the termination term?

Yes, ICO's must use the exact language provided in Appendix 3, with no edits.

3541.

The terminations continued. <u>See March 26, 2025 (R. 1639 - 1641); March 31, 2025 (R. 2488); April 1, 2025 (R. 760-761; 1274-1276; 1376 - 1378; 1394 -1396); April 2, 2025 (R. 35 - 36; 3762 - 3803); April 7, 2025 (R. 1652); April 8, 2025 (R. 1653 - 1667); May 9, 2025 (R. 3452).</u>

### IV. RULINGS OF LAW

A. This Court Maintains Jurisdiction Save For Category of China which has not Harmed these Plaintiffs

This Court retains jurisdiction. The Public Officials press that the Court has no jurisdiction because their high-level activities are interlocutory and the grant terminations, claiming there is no final agency action under the APA. With the exception of grant terminations on the basis of China, all of these arguments are rejected.

 The Plaintiffs Have No Standing as to the "China" Category

The parties do not dispute that action has not been taken concerning the category of "China." Accordingly, the Court

**VACATES** its earlier order solely as to this category, that does not apply.

### 2. Final Agency Action

Final agency action "includes the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act." 5 U.S.C.A. § 551 (13), and a "rule" thereunder "means the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency." 5 U.S.C. § 551(4). "As a general matter, two conditions must be satisfied for agency action to be 'final': First, the action must mark the 'consummation' of the agency's decisionmaking process. . . -- it must not be of a merely tentative or interlocutory nature. And second, the action must be one by which rights or obligations have been determined, or from which legal consequences will flow."

Bennett v. Spear, 520 U.S. 154 (1997).

The Challenged Directives, as a whole, constitute final agency actions at the macro-level, and the resultant, downstream individual terminations and other effects are also independent final agency action as to each of the affected grants. The Public Officials attempts to narrow the action to grant terminations and characterization of the Priorities Directives

by CMGO Bulls "as not independently challengeable" oversimplifies the record and is a myopic view of the Administrative Record.

Certainly, taking any particular document in isolation and out of temporal context is superficially appealing. But the agency action here occurred in the context of a wholesale effort to excise grants in 8 categories over a period of less than 90 days. HHS directed NIH to cut without a plan and NIH, with the assistance of DOGE, made it up as they went along, resulting in a paper trail of the Challenged Directives. The Public Officials were trying to comply with an Executive Order 60-day deadline. See EO 14151 § 2 (B)(i) ("Each agency, department, or commission head, in consultation with the Attorney General, the Director of OMB, and the Director of OPM, as appropriate, shall take the following actions within sixty days of this order: . . . terminate, to the maximum extent allowed by law, all. . .equity action plans," 'equity' actions, initiatives, or programs, 'equity-related' grants or contracts"). expedition in implementation included all of the Challenged Directives. The Public Officials argue "that this case is nothing like Biden v. Texas, where the agency directed personnel to take all necessary actions to shut down an entire program." Trial Br. 11. (citing Biden v. Texas, 597 U.S. 785, 808-09 (2022). They are correct -- this is worse.

The pronouncements of HHS and NIH in the Challenged

Directives are consistent: they are final agency action on their
evolving "eradication" of DEI, gender identity, and other topics
ostensibly under the Executive Orders as quickly as possible.

While the President is not typically subject to the APA,

Franklin v. Massachusetts, 505 U.S. 788, 801 (1992), the
agencies implementing his orders certainly are. New York v.

Trump, 133 F.4th 51, 70 n.17 (1st Cir. 2025) ("[T]he District

Court did not review the President's actions for consistency
with the APA. Rather, it reviewed—and ultimately enjoined—the
Agency Defendants' actions under the Executive Orders.").

Indeed, "[t]he APA contains no exception for agency actions . .

that carry out an executive order." Orr v. Trump, No. 1:25—

CV-10313-JEK, 2025 WL 1145271, at \*15 (D. Mass. Apr. 18, 2025)

(Kobick, J.).

#### B. The Administrative Procedure Act

"[F]ederal courts do not exercise general oversight of the Executive Branch; they resolve cases and controversies consistent with the authority Congress has given them." Trump v. Casa, Inc., No. 24A884, 2025 WL 1773631, at \*15 (U.S. June 27, 2025). Congress has provided such authority, in part,

Nor should it. As my colleague Chief Judge McConnell of the District of Rhode Island recently wrote about our system of government:

under the Administrative Procedure Act ("APA"), 5 U.S.C. § 701 et seq. Specifically, the APA provides that any "person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof." 5 U.S.C. § 702. It acts "as a check upon administrators whose zeal might otherwise have carried them to excesses not contemplated in legislation creating their offices," Loper Bright Enters. v. Raimondo, 603 U.S. 369, 391 (2024) (quoting United States v. Morton Salt Co., 338 U.S. 632, 644 (1950)), and "sets forth the procedures by which federal agencies are accountable to the public and their actions subject to review by the courts," Department of Homeland Sec. v. Regents of the Univ.

Our founders, after enduring an eight-year war against a monarch's cruel reign from an ocean away, understood too well the importance of a more balanced approach to governance. They constructed three coequal branches of government, each tasked with their own unique duties, but with responsibilities over the other branches as a check in order to ensure that no branch overstepped their powers, upsetting the balance of the fledgling constitutional republic. See Kilbourn v. Thompson, 103 U.S. 168, 191 (1880). These concepts of "checks and balances" and "separation of powers" have been the lifeblood of our government, hallmarks of fairness, cooperation, and representation that made the orderly operation of a society made up of a culturally, racially, and socioeconomically diverse people possible.

New York v. Trump, 769 F. Supp. 3d 119, 127-28 (D.R.I. 2025).

of Cal., 591 U.S. 1, 16 (2020) (quoting Franklin v.

Massachusetts, 505 U.S. 788, 796 (1992)). Proadly, the APA establishes a rebuttable presumption of judicial review [for] one suffering legal wrong because of agency action. Id. (alteration in original) (quoting Abbott Lab'ys v. Gardner, 387 U.S. 136, 140 (1967)). The rebuttal of this presumption is made

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall—

- (1) compel agency action unlawfully withheld or unreasonably delayed; and
- (2) hold unlawful and set aside agency action, findings, and conclusions found to be—
  - (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;
  - (B) contrary to constitutional right, power, privilege, or immunity;
  - (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

. . . .

In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.

<sup>12</sup> Section 706 provides in pertinent part:

"by a showing that the relevant statute 'preclude[s]' review, § 701(a)(1), or that the 'agency action is committed to agency discretion by law,' 701(a)(2)."13 Id. at 17. The first exception is self-explanatory, and the Supreme Court has read the second exception "quite narrowly," applying "it to those rare 'administrative decision[s] traditionally left to agency discretion.'" Id. (alteration in original) (first quoting Weyerhaeuser Co. v. United Staes Fish & Wildlife Serv., 586 U.S. 9, 23 (2018); and then quoting Lincoln v. Vigil, 508 U.S. 182, 191 (1993)); Department of Com. v. New York, 588 U.S. 752, 772 (2019) ("[W]e have read the  $\S$  701(a)(2) exception for action committed to agency discretion 'quite narrowly, restricting it to "those rare circumstances where the relevant statute is drawn so that a court would have no meaningful standard against which to judge the agency's exercise of discretion."" (quoting Weyerhaeuser Co., 586 U.S. at 23)). Examples of decisions traditionally left to agency discretion include "a decision not to institute enforcement proceedings, or a decision by an

<sup>13</sup> Section 701 provides in pertinent part:

<sup>(</sup>a) This chapter applies, according to the provisions thereof, except to the extent that--

<sup>(1)</sup> statutes preclude judicial review; or

<sup>(2)</sup> agency action is committed to agency discretion by law.

intelligence agency to terminate an employee in the interest of national security." New York, 588 U.S. at 772 (citations omitted).

# C. The 706(2)(A) Claims -- Arbitrary and Capricious ('10787 Action Count I, '10814 Action Count III)

Section 706(2)(A) of the APA "instructs reviewing courts to set aside agency action that is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'" Id. at 771 (quoting 5 U.S.C. § 706(2)(A)). "An agency action qualifies as 'arbitrary' or 'capricious' if it is not 'reasonable and reasonably explained.'" Ohio v. Environmental Prot. Agency, 603 U.S. 279, 292 (2024) (quoting Federal Commc'ns Comm'n v. Prometheus Radio Project, 592 U.S. 414, 423 (2021)).

Review by the Court under the arbitrary or capricious standard of Section 706(2)(A) is narrow, because all that is "required [is for] agencies to engage in 'reasoned decisionmaking.'" Regents of the Univ. of Cal., 591 U.S. at 16 (quoting Michigan v. Environmental Prot. Agency, 576 U.S. 743, 750 (2015)) (emphasis added). To be sure, this Court may not "substitute its judgment for that of the agency," but rather "must ensure, among other things, that the agency has offered 'a satisfactory explanation for its action[,] including a rational connection between the facts found and the choice made.'" Ohio, 603 U.S. at 292 (alteration in original) (first quoting Federal

Commc'ns Com. v. Fox Television Stations, Inc., 556 U.S. 502, 513 (2009); and then quoting Motor Vehicle Mfrs. Ass'n of United States, Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983)). Said another way, this Court's review "simply ensures that the agency has acted within a zone of reasonableness and, in particular, has reasonably considered the relevant issues and reasonably explained the decision." Prometheus Radio Project, 592 U.S. at 423.

"Generally, an agency decision 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." " Sierra Club v. United States Dep't of the Interior, 899 F.3d 260, 293 (4th Cir. 2018) (quoting Motor Vehicle Mfrs. Assn. of United States, Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43, 103 S.Ct. 2856, 77 L.Ed.2d 443 (1983)). "Determining whether an agency action is 'reasonable and reasonably explained' is 'measured by what [the agency] did, not by what it might have done." Green & Healthy Home Initiatives, Inc. v. Env't Prot. Agency, No. 25-CV-1096-ABA, 2025 WL 1697463, at \*20 (D. Md. June 17, 2025) SEC v. Chenery Corp., 318 U.S. 80, 93-94 (1943). "And to this end,

conclusory statements will not do; an 'agency's statement must be one of reasoning.'" <a href="Amerijet Int'l, Inc.">Amerijet Int'l, Inc.</a> v. <a href="Pistole">Pistole</a>, 753 F.3d 1343, 1350 (D.C. Cir. 2014) (quoting <a href="Butte Cnty.">Butte Cnty.</a>, Cal. v. <a href="Hogen">Hogen</a>, 613 F.3d 190, 194 (D.C.Cir.2010).

This Court, is "ordinarily limited to evaluating the agency's contemporaneous explanation in light of the existing administrative record." New York, 588 U.S. at 780. In the usual course, this is because "further judicial inquiry into 'executive motivation' represents 'a substantial intrusion' into the workings of another branch of Government and should normally be avoided." Id. at 781 (quoting Arlington Heights v. Metropolitan Hous. Dev. Corp., 429 U.S. 252, 268 n.18 (1977)). Indeed, this Court may neither "reject an agency's stated reasons for acting simply because the agency might also have had other unstated reasons" nor "set aside an agency's policymaking decision solely because it might have been influenced by political considerations or prompted by an Administration's priorities." Id. This general rule recognizes the reality that "[a]gency policymaking is not a 'rarified technocratic process, unaffected by political considerations or the presence of Presidential power.'" Id. (quoting Sierra Club v. Costle, 657 F.2d 298, 408 (D.C. Cir. 1981)). Agency "decisions are routinely informed by unstated considerations of politics, the legislative process, public relations, interest group relations,

foreign relations, and national security concerns (among others)." Id.

All that being said, while the Court's "review is deferential," it is certainly "'not required to exhibit a naiveté from which ordinary citizens are free.'" Dep't of Com. v. New York, 588 U.S. 752, 785 (2019) (quoting United States v. Stanchich, 550 F.2d 1294, 1300 (2nd Cir 1977) (Friendly, J.)).

The Public Officials argue as one of their reasons "[t]he change in democratically accountable leadership with different priorities is not a post hoc rationalization; it is historical fact" and that "[w]ith a new administration comes an appropriate opportunity to assess and reassess the agency's activities."

10787 Action, Defs. Resp. Trial Br. 4, ECF No. 111. True enough, but what the Public Officials fail to appreciate is that they have to work within the confines of the law. That is, a new administration certainly is entitled to make changes -- even unpopular or unwise changes. What it cannot do is undertake actions that are not reasonable and not reasonably explained. This is where the Public Officials miss the mark. Even under this narrow scope of review, the Public Officials' actions as evidence under the Challenged Directives are breathtakingly arbitrary and capricious.

A careful review of the Administrative Record confirms to this Court what Justice Jackson wondered aloud three months ago

(albeit from a different agency allegedly doing similar things): that there is no reasoned decision-making at all with respect to the NIH's "abruptness" in the "robotic rollout" of this grant-termination action. <a href="Department of Education">Department of Education</a> v. <a href="California">California</a>, 145</a> S.Ct. 966, 975-76 (Jackson, J. dissenting); <a href="See also Thakur">see also Thakur</a> v. <a href="Trump">Trump</a>, No. 25-CV-04737-RFL, 2025 WL 1734471, at \*14 (N.D. Cal.)

June 23, 2025) ("The pace of the review and the resulting large waves of terminations via form letters further suggests a likelihood that no APA-compliant individualized review occurred. These are precisely the kinds of concerns that the APA's bar on arbitrary-and-capricious agency decisionmaking was meant to address.").

The Court "cannot ignore the disconnect between the decision made and the explanation given." New York, 588 U.S. at 785. Based upon a fair preponderance of the evidence and on the sparse administrative record, the Court finds and rules that HHS and, in turn NIH, are being force-fed unworkable "policy" supported with sparse pseudo-reasoning, and wholly unsupported statements.

Starting with DEI, the record is completely devoid of a definition. This Court has been transparent on this issue, <u>see American Pub. Health Assn.</u> v. <u>Natl. Institutes of Health</u>, No. CV 25-10787-WGY, 2025 WL 1548611, at \*12 (D. Mass. May 30, 2025),

yet at trial the Public Officials can point only to the identification of DEI, but not the definition of DEI:

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

R. 3226; Tr. 58-59, ECF No. 156 (citing R. 3226). It is not an autological concept. The Court questioned the Public Officials' counsel in closing arguments: "So that's as close to a definition [of DEI] as we've got?", to which the Public Officials' counsel responded: "That is the agency's reasoning."

Id. The Public Officials' counsel's response while unsatisfactory in the sense that one would assume that DEI would be defined somewhere, was accurate and responsive. The Public Officials simply have no definition of DEI.

How, then, can the Public Officials act on "DEI" if there is no operative definition of "DEI"? The answer is plain: they cannot, at least within the confines of the APA. See Firearms

Regul. Accountability Coal., Inc. v. Garland, 112 F.4th 507, 523

<sup>&</sup>lt;sup>14</sup> The Court observes the Public Officials' counsel have been consistent and responsive to this Court on this issue. Id.; see also, May 22, 2025 Hrg Tr. 19-20, ECF No. 82;

(8th Cir. 2024) (rejecting as arbitrary and capricious an agency standard that relies on circular reasoning because it "allow[ed] the ATF to reach any decision is wish[ed] only looking to specific evidence of community misuse [of a weapon] while ignoring any other examples of the community's compliant use"). Reliance on an undefined term of DEI (or any other category) "is arbitrary and capricious because it allows the [Public Officials] to arrive at whatever conclusion it wishes without adequately explaining the standard on which its decision is based." Id. at 525 (cleaned up). Unfortunately, the Public Officials did just that.

The Court need not delve deeply into the rudderless EOs concerning DEI: they do not even attempt to define DEI, but instead set it up as some sort of boogeyman. This lack of clarity was (and is), in the first instance, wholly unfair to the career-HHS and NIH personnel, which must attempt to "align" themselves with the Executive through direction by partisan appointed public officials. Without a definition of DEI, they embarked on a fool's errand resulting in arbitrary and capricious action.

Then-Acting Secretary of Health and Human Services Dr.

Dorothy Fink, picked up the mantle first in the Secretarial

Directive, equating without any stated-basis still-undefined DEI with "initiatives that discriminate on the basis of race, color,

religion, sex, national origin, or another protected characteristic." R. 5 (emphasis added). Further, she claims that "[c]ontracts and grants that support DEI and similar discriminatory programs can violate Federal civil rights law and are inconsistent with the Department's policy of improving the health and well-being of all Americans." Id. (emphasis added)

What wordsmithing! Of course discriminatory programs, or initiatives that discriminate, can violate federal laws, but there is absolutely nothing in the record that demonstrates this is a reasonable statement in the context of DEI -- again undefined -- nor are her statements reasonably explained at all. The statement, respectfully, is utterly meaningless.

On February 13, 2025, the then-NIH Deputy Director of Extramural Research, Dr. Lauer, who provided supposed guidance with respect to still-undefined DEI, using the language of HHS, lumped in "DEI" with "initiatives that discriminate on the basis of race, color, religion, sex, national origin, or another protected characteristic" and advised that if the "sole purpose" of the grants etc. "supports DEI activities" - again undefined - "then the award must be fully restricted." R. 16. Again, this memorandum and the lack of a definition of DEI or what supporting DEI activities reveals a reluctance to engage.

Indeed, though not determinative, Dr. Lauer resigned from a long career in government service the same day he penned the February

13, 2025 memorandum, effective Valentine's Day. Notably, his successor, Ms. Bundesen lasted only 3 weeks after which she too resigned from government service as well. While the Court makes no finding as to Dr. Lauer's or Ms. Bundesen's motivations or reasons for resigning, it is not lost on the Court that oftentimes people vote with their feet.<sup>15</sup>

Next, on February 21, 202k, Dr. Fink's appointee, Acting
Director Matthew Memoli took the reins. This time, there is
evidence that HHS provided him with some circular and
nonsensical boilerplate language that was used almost verbatim
later on in the grant termination letters. That aside, Dr.
Memoli tripled down on the DEI mystery, and added -- in a truly
hold-my-beer-and-watch-this moment -- "gender identity" to the
mix. The similar nonsensical phrasing appears.

Like his boss at HHS, and whoever drafted the Executive

Orders for that matter, Dr. Memoli can certainly identify

"diversity, equity and inclusion (DEI)," but is unable (or

unwilling) to define it. Instead, he follows Dr. Fink's lead,

relegating it to a category "low-value and off-mission research

<sup>15</sup> The lack of any demonstrable pushback on these nonsensical Challenged Directives in the Administrative Record belies the tremendous bureaucratic pressure at play here. It is palpable. While HHS and the NIH bureaucrats are scientists at heart, they are trying to keep their jobs. Scientists cling to reason, not whim -- merit, not loyalty.

programs", including not only DEI, but also undefined gender identity.

Dr. Memoli then goes back in time, attempting to state that even though his "description of NIH's mission is consistent with recent Executive Orders issued by the President," his directive is "based on my expertise and experience; consistent with NIH's own obligation to pursue effective, fiscally prudent research; and pursuant to NIH authorities that exist independently of, and precede, those Executive Orders." See Memoli Directive. While intriguing, the regurgitation of the HHS language belies this separation. Indeed, his description obscures any definition of DEI. The first sentence is untethered to DEI, and is true in the abstract:

"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." <a href="Id.">Id.</a> Simply put, non-scientific research is non-scientific research, and should not be an NIH priority.

Then Dr. Memoli goes on, "Worse, DEI studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans." <a href="Id.">Id.</a>

What does this mean? Apparently, by using the transition "worse," the term "DEI studies" -- again DEI is undefined -- are somehow inherently "artificial and non-scientific." Without citing a single example, Dr. Memoli claims that DEI studies are "often used in support of unlawful discrimination on the basis of race and other protected characteristics," which he connects with harm to the health of Americans. So, is it the DEI studies that are the problem or how others use them? Who knows. There is not a shred of evidence supporting any of these statements in the record.

Dr. Memoli then transitions to "gender identity", the next boogeyman: "Likewise, 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." R. 3821 (emphasis added).

There is not a shred of evidence in the Administrative Record backing this up either. Phrases like "often unscientific" and "many studies ignore" are unsupported with anything other than (apparently) Dr. Memoli's experience. Ironically, these kinds of phrases would never survive peer review.

HHS's and the NIH's implementation of the EOs is based literally upon nothing but an undefined term. Without defining it, DEI becomes whatever DEI means to the Public Officials

untethered to anything. This is not reasoned decision-making, in fact it is just the opposite. It is neither reasonable, nor reasonably explained. Indeed, "the fact that an agency's actions were undertaken to fulfill a presidential directive does not exempt them from arbitrary-and-capricious review." Kingdom v. Trump, No. 1:25-CV-691-RCL, 2025 WL 1568238, at \*10 (D.D.C. June 3, 2025). The HHS and, in turn the NIH's, best possible (but losing) argument is on this record that they were simply following orders of the Administration (or DOGE), but this is an argument that simply falls flat. Id. ("[I]f an agency could avoid the need to justify its decisions simply by gesturing to an Executive Order and claiming that it was just following the President's directions, the President could unilaterally eviscerate the judicial oversight that Congress contemplated in passing the APA simply by issuing a carbon-copy executive order mandating that an agency act in a particular way before it does so."). That is essentially what has been done here. This is evidenced by the lack of any reasoned decisionmaking at all in the Administrative Record. The Public Officials have decided that they are going to "eradicate" something that they cannot define. That agency action is arbitrary and capricious. Pivoting to gender affirming care, vaccine hesitancy, COVID, Climate Change and Influencing Public Opinion, these terms evolve in the Priorities Directive, evidence that the NIH was

trying to figure it out, all the while being tasked with using those same terms to wipe out grants. None of these terms have a reasonable explanation in the record. The Public Officials "must show that there are good reasons for the new policy. . . . that the new policy is permissible under the statute, that there are good reasons for it, and that the agency believes it to be better." F.C.C. v. Fox Television Studios, 556 U.S. 502, 515 (2009). In plain terms, "this means that the agency need not always provide a more detailed justification than what would suffice for a new policy created on a blank slate." Id. It must do more when, as here, "for example, its new policy rests upon factual findings that contradict those which underlay its prior policy; or when its prior policy has engendered serious reliance interests that must be taken into account." Id. The HHS and NIH have not done so here, and with the exception of a scintilla of evidence with respect to potential disruptions of withdrawn NOFOs, there is no evidence that they even considered the reliance interests that naturally inure to NIH grant process. It is "arbitrary or capricious to ignore such matters." Id. Public Officials "fail[] to provide an intelligible explanation," which "amount[] to a failure to engage in reasoned decisionmaking  $\dots$  "Constellation Mystic Power, LLC v. FERC, 45 F.4th 1028, 1057 (D.C. Cir. 2022) (quoting FPL Energy Marcus Hook, L.P. v. FERC, 430 F.3d 441, 448 (D.C. Cir. 2005);

<u>see</u> Thakur, 2025 WL 1734471, at \*15 ("The terminated grants were being used to pay Plaintiffs' and their staff's salaries, and to fund graduate student programs, field research, and community outreach. These facts indicate significant reliance interests that cannot simply be ignored.").

As the Court has already ruled, the Court -- relying on the Certified Administrative Record -- rules that on a fair preponderance of the evidence that the Challenged Directives are arbitrary and capricious under Section 706(2)(A), as are the concomitant grant terminations, which action are all set aside and vacated.

# D. Section 706(2)(A) Claims -- Not in Accordance with Law ('10787 Action Count II; '10814 Action Count II)

The APA claim that agency action is "not in accordance with law" is a subpart of Section 706(2)(A). In reviewing this claim "a reviewing court must uphold an agency's decision if it is:

(1) devoid of legal errors; and (2) "supported by any rational review of the record." New York v. Trump, No. 25-CV-39-JJM-PAS, 2025 WL 715621, at \*9 (D.R.I. Mar. 6, 2025) (quoting Mahoney v. Del Toro, 99 F.4th 25, 34 (1st Cir. 2024)).

The Plaintiffs attack the Public officials claim that 2 C.F.R. § 200.340(a)(4) operates as a trump card and permits termination of and award that "no longer effectuates the programs goals or agencies priorities." Id.

Section 340 is part of OMB's guidance, and that is all that is — nonbinding guidance. See 2 C.F.R. §1.105(b) ("Publication of the OMB guidance in the CFR does not change its nature—it is guidance, not regulation."). That provision falls under the section entitled "Remedies for Noncompliance." Section 200.339 provides "remedies for noncompliance." 2 C.F.R. §

That provision provides in pertinent part:

- (a) The Federal award may be terminated in part or its entirety as follows:
- (1) By the Federal agency or pass-through entity if the recipient or subrecipient fails to comply with the terms and conditions of the Federal award;
- (2) By the Federal agency or pass-through entity with the consent of the recipient or subrecipient, in which case the two parties must agree upon the termination conditions. These conditions include the effective date and, in the case of partial termination, the portion to be terminated;
- (3) By the recipient or subrecipient upon sending the Federal agency or pass-through entity a written notification of the reasons for such termination, the effective date, and, in the case of partial termination, the portion to be terminated. However, if the Federal agency or pass-through entity determines that the remaining portion of the Federal award will not accomplish the purposes for which the Federal award was made, the Federal agency or pass-through entity may terminate the Federal award in its entirety; or
- (4) By the Federal agency or pass-through entity pursuant to the terms and conditions of the Federal award, including, to the extent

# authorized by law, if an award no longer effectuates the program goals or agency priorities.

2 C.F.R. § 200.340(a). That provision requires that an agency "must clearly and unambiguously specify all termination provisions in the terms and conditions of the Federal award."

Id. at § 200.340(b). An agency terminating an award "must provide written notice of termination to the recipient or subrecipient . . [which] should include the reasons for termination, the effective date, and the portion of the Federal award to be terminated, if applicable. 2 C.F.R. § 200.341

Section 200.340 is an OMB Regulation that provides only guidance to all agencies, and is not binding. See 2 C.F.R. §1.105(b)

("Publication of the OMB guidance in the CFR does not change its nature — it is guidance, not regulation.")

As an initial matter, HHS's adoption of the regulation is not effective until October 2025; accordingly, the regulation is wholly inapplicable here. See Health and Human Services

Adoption of the Uniform Administrative Requirements, Cost

Principles, and Audit Requirements for Federal Awards, 89 FR

80055-01 ("HHS will adopt all of the rest of 2 CFR part 200 with an effective date of October 1, 2025."). Instead, a different statue, 45 C.F.R. § 75.372(a) (2024) allows for unilateral termination only where there is a failure "to comply with the terms and conditions of the award" or "for cause." 45 C.F.R. §

75.372(a)(1) (2024). Plaintiffs argue that "the plain language of the regulation mandates that these are the exclusive conditions under which HHS and its sub-agencies may terminate a grant." ECF 103 28 (citing Pol'y & Rsch., LLC v. United States Dep't of Health & Human Servs., 313 F. Supp. 3d 62, 76 (D.D.C. 2018); Healthy Teen Network v. Azar, 322 F. Supp. 3d 647, 651 (D. Md. 2018). That in and of itself demonstrates legal error. Simply put, the Public Officials cannot rely on a regulation that does not yet apply to their respective agencies in their template.

But even if it applied, under the cited regulation, an agency can terminate an award "pursuant to the terms and conditions of the Federal award, including, to the extent authorized by law, if an award no longer effectuates the program goals or agency priorities." 2 C.F.R. § 200.340 (emphasis added). This is a distinction with a difference, because ""this regulation cannot authorize actions that contravene statutory requirements, nor does it relieve [the Public Officials] of [their] duty to follow the law." Pacito v. Trump, No. 2:25-CV-255-JNW, --- F.Supp. 3d ----, ----, 2025 WL 893530, at \*9 (W.D. Wash. Mar. 24, 2025) (quoting 2 C.F.R. § 200.340(a)(4)).

The Public Officials counter that the regulation has been incorporated into the terms and conditions of the grantees' awards. Even if the regulation applied as a contractual term,

whether the "award no longer effectuates the programs goals or agency priorities" can still be challenged under the APA where the underlying reasons violate the APA. See Thakur v. Trump, No. 25-CV-04737-RFL, 2025 WL 1734471, at \*14 (N.D. Cal. June 23, 2025) ("2 C.F.R. § 200.340, to the extent it applies, does not alter the requirement under the APA that Defendants must provide a reasoned decision for their termination."); American Ass'n of Colls. for Tchr. Educ. v. McMahon, 770 F. Supp. 3d 822, 851 (D. Md. 2025 (ruling that even if termination letters invoked a valid reason to terminate under 2 C.F.R. § 200.340, APA claims survived because the letters "fail[ed] to provide [the plaintiffs] any workable, sensible, or meaningful reason or basis for the termination of their awards"). Reliance on these inapplicable regulation as basis for template letter terminations in conjunction with meaningless descriptions is contrary to law under Section 706(2)(A) of the APA.

# E. Section 706(2)(C) Claims -- In excess of Statutory Authority ('10787 Action Count III; '10814 Action Count I)

An APA action brought under Section 706(2)(C), challenges agency action "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." Id. The "[C]ourt[] must exercise [its] independent judgment in deciding whether an agency has acted within its statutory authority." Loper Bright, 603 U.S. at 412. "[T]he [C]ourt fulfills [its]

role by recognizing constitutional delegations, 'fix[ing] the boundaries of [the] delegated authority. . .and ensuring the agency has engaged in '"reasoned decisionmaking"' within those boundaries." <u>Id.</u> at 395 (citation omitted) (first quoting Henry P. Monaghan, <u>Marbury and the Administrative State</u>, 83 Colum. L. Rev. 1, 27 (1983); and then quoting Michigan, 576 U.S. at 750).

The Plaintiffs identify a litany of statutes that they claim violate Congress's mandate to the Public Officials to conduct research various areas such as women's health, gender identity, COVID, vaccination. See DEI: 42 U.S.C. §§ 282(b)(4); 282(b)(8)(D)(ii), 282(h), 2830(b)(2), 285a-6; 285b-7a(c)(1), 285t(a), 285t(f)(1)(D); gender identity: 42 U.S.C. §283(p); COVID-19: 42 U.S.C. §285f-5(a); vaccine hesitancy: 42 U.S.C. §283d. They also contend the DEI provision conflicts with Congress's mandate to embrace diversity. See 42 U.S.C. §\$ 282(h), 287d(e), 2830(b)(2), 285(t)(a), 288(a)(4), 285t-1(a), (b). To be sure the ill-defined categories certainly can be read to overlap these statutes. Inasmuch as the Court has declared the Public Officials' actions arbitrary and capricious and set them aside on that ground, it need not dive into the contours of the statutory overlap.

As for the Strategic Plan, as the Public Officials correctly argue, they have, in fact, complied with that statute. The Strategic Plan is evidence of how the NIH typically

proceeds, giving guidance and providing researchers with predictability on which to generally rely. The Court rules that the Challenged Directives do not contravene the statutory requirement under 42 U.S.C. § 282(m) of a Strategic Plan, under Section 706(2)(A), or Section 706(2)(C). At the same time, the Strategic Plan demonstrates that more than a sentence or two is necessary to change priorities that wipe out categories of research.

### V. CONCLUSION

Every Administration has political priorities and enjoys the ability to make policy changes. But the agencies that implement those changes have to have a reasoned and reasonable explanation for doing so. The Public Officials are not prohibited from blacklisting a handful of categories of research. They must, however, comply with Congress's mandate as to research and other priorities, and even where the Public Officials have discretion, they must provide a reasoned and reasonable explanation. The Public Officials in their haste to appease the Executive, simply moved too fast and broke things, including the law. As previously ordered, partial separate and final judgments have entered in favor of the Plaintiffs in the '10787 Action, ECF No. 138, and in the '10814 Action, ECF No. 151. This Court was careful to limit the relief, as it must, only to the parties before it. See CASA, Inc., No. 24A884, 2025

WL 1773631, at \*15 (U.S. June 27, 2025) ("When a court concludes that the Executive Branch has acted unlawfully, the answer is not for the court to exceed its power too.")

SO ORDERED.

/s/ William G. Young
WILLIAM G. YOUNG
JUDGE
of the
UNITED STATES16

<sup>16</sup> This is how my predecessor, Peleg Sprague (D. Mass. 1841-1865), would sign official documents. Now that I'm a Senior District Judge I adopt this format in honor of all the judicial colleagues, state and federal, with whom I have had the privilege to serve over the past 47 years.