### APPENDIX

Appendix A: Department of Health & Human Services, "Secretarial Directive on DEI-Related Funding" (February 10, 2025)
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Appendix A





#### 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

Appendix B

#### **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

<sup>&</sup>lt;sup>1</sup> To be clear, these citations are illustrative, not exhaustive. Further explanation of the range of statutory and regulatory authorities that support actions taken pursuant to this Directive will be issued as appropriate.

Appendix C

# 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
  grant file.
- 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.



#### **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

#### Appendix 2 – Guidance for staff to use when terminating awards identified by HHS or the IC.

- Issue a revised NOA.
  - Change the budget and project period end dates to match the date of the termination letter.
  - Check PMS, determine amount of funds remaining, and deobligate the amount reflected in PMS when revising the NOA. Note: This applies to Multi-Year Funded Awards, as well.
     Work with FFR-C if you have questions regarding deobligating funds to avoid placing the recipient in debt collection.
  - Remove all future years from the project, where applicable. If the grant is in a no cost extension, and the HHS requests a termination, the project must be terminated
  - Use the following termination term: This award related to [select the appropriate example relevant to your project by choosing one of the highlighted examples DEI, China, or Transgender issues] no longer effectuates agency priorities. It is the policy of NIH not to further prioritize these research programs. Therefore, the award is terminated. [Refer to Appendix 3 for language provided to NIH by HHS.] 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)) within 120 days of the end of this grant to avoid unilateral closeout.
  - Insert restriction language that allows for the recipients to use a portion of funds to support the health and safety of patients and orderly closeout of the project.
    - Sample language for use: "Funds in the amount of \$xxxxxxx [insert \$ amount total cost] may be used to support patient safety and orderly closeout of the project. Funds used to support any other research activities will be disallowed and recovered."
- Appeals language must be used (prior to October 1, 2025):
  - NIH is taking this enforcement action in accordance with <u>2 C.F.R. § 200.340</u> as implemented in <u>NIH GPS Section 8.5.2</u>. This letter 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 postmarked no later than 30 days after the postmarked date of this notice.
- Termination actions taken based on agency priorities do not require appeals language because the action was not based on administrative nor programmatic noncompliance

## 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.

Appendix D

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

To: Chief GMOs

Cc: <u>Bulls, Michelle (NIH/OD) [E]</u>; <u>Ta, Kristin (NIH/OD) [E]</u>

**Subject:** Award Revision Guidance and List of Terminated Grants via letter on 3/12

Date:Thursday, March 13, 2025 4:03:00 PMAttachments:Termination Categories 3.13.25.docx

Terminated Grants 3-12 no subprojects.xlsx

#### Chiefs,

Attached are two items: 1) updated categories for you to use when issuing NOAs to officially terminate the awards where letters were issued, and 2) the list of termination letters that were issued yesterday. Please revise your NOAs related to the attached list by next **Wednesday**, **March 13**, **2025**, **cob**. It is extremely important that issue the revised awards timely. If there are delays, please let me know and we can try to help somehow/some way. I appreciate you all.

<u>Please save this guidance</u> until we can clear the updated staff guidance, and you will need this to issue revised awards. Note: If your IC is not listed on the attached spreadsheet – no action is required, at this time.

**Guidance** for IC staff to use when terminating awards identified by HHS or the IC due to DEI or other agency priorities.

- Issue a revised NOA.
  - 1. Change the budget and project period end dates to match the date of the termination letter.
  - 2. OPERA will place a hard funds restriction on all documents within the excel spreadsheet. Do not deobigate any funds when you issue the revised award to terminate the projects. If there are no animals and humans, FFR-C will deobligate the awards after the Final FFRs are submitted. No deoblgiation actions required from the ICs.
  - 3. 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.
  - 4. Termination Term to be used <u>DELETE THE OLD TERM RELATED TO DOLLAR AMOUNTS</u>
    <u>FOR HARD FUNDS RESTRICTIONS IT IS NO LONGER APPLICABLE</u>.

It is the policy of NIH not to prioritize [insert termination category language]. 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.

Thanks, Michelle

#### **Termination Categories**

- 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.
- Gender: Research programs based on gender identity are often unscientific, have little
  identifiable return on investment, and do nothing to enhance the health of many
  Americans. Many such studies ignore, rather than seriously examine, biological realities. It is
  the policy of NIH not to prioritize these research programs.
- Vaccine Hesitancy: It is the policy of NIH not to prioritize research activities that focuses gaining
  scientific knowledge on why individuals are hesitant to be vaccinated and/or explore ways to
  improve vaccine interest and commitment. NIH is obligated to carefully steward grant awards to
  ensure taxpayer dollars are used in ways that benefit the American people and improve their
  quality of life. Your project does not satisfy these criteria.

Appendix E

NIH Grants Management Staff Guidance – Award Assessments for Alignment with Agency Priorities – DRAFT

Final Issue Date: Pending NIH Director's updated priorities

#### **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). This guidance seeks to expand the scope of the categories within to include other agency priorities that will be defined by the Director, NIH. The Director will issue a guide notice to publicize the agency's updated priorities in an effort to be transparent as research priorities shift.

#### **NOFO Guidance**

NIH is required to submit forecast reports to HHS prior to issuing new or reissued Notices of Funding Opportunities (NOFO's) within the NIH Guide for Grants and Contracts and Grants.gov. See Appendix 5 for the workflow.

#### **Award Guidance**

Prior to issuing all awards (competing and non-competing, monetary and non-monetary (e.g., carryover requests, no-cost extensions, etc.)), ICO's must review the specific aims/major goals of the project to assess whether the proposed project contains any DEI and/or other research activities that are not an NIH/HHS priority/authority. To avoid issuing awards, in error, that support these activities ICO's must take care to completely excise all non-priority activities using the following categories.

ICO's should review the current application/RPPR under consideration, only. ICO's should not request retroactive changes to previous RPPRs and competitive applications to modify language related to research that has already been conducted.

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, etc. after the priorities memo is issued), 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. Whether the NOFO was unpublished or expired naturally, if the sole purpose was DEI or another category that does not effectuate the NIH/HHS priorities, ICO's cannot make the award.

This applies to all projects, including phased awards, etc. Reminder: CGMOs requested access to the NOFO list, and NIH leadership provided the following interim process: CGMOs must consult with their Division of Extramural Activities (DEA) rep to obtain up to date information on NOFOs.

- Action: ICO's must not issue the award (competing or non-competing).
- 1 DRAFT NIH GM Staff Guidance Award Assessments for Alignment with Agency Priorities

- For ongoing projects where NIH will not issue the next Type 5 (ICO determination not HHS list), the ICO must:
  - Issue a revised award to end the award at the end of the current budget period and remove all outyears. A termination letter is not required.
  - Add the action to the master spreadsheet located at: <u>OD OPERA Grant Action</u>
     <u>Tracking</u> (Access limited to CGMOs. CGMOs may email OPERA leadership to
     identify a delegate, if needed).
  - o Include the following term in the revised NOA:

#### Term of Award:

Effective with this Notice of Award, this project is terminated. [Insert appropriate category from Appendix 3, verbatim]. Therefore, no additional funding will be awarded for this project, and all future years have been removed. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare to support an orderly phaseout of the project.

Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination (with proof of the date), or costs for patient safety or animal welfare, in support of an orderly phaseout 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 phaseout 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 60 days (non-human subjects and animals) 120 days (human subjects and animals) after the end of this project.

This action aligns with <u>Termination - 2 C.F.R. § 200.340 (a)(4)</u>. This is a final determination. If you wish to seek a reconsideration because you object to the ICO's termination, please submit a reconsideration request to [IC Director Name], Director, [IC Name].

- In this instance, there is no hard funds restriction required. The recipient will submit their Final FFR in accordance with the term and conditions, and any remaining funding will be deobligated by the FFR-C upon review and acceptance of the FFR.
- NOTE: OPERA recognizes that the closeout letters will be automatically sent, so we are
  working internally with the closeout support center staff to manage this process. If you
  receive inquiries, please point the inquirer to: OPERALeadership@nih.gov
- No cost extension requests: For all NCE requests, ICO's must determine if the sole purpose of the grant was to support research activities that are no longer an NIH/HHS
- 2 DRAFT NIH GM Staff Guidance Award Assessments for Alignment with Agency Priorities

priority/authority and, if so, issue an award to immediately 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, ICO staff must still determine if non-NIH/HHS priority/authority activities are proposed during the extension period. Extensions may only be approved for orderly phaseout, and funds may not be used to support any non-NIH/HHS priority/authority research activities.

- ICO's 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 an orderly phaseout of the project, no other reasons are allowed. NIH grants funds must not be used to support [insert category e.g., Diversity, Equity and Inclusion (DEI), COVID 19, 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 phaseout 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 (see Action 2) 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 <u>NIH inclusion policies</u> are not considered DEI activities.
- Action 1: Funding ICO 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.
  - After an informal conversation, the ICO must send a written request to the AOR outlining what portion of the aims and budget must be modified to document the renegotiation process:
    - 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, or other non-HHS/NIH
      priorities, or countries of concern]. [Funding IC] has identified [insert
      appropriate activity taken from the list above] activities within section

3

[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.

- Once the recipient responds and the ICO and the recipient agree to the changes, the ICO must direct the AOR to submit a revised face page, specific aims and budget via the prior approval module 'Other Request' type. See <u>eRA online help</u> for instructions.
- Once the ICO renegotiates the revised specific aims, the ICO must upload into the Additions for GM section of the grant folder the new aims. These must be uploaded under the file group "Award Documents: Revised Aims and Abstract".
- If the ICO renegotiates a revised budget, the ICO should update the GM workbook, as appropriate.
- Action 2: Once the ICO and the applicant/recipient have reached an agreement, and updated documents are received and properly filed as outlined above, 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, vaccine hesitancy, climate change, 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.

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O Unable to remove activities that are not an NIH/HHS priority: If the ICO and the applicant/recipient cannot reach an agreement, or the project is no longer viable without the non-compliant activities, the ICO cannot proceed with the award. For ongoing projects, the ICO must notify OPERA (OPERAleadership@nih.gov) and negotiate a bilateral termination of the project. For bilateral terminations, the ICO must Issue a revised award to remove all outyears and include the following term in Section IV of the NOA.

NIH is bilaterally terminating this award effective [effective date] in accordance with the request dated [date], because the project does not align with NIH priorities. No additional funding will be awarded for this project, and all future years have been removed. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare to support an orderly phaseout of the project.

Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination (with proof of the date), or costs for patient safety or animal welfare, in support of an orderly phaseout 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 phaseout 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 60 days (non-human subjects and animals) 120 days (human subjects and animals) after the end of this project.

Where bilateral termination cannot be reached, the ICO must unilaterally terminate the project. Unilaterally terminated awards should follow the process identified **Termination Type 3: ICO-Terminations** to send the termination letter and revise the award.

Diversity Supplements: Type 5 Diversity supplements may no longer be awarded. For ongoing awards, ICO's must remove the diversity supplement activities prior to issuing the next Type 5 for the parent award and include the following term in Section IV of the NOA of the parent grant. The ICO must revise the Diversity Supplement award to remove all outyears. If diversity supplement outyears were included in the previous NOA, the ICO must revise the prior year award to remove references to those outyear commitments.

**Term of Award:** The diversity supplement associate with this project, [insert diversity supplement grant number], is being terminated. No additional funding will be awarded, and all future years have been removed. Research programs

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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 classes, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Funds issued for the Diversity Supplement may no longer be utilized and cannot be rebudgeted nor carried over to future years.

- Conference Grants: If a conference supported by an NIH grant focuses on scientific top ICO's that are unrelated to DEI, but the conference itself is targeted at a specific population (e.g., underrepresented groups), the ICO 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 ICO must terminate the award following the process in Category 1.
- 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 ICO's 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. ICO's 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. ICO's 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 and/or 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, ICO should consider using the Category 2 term of award but remove the negotiation language from the term. ICO's do not need to request revised materials from the recipients. However, the project title and/or abstract may need to be updated to remove any language that does not align with NIH/HHS priorities/authority. The changes must be noted in the grant file. Reminder: ICOs do not need to modify the historical record to modify language.

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- Resource Section
- Biosketch
- RPPRs
- Letters of Support

#### Category 2C: Subprojects/cores terminated by HHS.

ICO's do not need to terminate the subprojects/cores. The funds can be restricted and recovered, unless there is a negotiation where a new subproject/core is identified that does not violate the priorities of the agency. The following actions will occur in these cases:

- OPERA will restrict the funds associated with the project and notify the ICO.
- The ICO must revise the award to remove the subproject/core, only and must not issue a termination letter nor termination language within the terms and conditions. ICO
- The revised award must include the following term in Section IV.

[Insert category from Appendix 3, verbatim]. Therefore, no additional funds may be used to support the activities under [insert subproject or core title], and all activities must cease, effective with the date of this revision. Funds used to support these activities will be disallowed and recovered. Funds issued for this subproject/core may no longer be utilized and cannot be rebudgeted nor carried over to future years.

## Category 3: Project does not support any DEI or other activities that go against the HHS/NIH priorities.

Action: ICO may proceed with issuing the award.

#### Category 4: Foreign Awards.

Note: Effective May 1, and until the details of the new foreign collaboration award structure are released, NIH will not issue awards to domestic or foreign entities (new, renewal or non-competing continuation), that include a subaward to a foreign entity. See NOT-OD-25-104.

#### 4A. Agency priorities:

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- South Africa: Note: Currently (April/May 2025), continue to hold award actions related to entities in South Africa until final determinations are made by NIH leadership. This applies to both monetary and non-monetary award actions. ICOs may negotiate with recipients to remove activities in South Africa from ongoing awards as long as the project remains viable. IMPORTANT NOTE: Funds may only be provided to entities in South Africa to support health and safety of human participants in clinical trials/clinical research.
- China: Note: Currently (April/May 2025), hold on making awards to entities in China until the final determinations are made by NIH leadership. This applies to both monetary and non-monetary award actions. IMPORTANT NOTE: ICOs may negotiate with recipients to remove activities in China from ongoing awards as

long as the project remains viable, or a suitable domestic replacement is identified. Funds may only be provided to entities in China to support health and safety of human participants in clinical trials.

#### 4B. Countries of Concern:

- The State Department's countries of concern lists are updated regularly. Therefore, ICOs must check the list annually prior to making new, renewal, and noncompeting continuation awards. Additionally, out of an abundance of caution related to the United States national security threats, if a country is added to either of the two lists below, ICO's must submit a request through FACTs to obtain State Department clearance. If clearance is not received within 14 days, the award cannot be made until it is received (i.e., new, renewal, and noncompeting continuations).
- At this time, ICO's should note in FACTs when awards (new, renewal, non-competing continuation) involve entities on the following State Department lists:
  - Countries in which the government of has engaged in or tolerated "particularly severe violations of religious freedom": <u>State Department</u> <u>Countries of Particular Concern</u>
  - Countries determined by the Secretary of State to have repeatedly provided support for acts of international terrorism: <u>State Sponsors of</u> Terrorism
- Awards may only be issued once State Department clearance is obtained. Do not assume approval unless a response is received from the State Department. The staff guidance on FACTS clearance will be updated to reflect this change. This applies to all direct foreign awards and foreign collaborations (monetary and non-monetary).

OPERA has not included the <u>Final Rule Restricting Transfer of Personal U.S. Data to Countries of Concern</u> (please consider this list related to sensitive or PII data is involved for clinical trials/clinical research) or <u>Office of Foreign Assets Control Sanctions List</u>, as these are not factors in award decisions. In all cases, if there are questions contact the Fogarty International Center for expert assistance.

#### **Termination Types:**

As NIH implements the Director's agency's priorities, NIH will take various measures to integrate these priorities into the Institutes and Centers across the enterprise there are various types of terminations that may take place where the project cannot be renegotiated. As such, there steps that must be taken once the need for termination has been identified and/or provided.

Terminations that result from science that no longer effectuates NIH's priorities related to DEI, gender identity and other scientific areas do not require a formal appeals process. If a recipient requests an ICO to reconsider a termination action, the ICO can work with the recipient to determine whether the action will stand. All other terminations for noncompliance require the agency to include appeals language within the termination letter and NOA - appeal language.

#### Type 1: 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 ICO 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 ICO 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 ICO's.
    - 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:

This award is terminated effective [effective date]. [Insert category from Appendix 3, verbatim]. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare in support of an orderly phaseout of the project.

Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination, or costs for patient safety or animal welfare, in support of an orderly phaseout 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 phaseout 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 60 days (non-human subjects) 120 days (human subjects and animals) after the end of this project.

NIH is taking this action in accordance with <u>2 C.F.R. § 200.340</u> as implemented in <u>NIH GPS Section 8.5.2</u>. 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 <u>prior to</u> October 1, 2025. After October 1, 2025, when HHS will fully adopt 2 CFR 200, per <u>2 CFR 200.340</u>, termination actions taken based on agency priorities are not appealable. This is different from terminations based on noncompliance (administrative and programmatic).
- eRA provides OPERA with daily reports on NOAs issued, so ICO's do not need to report to OPERA on each action completed.
- When a terminated award must be reinstated, OPERA will notify the IC.
- ICOs must issue a revised award and replace the previous termination language with the following term:
  - Effective with the date of this revised Notice of Award, funding for Project Number [insert grant number] is hereby fully reinstated; therefore, the termination letter dated [insert date] is rescinded without conditions. Funds made available to [insert institution name] used to support [insert the title of the project] are no longer restricted and are available for use in accordance with the terms and conditions of the award.
  - OPERA will coordinate with HHS PMS to lift the hard funds restriction and will copy Alan Whatley on the request to the ICO.

Screenshot: Example of reinstatement. **Note – please make it clear that previous termination term has been deleted or is no longer applicable.** 

#### **Directed Terminations.**

- The Immediate Office of the NIH Director evaluates a program and determines that a program must be terminated due to agency priorities (e.g., COMPASS, FIRST). OPERA receives a list from OD. In such cases, this determination could impact multiple projects and each individual project under the program must be addressed.
- 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 ICO 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 ICO's.
    - 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
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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:

This award is terminated effective [insert effective date]. [Insert category from Appendix 3, verbatim]. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare in support of an orderly phaseout of the project.

Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination, or costs for patient safety or animal welfare, in support of an orderly phaseout 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 phaseout 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 60 days (nonhuman subjects and animals) 120 days (human subjects and animals) after the end of this project.

This is a final determination. If you wish to seek a reconsideration because you object to the ICO's termination, please submit a reconsideration request to [IC Director Name], Director, [IC Name].

- When a terminated award must be reinstated, OPERA will notify the ICO.
- Once alerted, ICO's must issue a revised award and replace the previous termination language with the following term:
  - Effective with the date of this revised Notice of Award, funding for Project Number [insert grant number] is hereby fully reinstated; therefore, the termination letter dated [insert date] is rescinded without conditions. Funds made available to [insert institution name] used to support [insert the title of the project] are no longer restricted and are available for use in accordance with the terms and conditions of the award.
  - OPERA will coordinate with HHS PMS to lift the hard funds restriction.

**Tracking Note:** eRA provides OPERA with daily reports on NOAs issued, so ICO's do not need to report to OPERA on each action completed.

#### Type 3: ICO- Terminations.

- ICO conducts a portfolio analysis and determines that a project no longer effectuates the agencies priorities.
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- Project cannot be renegotiated. The ICO must a letter to the recipient notifying them that the project will be terminated (see Appendix 8 for sample letter).
  - 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.
      - The <u>ICO's</u> 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 ICO's.
    - Remove all future years from the project, where applicable.
    - Include the following Termination Term in the revised NOA:

This award is terminated effective [insert effective date]. [Insert category from Appendix 3, verbatim]. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare in support of an orderly phaseout of the project.

Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination, or costs for patient safety or animal welfare, in support of an orderly phaseout 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 phaseout 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 60 days (non-human subjects and animals) 120 days (human subjects and animals) after the end of this project.

This is a final determination. If you wish to seek a reconsideration because you object to the ICO's termination, please submit a reconsideration request to [IC Director Name], Director, [IC Name].

#### Type 4: Bilateral Terminations.

The recipient and the ICO agree that the project is no longer viable, and the project cannot be saved upon the removal of the research that no longer aligns with agency's priorities. As such the ICO must:

- Request a bilateral termination letter from the recipient agreeing to terminate the project on the basis that the project is no longer viable with the aims that need to be negotiated out of the project.
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- Issue a letter responding to the recipient's request notifying them that the ICO
  has accepted the bilateral termination and will issue a revised award to modify
  the project period end date to the date requested.
- ICO must issue a NOA to the recipient.
  - Change the budget and project period end dates to match the date of the termination letter.
    - The <u>ICO</u> 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 ICO's.
  - 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:

NIH is bilaterally terminating this award effective [effective date] in accordance with the request dated [date], because the project does not align with NIH priorities. No additional funding will be awarded for this project, and all future years have been removed. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare to support an orderly phaseout of the project.

Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination, or costs for patient safety or animal welfare, in support of an orderly phaseout 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 phaseout 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 60 days (non-human subjects and animals) 120 days (human subjects and animals) after the end of this project.

#### **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 Teams.

#### Impacts on the Biomedical Workforce:

NRSA Payback: NIH recognizes that award terminations may prematurely end the training period
for NRSA fellows and trainees. Fellows and trainees may not have received sufficient training to
be qualified to perform the service requirement before the grant terminated or may be unable
to find employment opportunities due to the termination. NIH will accept payback waiver
requests from trainees and fellows impacted by terminations. See NIH GPS 11.4.3.4 for
instructions on submitting waiver requests.

#### - Early-Stage Investigators (ESI):

- Short Term Extension for ESI investigators: NIH will automatically extend the Early-Stage Investigator (ESI) eligibility period by four (4) months for all investigators whose ESI status was active during the period January 1, 2025, to May 31, 2025. NIH is implementing this short-term extension to assist ESI investigators who are working under strict eligibility timelines to remain competitive for NIH support. Updated ESI end dates will appear in eRA commons by June 1, 2025.
- o **Restoring ESI status:** Investigators lose their <u>ESI eligibility</u> when they successfully compete for and receive a substantial independent research award. In the event an investigator's first substantial independent research award is terminated within the first three years of the project period, the investigator can request the reinstatement of ESI status, using the ESI Extensions request tool in eRA commons. To be eligible, an investigator's grant may not have been terminated due to misconduct or ethical violations. See Requesting an Extension for instructions.
- K award eligibility: NIH has implemented a temporary exception to the NIH GPS Section 12.3.7, which generally limits eligibility for mentored career development (K) awards to those who have not previously been the recipient of such awards. NIH will allow individuals whose NIH-funded mentored career development awards were ended on or after January 1, 2025, to be eligible to apply for a new mentored career development award, contingent upon all other eligibility requirements being met. Investigators that meet all other NIH eligibility requirements for other mentored career awards may take advantage of applying for such awards to allow for the completion of the years that were remaining at the time the award ended.

#### Definition(s):

Gender-affirming care: An array of services that may include medical, surgical, mental health, and non-medical services for transgender and nonbinary people. This includes, but is not limited to, therapy; mental health care; assistance with elements of a social transition (e.g., new name and pronouns, modification of clothing, voice training); evaluation of persistency of gender dysphoria, emotional and cognitive maturity, and coexisting psychological, medical, or social problems; puberty-suppressing medications; hormone therapy; and surgery. By way of clarification and not limitation, "gender-affirming care" includes patient care provided as part of research or education grants, including but not limited to routine services, ancillary services, outpatient services, inpatient services, and usual patient care received during the study.

**Health Disparities: Pending.** 



#### Appendix 1 – HHS's Secretarial Directive on DEI-Related Funding – February 10, 2025.



#### 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.

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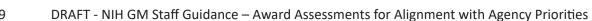
This Directive shall be implemented through the Department's contracts and payment management systems by personnel with responsibility for such systems who shall, in doing so, comply with all notice and procedural requirements in each affected award, agreement, or other instrument. Whenever a DEI or 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

#### Appendix 2 – Guidance for staff to use on specific programs, awards, supplements.

- 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.
- Linked (or equivalent) Awards: If one linked award is terminated, the ICO is only required to terminate the specific award noted in the letter. The is should review and determine whether terminating that ward will have a structural impact on the scientific outcome originally intended by the ICO and act as appropriate on the remaining awards.
- o **Diversity Tables** Ignore and issue the grant using the term provided above.
- o **Diversity Plans** Ignore and issue the award using the term provided above.



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."

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

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

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

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

Cc: Bulls, Michelle G. (NIH/OD) [E]; Lankford, David (NIH/OD) [E]; Butler, Benjamin (NIH/OD) [E]; Jacobs, Anna

(NIH/OD) [E]; Burklow, John (NIH/OD) [E]

Subject: Re: Clean Version of DEI Restriction Term - Final Date: Friday, February 28, 2025 2:54:19 PM

approved

Matt

#### Get Outlook for iOS

From: Bundesen, Liza (NIH/OD) [E] < lbundese@mail.nih.gov>

Sent: Friday, February 28, 2025 2:53:21 PM

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

Cc: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>; Lankford, David (NIH/OD) [E]

<lankford@od31tm1.od.nih.gov>; Butler, Benjamin (NIH/OD) [E] <butlerben@mail.nih.gov>; Jacobs,
Anna (NIH/OD) [E] <anna.jacobs2@nih.gov>; Burklow, John (NIH/OD) [E] <butlerben@mail.nih.gov>

Subject: Clean Version of DEI Restriction Term - Final

Hi Matt,

Attached is the term and condition of award for your approval. Please let us know if you approve and we will implement.

Thank you,

Liza

## Appendix 5 - Workflow for NOFO Forecasts and NOFO Approvals

#### • Prioritization of NOFOs

Owner	Action	
ICO	Sends a priority list of upcoming NOFOs in two categories:	
	1) those that already have Concept Clearance (Option A) <sup>1</sup> .	
	2) those requiring Concept Clearance (Option B).	
	Note: This is a temporary step while process is being refined.	
Guide	Maintains the data on ICO records, approvals needed (for example concept	
	clearance), and priorities for publication in ICO Guide priorities spreadsheet.	

#### • Creation of Forecast Records

Owner	Action
ICO	<ul> <li>Creates a forecast in FOAM for NOFOs prior to concept clearance and at least 6 months prior to the desired NOFO publication date. Forecast is used for approval of the concept by NIH and HHS. Note: Forecast information will become publicly available in Grants.gov after concept clearance is obtained.         <ul> <li>Create a Forecast record.</li> <li>Fill in required fields (red asterisks): NOFO type (PAR, PA, etc.), Title, Contact.</li> <li>Click "Save".</li> <li>Click "Create NOITP" button within the NOFO record.</li> <li>Select most recent Forecast Template.</li> <li>Click "Save".</li> <li>Go to Content and fill in required fields (red asterisks).</li> <li>Title, estimated date, related information (publication, first application, first awards, project start), eligibility – note, activity code not required.</li> <li>Note: the forecast Description section is what NIH Leadership will be reviewing and requires the appropriate ICO leadership approval.</li> <li>Save record and notify the Guide when the forecast is ready for leadership approval (see below).</li> </ul> </li> <li>Sends email to the Guide mailbox when ready for leadership approval</li> <li>NIH Guide (NIH/OD) ninguide@OD.NIH.GOV</li> <li>Subject: NOITP ###-##-##-##-[IC Name] – [Desired Clearance Date]         <ul> <li>Note: the number is important because of the variety of draft versions in FOAM.</li> <li>Plan to implement FOAM task in future to remove dependence on email.</li> </ul> </li> </ul>

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<sup>&</sup>lt;sup>1</sup> For programmatic concepts that have already undergone concept clearance within the last five years, but the NOFO has not been published (for example, NOFO pending in FOAM or not yet drafted).

## Preparing Forecasts for Leadership Approvals

Owner	Action
Guide	Indicates that the forecast is ready for review on the tracking spreadsheet (if not
	done through FOAM task).
Leadership	Places relevant fields on a leadership approval spreadsheet and the Acting DDER is
Approval	alerted when entries are ready for review.
Contact	

## (Acting) DDER and NIH Director Approvals

Owner	Action
(Acting)	Reviews entries on leadership review spreadsheet and updates with approval
DDER	outcome.
	Notifies ICOs regarding the forecasts that are <b>not approved.</b>
Leadership	Monitors the review spreadsheet and adds entries and dates on tracking
Approval	spreadsheet
Contact	Notifies ICOs of approvals and indicates next steps.
ICO	Archives the FOAM entries for those not approved.
	Uploads the approval document into FOAM.

# • HHS Approval & Concept Clearance (if needed)

Option A: After NIH Approval for NOFOs not requiring Concept Clearance

Owner	Action		
Guide • Sets NOITP status to "published" in FOAM once the content has been fu			
	Notifies <b>OPERA</b> of the status via email.		
OPERA	Sends Forecast report to HHS <sup>2</sup> .		
	Records forecasting information in Grants.gov (forecast is publicly available at		
	Grants.gov, but not NIH Guide).		
ICO	Works on NOFO development:		
	<ul> <li>Convert to the newest template in FOAM.</li> </ul>		
	<ul> <li>Ensure that the NOFO record indicates in Key Attributes that Concept</li> </ul>		
	Clearance has been obtained.		
	<ul> <li>Check that the approval document(s) has been uploaded in FOAM.</li> </ul>		
	<ul> <li>For NOFOs in various stages of development, follow the standard processes</li> </ul>		
	for content <u>development</u> and <u>approvals</u> .		
	<ul> <li>For NOFOs with previous OER approvals, ICO should upload a "compare</li> </ul>		
	documents" of the NOFO drafts into FOAM to verify that the ICO did not		
	change any text except to align with current agency priorities. <b>Note:</b> FOAM		
	has a compare documents feature.		

<sup>&</sup>lt;sup>2</sup> Until the Grants.gov Forecast functionality has been deployed in FOAM, OPERA will assist with manual updates of all of NIH's NOFOs to Grants.gov monthly (by the 5<sup>th</sup> of each month—if the 5<sup>th</sup> falls on a holiday or weekend, we will act by the next business day).

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0	Responds to all approval comments and tasks and indicates that the final
	NOFO draft is ready for NIH leadership approval.

#### Option B: After NIH Approval for NOFOs requiring Concept Clearance

Owner	Action		
ICO	After receiving NIH leadership approval, proceed with obtaining Concept Clearance.		
	Enters the Concept Clearance information in the Key Attributes of the FOAM record.		
	If no changes to the forecast are required after Concept Clearance, the steps		
	described in Option A should be followed.		
	If the content of the forecast changes after Concept Clearance, the content must go		
	back through leadership approvals.		

# NIH Leadership Review of Completed NOFOs

Owner	Action
Leadership	Downloads completed NOFOs to a folder (with hyperlinks embedded in the
Approval	spreadsheet).
Contact	<ul> <li>Places relevant fields on a NOFO NIH Leadership Approval spreadsheet.</li> </ul>
	<ul> <li>Alerts NIH Leadership when entries are ready for review.</li> </ul>
(Acting)	Notifies ICOs regarding the NOFOs that are not approved.
DDER	
Leadership	Notifies ICO, Guide, OPERA of approvals.
Approval	
Contact	
Guide	• Enters positive approvals in the FOAM record and publishes the NOFO.

## Questions:

Inquiries about the Forecast requirements and processes should be directed to: Division of Grant Systems Integration, Office of Policy for Extramural Research Administration Office of Extramural Research: operasystemspolicy@nih.gov.

Inquiries about FOAM should be directed to the Guide: NIH Guide (NIH/OD) nihguide@OD.NIH.GOV.

#### Appendix 6 – Frequently Asked Questions

1. When reviewing applications for activities that are no longer an NIH/HHS priority/authority, should ICO's review the content of Other Support submissions?

Other Support is used to disclose the PIs ongoing activities and support and should not be modified. ICO's do not need to review Other Support for alignment with NIH/HHS priorities/authority.

2. For phased awards where the second phase (i.e., Type 4) will not be awarded due to NIH/HHS priority/authority, how should the ICO notify the recipient that the Type 4 will not be issued?

In these cases, ICO's must contact OPERA, and OPERA will issue a termination letter. Type 4 awards are subject to the availability of funds and/or agency priorities.

3. When revising awards to terminate a project, how should the ICO respond to red bars in SEAR?

The ICO should not contact recipients to request any additional information to address SEAR flags, because the project is being terminated. ICO's can clear the SEAR flag with a comment that the project is being terminated.

4. If a project is terminated on an HHS list or a Type 5 is withheld because the project is no longer an NIH/HHS priority/authority, can the ICO issue a subsequent Type 2 award?

No. If a project has been terminated due to agency priorities, it is no longer eligible for a renewal award.

5. For recipients of K awards that are terminated due to NIH/HHS priority/authority, will eligibility requirements be modified to allow the individual to apply for another K award?

Yes, NIH will allow recipients of terminated K awards to submit applications for new K awards.

6. If a PD/PI receives a 'substantial NIH independent research award' and loses ESI status, but the award is terminated, can the PD/PI have their ESI status reinstated?

Yes. Investigators can request the reinstatement of ESI status, using the ESI Extensions request tool in eRA commons. See Requesting an Extension for instructions.

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.

8. Can ICO's make awards for applications that came in under a NOFO that has expired (not unpublished) if the NOFO's sole purpose was DEI or another category that does not effectuate the NIH/HHS priorities?

No. Whether unpublished or expired, if the sole purpose was DEI or another category that does not effectuate the NIH/HHS priorities, ICO's cannot make the award. For updated information on

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NOFOs, CGMOs must contact their DEA rep.

9. If a NOFO is taken down for modification, and re-posted, can ICO's issue awards in response to that NOFO?

Yes. If the NOFO has been modified and reposted, ICO's may proceed with making awards after confirming that the award aligns with agency priorities.

10. If an ICO is modifying a Type 5 restore full amount, does the ICO need to conduct a review of the project activities as outlined in this guidance?

Yes. All monetary revisions are subject to this guidance.

11. Can ICO's approve requests from recipients to modify the project title?

Requests to change project titles must be submitted as a prior approval request. Changes to titles may only be made in the context of negotiations to remove activities/language that do not align with HHS/NIH priorities/authority. Title changes should only be made alongside associated changes to the abstract and specific aims.

12. When ICO's receive questions from recipients regarding HHS terminations, what should they do?

ICO's should not engage in discussions with recipients regarding HHS directed terminations. ICO's must direct recipients to submit any appeals to Dr. Memoli, as outlined in the termination letter.

13. For terminations where the ICO is making the determination, who is listed as the point of contact for appeals?

An ICO determination that an award no longer aligns with agency priorities is not appealable. Therefore, appeals language is not included in the termination term. Recipients may contact the ICO Director to request a reconsideration of the ICO determination.

14. What is the difference between an HHS-directed termination vs. and ICO or OD determination to terminate a project?

For HHS directed terminations, the template letter and appeals language were provided by HHS, and must be used as is. When an ICO or the OD determines that an award no longer aligns with agency priorities, the termination is made in accordance with <u>2 CFR 200.340(a)(4)</u>. This is not a termination for material failure to comply with the terms and conditions of award and is not appealable.

15. When will the Final RPPR become available for recipients to prepare and submit?

The F-RPPR link will open once the project period has ended.

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### 16. Can recipients draw down funds after the stated termination date?

For activities that were incurred on or before the termination date, with supporting documentation, NIH will approve the payment. For costs after the project period end date, outside of patient safety and animal welfare, costs will not be approved.

# 17. When will the Federal Financial Report (FFR) become available in PMS for recipients to submit?

The FFR will become available once the project period has been updated via a Notice of Award. Recipients should direct any questions to PMS or the OPERA FFRC.

# 18. Will recipients have the standard 120-day period following the termination date to submit closeout reports?

Because there are no new activities after the date of termination, NIH is directing that all closeout reports be submitted within 60 days of the termination unless animals or human subjects are involved.

# 19. If an ICO negotiates a change in a foreign site (e.g., South Africa to Nigeria), can the funds be rebudgeted from the original site to a new site?

Yes. Funds can be rebudgeted to conduct the activities at a new site as long as the site is domestic. All new foreign collaborations will need to follow the new structure once rolled out. If research aims are fully removed from a project, the funds cannot be rebudgeted for another purpose.

# 20. For awards that were terminated before the term and condition of award was modified to provide instructions for requesting approval of drawdowns, how should ICO's notify the recipient of the process?

When ICO's receive questions from recipients about the process for requesting drawdowns, the ICO must notify the recipient that they should contact the OPERA FFRC (OPERAFFRInquiries@od.nih.gov) for prior approval. The request must include details related to human subjects or animal welfare or outline that the costs were incurred prior to the termination date. The recipient must provide supporting documentation.

# 21. If a recipient requests prior approval to change a performance site from South Africa to another location, can the ICO approve the change?

Yes. ICO's may approve change to move activities from South Africa to another site. At this time, awards involving South Africa remain on hold. ICO's should not initiate negotiations or restrict funds.

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22. Does the COVID category apply to long-COVID and pandemic preparedness research? Or is it focused only on the immediate COVID-19 pandemic response.

The COVID category relates to awards made to address the immediate COVID-19 pandemic response. Awards to support general biology of coronavirus, long COVID and pandemic preparedness, at this time, may continue.

23. If a letter of support on a training grant references a university resource for DEI, but the abstract and aims do not include any DEI activities, does the letter of support need to be revised?

No. Under the concepts outlined in Category 2B, updated documents are not required to modify language when there are no DEI activities under the project.

24. For diversity fellowships awarded prior to January 20, 2025, are recipients permitted to activate their awards?

Yes. Recipients may activate the fellowship. ICO's must review these awards in accordance with this staff guidance, and future funds must not be awarded.

25. For joint NIH-NSF programs, where the initial application came in to NIH via a 'dummy' NOFO, can ICO's negotiate the award to remove any activities that do not align with NIH/HHS priority/authority?

Yes. These awards must be reviewed, and any unallowable activities must be negotiated out.

26. If NIH funds were awarded to support conference attendance, and the conference has a session on DEI, can the recipient use the NIH funds to attend?

No. NIH funds may not be used to pay for participation in a conference that includes DEI sessions or activities.

27. If a conference proposes a session on DEI (e.g., DEI Power Hour), can the ICO negotiate with the recipient to remove those activities from the conference agenda?

Yes. The ICO can negotiate with the applicant/recipient to remove the DEI activities.

28. For programs that have been terminated, in whole (e.g. MOSAIC K99/R00), will there be any central announcement, or should ICO's proceed with revising awards in accordance with the staff guidance.

In these cases, the NOFO will be unpublished. There will not be any other announcement. ICO's should take action on the awards as outlined in this staff guidance.

#### Appendix 7 - Managing PMS Hard Funds Restrictions

OPERA directs PMS to hard funds restrict awards terminated as a result of agency priorities and HHS authorities.

Recipients are required to request approval from OPERA (<a href="OPERAFFRInquiries@od.nih.gov">OPERA (OPERAFFRInquiries@od.nih.gov</a>) before any draw that occurs after the termination. The request must include details related to human subjects or animal welfare and provide supporting documentation. These are the only approvals that will be issued. OPERA will work with the ICO to facilitate approvals and facilitate lifting restrictions in PMS. After approval is issued, the recipient can request the drawdown in PMS. Note: Any other costs that are not related to human subject protection or animal welfare will not be approved. No exceptions.

Recipients are also required to request approval from OPERA to lift the restriction for payments of costs incurred on or before the date of the termination. For costs incurred, with supporting documentation, on or before the date of the termination, OPERA will work with PMS to lift the restriction as appropriate.

Note: Balances reported to HHS will change, as drawdowns are approved as outlined above. Reports to HHS will be updated as balances are modified. OPERA is responsible for maintaining up to date information for HHS reporting.

When recipients draw funds in PMS, they normally request funds from multiple awards within a single draw request. For awards terminated as a result of agency priorities and HHS authorities, recipients cannot request funds from multiple awards within a single draw request. Each draw request must contain only one terminated award. If a recipient combines a draw request for a terminated award with any other award, the request will be rejected.

#### **Entity Restrictions:**

At times, HHS or NIH may place a hard funds restriction on an entity in PMS, at the entity level, during compliance reviews. When this occurs, OPERA will notify ICO's. During the restriction period, ICO's should hold awards to the institution until the restriction is lifted.

#### Appendix 8 – Template ICO Termination letter.

[Address block & date]

[Authorized Organization Representative]:

Funding for Project Number [INSERT] is hereby terminated pursuant to the 2024 National Institutes of Health ("NIH") <u>Grants Policy Statement</u>, and 2 C.F.R. § <u>200.340(a)(4)</u>. This letter serves as a termination notice.

The 2024 Policy Statement applies to your project because NIH approved your grant on [INSERT DATE], and "obligations for federal grants are generally determined by the laws, regulations, and terms in effect at the time the grant was awarded, as outlined in the Notice of Award (NOA) or grant agreement". This "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 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)(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."

This project no longer effectuates agency priorities. [insert termination category language (e.g., DEI) verbatim]. Therefore, there is no modification of the project that would align with agency priorities.

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.

Costs resulting from financial obligations incurred after termination are not allowable. Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by <u>2 C.F.R.</u> §200.344. However, due to the immediate termination of this project, NIH may require a shortened timeframe to submit closeout reports. Details will be provided in the revised NOA issued by the Grants Management Official.

This is a final determination. If you wish to seek a reconsideration because you object to the ICO's termination, please submit a reconsideration request to [IC Director Name], Director, [IC Name].

Sincerely,

IC CGMO

Appendix F

1	UNITED STATES DISTRICT COURT
2	DISTRICT OF MASSACHUSETTS (Boston)
3	No. 1:25-cv-10814-WGY
4	
5	COMMONWEALTH OF MASSACHUSETTS, et al,
6	Plaintiffs
7	VS.
8	
9	ROBERT F. KENNEDY, JR., et al, Defendants
10	Delendants
11	* * * * * * *
12	
13	For Hearing Before: Judge William G. Young
14	Juage William G. Toung
15	Case Management Conference
16	United States District Court
17	District of Massachusetts (Boston.)
18	One Courthouse Way Boston, Massachusetts 02210
19	Tuesday, May 13, 2025
20	*****
21	
22	REPORTER: RICHARD H. ROMANOW, RPR
23	Official Court Reporter United States District Court
24	One Courthouse Way, Room 5510, Boston, MA 02210 rhr3tubas@aol.com
25	

1	APPEARANCES
2	
3	KATHERINE B. DIRKS, ESQ.
4	RACHEL M. BROWN, ESQ.  Massachusetts Attorney General's Office
5	One Ashburton Place, 20th Floor Boston, MA 02108
6	(617) 963-2277 E-mail: Katherine.dirks@mass.gov
7	and DANIEL AMBAR, ESQ.
8	Office of the Attorney General Healthcare Rights & Access
9	300 S. Spring Street, Suite 1702 Los Angeles, CA 90013
10	(213) 453-3598 Email: Daniel.ambar@doj.ca.gov
11	For Plaintiffs
12	THOMAS PORTS, JR., ESQ.
13	DOJ-Enrd P.O. Box 875
14	Ben Franklin Station Washington, DC 20044
15	(202) 307-1105 Email: Thomas.ports@usdoj.gov
16	and ANUJ K. KHETARPAL, ESQ.
17	United States Attorney's Office 1 Courthouse Way, Suite 9200
18	Boston, MA 02210 (617) 823-6325
19	Email: Anuj.khetarpal@usdoj.gov For Defendants
20	
21	
22	
23	
24	
25	

PROCEEDINGS

(Begins, 2:00 p.m.)

THE CLERK: The Court will hear Civil Action 25-10814, the Commonwealth of Massachusetts, et al versus Robert F. Kennedy, Jr., et al.

THE COURT: Good afternoon. I have permitted internet access for this hearing, though it's appropriate that I say that if you are attending this hearing via the internet, you must observe all the rules of court, that is to say you must keep your microphone muted, there is to be no taping, streaming, rebroadcast, screen shots, or other transcription of these proceedings.

Well, good afternoon, counsel. You've seen the Court's order, um, and the first order of business is to -- now that I am satisfied that this court has, um, jurisdiction, to entertain the motion for a preliminary injunction. I do, after some consideration, pursuant to Federal Rule of Civil Procedure 65(a), collapse further hearing on the motion for a preliminary injunction with trial on the merits, and I am going to use this hearing as a, um, really a case management conference.

I acknowledge the -- and I appreciate the plaintiff states' listing of the specific grants which are at issue, though this does not preclude them from

coming up with additional data. I more carefully reviewed your complaint, and in fact at Paragraph 152 you say, "perhaps more than 100" actually.

What's the count here? It's 500 and something, isn't it?

MS. DIRKS: Yes, your Honor. Katherine Dirks for Massachusetts. I don't know the final tally, it might have been 563 or so. But I don't have it in front of me.

THE COURT: Well the exact amount is not important, but our count is roughly the same.

Let me take just a moment and try to explain what I'm doing.

It has been this Court's practice, when injunctive relief is sought, um, in most cases, to make use of Rule 65(a) and, um, move promptly to the merits. It has been the Court's considered opinion that a trial, with evidence, with all the safeguards of a trial, is to be preferred to affidavits where -- which I have called in other circumstances, "The Potemkin villages of modern American litigation, all lawyer-created flash and no interior architecture." I am a person who believes in cross-examination. And, um, because federal court proceedings are unfortunately too slow and too expensive, I think it makes sense to deal with the

actual reality. So I followed my usual procedure. And now -- and I say this candidly, I don't know what to do.

I had another of these cases, spawned by the actions of the current administration -- and I don't compare them in any way, and they're completely separate, but I have a case involving alleged free speech rights, and I did the same thing. And to me the case is a knotty case, but the prima facie proof seems pretty obvious. That's not obvious here. Or rather I'm not sure how to grab hold of this case.

This case primarily is an Administrative Procedure Act case. Such cases proceed usually, though I'm authorized to make modifications, on a record, and, um, the record, um, supplemented by argument, is as close as we get.

Here the case is a rather sprawling case, um, I don't mean that critically, that's just the nature of the claims here, that it is this Court's obligation now promptly to address. So I'm groping for a way to do just that, to address the claims promptly, and I am very much open to advice from counsel. This is not the only case on the Court's docket. And I recognize that many other cases have dealt with similar situations by denying or granting preliminary injunctions. We'll see if I can't get to the merits and, um, work through some

of this very promptly.

So without committing ourselves in any way, I did want to quote you something really beautiful, that we, um, held the investiture for Magistrate Judge Jessica Hedges last week and she spoke and spoke brilliantly. But there was one phrase that she used that has stuck with me, and I'm sure I will refer to it frequently. She says, "Judges must be brave, meticulous, thoughtful. They are invited to these virtues by lawyers who are brave, meticulous, and thoughtful." And that, in all candor, is what I invite now.

So here's what I'm thinking as a way to start, and I -- this does not deal will all the issues, but it promptly, or as promptly as I can conceive, deals with some. Now -- and I'll sketch it out. But don't think I'm wedded to this. I think I'm being candid.

I'm very grateful to the, um, document provided me by the plaintiffs. Let me say -- this activity in Congress about nationwide injunctions, I'm not one who believed in nationwide injunctions. I had always thought that you dealt with the parties before you, that you could bind the parties before you, give them relief and enjoin them, if necessary, but nonparties, the government could always -- they can always appeal, the right is to appeal, but the government could, as I

learned it in law school, say they don't accede to the decision of the District Court and therefore the decision of the District Court would have effect only to the parties who came before the Court and have their matters adjudicated. So I approach this case believing that that is the appropriate approach.

So this spreadsheet and these 500-and-however-many grants there are pretty much defines -- well, no, it doesn't, because you were asking for relief more prospectively as to what you're thinking comes down the Pike, and I'm not dismissing things. I guess I do want to say I was told, in one of these hearings, that there were like 800 grants. Well grants to institutions in states other than the plaintiffs' states, this Court doesn't speak to, doesn't purport to adjudicate, and I -- and any injunction, if ever an injunction were to issue, wouldn't apply, um, save as to specific grants or specific institutions, specific states that are called out. So here's what I'm thinking, but it's only a first shot.

I'm struck by the fact that the letters of termination here are -- they're not all identical, but they're virtually identical, and they were issued in March on or about just a few days. I mean they all came out in a great blast. And they set forth, as much as I

can understand, the government's position here. So let me just quote from an exemplar letter and tell you both my concerns and where I think we might fill it.

So I'm picking out one issued on March 21st to Ayain Denson, the University of Massachusetts at Amherst, and I'm just picking it out. After some citations, it, um -- and there's this paragraph, and I'll just go sentence by sentence.

"This award no longer affects agency priorities."

Well one imagines that that's so, um, and I have some concern for statutory mandates. But I understand it does not. I'll accept that it does not. And then there comes this sentence.

"Research programs based on gender identity are often unscientific." I don't know that. And there's a comma. And then it says, "have little identifiable return on investment." I don't know that. Maybe that's so. And then another comma. "And do nothing to enhance the health of many Americans." I don't know that.

Then the next sentence says, "Many such studies"

-- no reference to the particular study at hand here.

"Many such standards ignore rather than seriously

examine biological realities." I don't know that. "It

is the policy of NIH not to prioritize these research

programs." Again that's a policy statement. I don't

take issue with it for the moment.

The next paragraph. "Although," and then they're quoting, "NIH generally will suspend rather than immediately terminate a grant and allow a recipient an opportunity to take appropriate correction action before NIH makes a termination decision," closed quote. "No correction" -- "No corrective action is possible here." I don't see why that's so? But we could examine that.

And then on the next page, and I'm not going to quote this, but there is a reference to an "administrative appeal." That's one exemplar.

Another exemplar, um, has an added sentence, um, to what I've read -- and this one comes from a letter of the same date to a Chake Camara, the University of Massachusetts Medical School in Worcester, and after a couple of the sentences I've read, comes this sentence.

"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."

I didn't know that. And I don't know it.

Now because these letters are common -- and you see where I'm going here, I'm, um, channeling, if you will, Justice Kagan's dissent. If there's basis for this, maybe so, but if there's no basis for these

factual statements -- put aside the ones I term "policy statements," if there's no factual basis for these statements, grant by grant, then it's arguable that they are -- the terminations are arbitrary and capricious, and the Court, on the statements alone, could, um, order an injunction that reinstates the grant, with all its terms and conditions, as though the letter never was issued.

Now that doesn't get the plaintiffs entirely where they want to go, but it gets them a significant way there, it seems to me, if that were true. Congress of course can change the laws, Congress can do that, and maybe they will. And we're talking only now about a way to start in as to these specific regs.

If in fact there are studies that support any of these factual statements, or any internal analysis that support those statements, certainly the NIH, the defendants here, they have to have the full and fair opportunity to lay that analysis out before this Court. The fact they didn't state it doesn't mean that it doesn't exist.

Likewise, perhaps it doesn't exist in writing.

Perhaps some official looked -- actually looked at a grant or looked at a group of grants and came to this conclusion with some sort of analysis, and, um, the

record on which this Court could act should include affidavits from those individuals. I have to say, given the framework here, that while I would accept such affidavits, I would expect that they be produced to testify and be cross-examined.

Now that's a -- another part of the record here. If an appeal has been taken by any of these grant recipients, the appeal, the results of the appeal, and any documents that reflect the discussion, um, in the appeal, should be before the Court, and I'm entitled to look at them and see whether any of these grants -- and the grant has to be evaluated on the specifics of the grant.

At least my understanding of medical research, but I stand to be corrected, is that it -- it should take account of race and gender. Sickle-cell anemia is more prevalent in a particular race. A certain type of cancer is, um, affects Ashkenazi Jews more than other people. I believe that it is the received medical wisdom that, um, gender differences are significant in providing the best possible medical care. So it can't be that we're just going to ignore those.

And, um, when I look at -- and I've -- you filed it timely, but I've spent the time since it was filed looking at this, it really does seem that, um, many of

these grants go to study, anyway, vulnerable populations. That's how I understand the medicine to work. That doesn't seem illogical to this Court, to, um -- well these are my concerns.

So if we started there -- and in terms of procedure, if we started there, we created a record for these, the Court ruled on that record that the actions were or were not arbitrary and capricious, and then under Rule 54(d), (1) I'm required to write an opinion, and I expect to, as to each variation that, um, I may have to deal with, but I can immediately -- once I'm satisfied that I've thoroughly reviewed the record, I can immediately enter a partial judgment under Rule 54(d) because the interests of justice require it. If the states lose or a state loses or some states lose as to some grant, I'd enter judgment. An appeal from an actual record with a decision can take place.

And contrary-wise, if I entered any such injunction that a grant, the termination of the grant was arbitrary and capricious, again I'm not going to sit on it, I'm going to enter in a -- in an area where one expects that Congress -- and indeed will expect that the agency may alter its or put out different guidance, this may, um -- it would be permanent only until the legal framework changes.

And I recognize that I'm groping, but let me start with the plaintiffs.

Can you think of any way to get at this better?

MS. DIRKS: Um, your Honor, again Katherine Dirks

from Massachusetts, I'll just preface by saying your

comment about Judge Hedge's statement about lawyers

inviting the bench, the Court to think of things a

different way, that really spoke to me. I really see

that as my role, and I want to thank you for that, and I

think maybe I can apply some of that principle here

today.

THE COURT: Thank her.

MS. DIRKS: I will.

THE COURT: There's much other wisdom in what she had to say, but that was the part I was able to quote.

And you're right to pick up on it, because it inspired me.

Please.

MS. DIRKS: My invitation is as follows, and it calls for hearkening back to how we frame these allegations in our amended complaint. Which is that we are not alleging that the terminations themselves are the final agency action and we are not asking the Court to conduct an individualized review of termination decisions, or other grant-based decisions, the final

agency actions that we are challenging are the directives, the challenged directives. And we're seeking ultimately, at the end of the day, for those directives to be vacated, and for the implementation of those directives to be enjoined.

Now we realize that the implementation comes in the form of the grants we've listed here and we believe that list will grow as we confirm further details with our clients, and crafting the relief might require some individualized identification of grants, but as to liability and as to the vacatur of the agency action, it is the challenged directives and the decision-making as to those directives that we're seeking to present to the Court.

THE COURT: How do we put together the record on which the Court is going to make its decision?

MS. DIRKS: So we have initiated a conference with the Department of Justice and federal defendants on that question. As to the administrative record for the challenged directives, that will be a more finite universe because it's a discrete list of directives, and that could be somewhat contained.

Now should there -- might there be some need for discovery? Potentially, yes, your Honor, because of the fact that some of these directives have not been made

publicly available, um, and we already have seen some deposition testimony in other cases regarding some of the murkiness behind the development of those directives that might require putting someone in a chair for a 30(b)(6) deposition, for instance, and there might be some redesignation of 30(b)(6) witnesses. But we still think that the universe of discovery there is quite contained, and we could move on a very expedited schedule or a resolution of the challenged directives, both the administrative record and a very very narrowly-tailored set of discovery for those issues that might be encompassed in the administrative record.

THE COURT: How long?

MS. DIRKS: We think that 14 days for the administrative record would be sufficient. Now we have had conversations with federal defendants there, we think that is not quite what they could live with, and we understand that and will obviously let them have their turn.

THE COURT: Well let me hear from --

MS. DIRKS: But we think 14 days for that, and an additional 14 days for resolving any other fact issues that might not be encompassed in the administrative record. But that does leave the question of the implementation question, and we can visit that, your

Honor. Um -- and if I could just tag on one piece of it that might not be in the administrative record.

Our understanding -- and this is to some extent in the PI papers, is that the ultimate decision as to what grants would be terminated was not granular, it was not on a program-officer basis, rather a blast e-mail went out saying, "Here are the hundreds of grants being terminated today, program officers get your notices out." And so it really should be a finite list of e-mails.

"administrative record," because that might post-date the directive itself, but there is a discrete period of time in which the directives were implemented. And it does not require individual deposition testimony from every program officer, it really is, um, a request for a production of documents that would be very specifically defined and could be produced with a few e-mails, is our understanding.

So we would look to a bench trial. You know we've often discussed summary judgment versus trial and the Court has, um, indicated, at the last hearing, that there might be disputes of fact, and that we're hearing today from the Court that the Court is anticipating some sort of dispute -- some disputes of fact that would

require in-court resolution and testimony. And so our inclination would be to not do summary judgment and instead put this on for trial, trial to resolve as much as we can through proposed findings of fact, so that we identify the short list, hopefully a short list of disputed facts, we can have a condensed bench trial, um, and can move this to a final resolution as quickly as possible.

THE COURT: Thank you. And that is very helpful.

Mr. Ports, what do you think of all this? You can go back to my meandering as well and, um, give me your thoughts. I much appreciate it.

MR. PORTS: Yes, your Honor.

I'll say the United States' thinking about the case is more aligned with what your Honor seems was describing than what Mr. Dirks described with her -- involving discovery and trial and things along those lines.

As your Honor stated at the beginning, this is an APA case at core, that the Court has ruled it would be decided as an APA case. Such cases need to be decided based on the agency's stated reason at the time it took an action and the documents that it considered in taking that action.

So there is -- there's a final agency action that

plaintiffs fall back in their brief was -- it's the grant terminations, that's what we end up with as the final agency action. Which although we said can't be challenged, I'll put that aside and not revisit our argument previously on this point. But, you know, we would agree that that's final, it has a legal consequence.

Your Honor mentioned appeals. Where an appeal is ongoing, there it is not final any longer, although there was a legal consequence with the termination that has reopened the agency's decision-making and the agency has not stated its final position on the matter, it is currently considering it.

But so putting aside the appeals that are ongoing, because they've been reopened, whether terminated and have been appealed, looking just at the terminated grants where there is no appeal, as your Honor described, there are a variety of reasons that grants would no longer effectuate agency priorities.

It -- we believe that the agency could compile an administrative record for those grant terminations. As long as the record from each individual grant file could, um, with agreement, include the termination letter itself and the notice of award and the agency could avoid going through the hundreds of additional

pages that are in individualized grant files that may contain sensitive information that can't be disclosed, if we included the grant termination and the notice of award to provide those stated reasons of the agency in terminating a grant, and the background on the grant, what is the award that was terminated, then we believe we could compile an administrative record of what the agency — the decision—maker considered in terminating those grants, in 30 days.

I will say, your Honor, that's a good deal longer than what plaintiffs had asked for here, but it is after substantial back and forth and consideration within the agency about how fast it could proceed, and it is shorter than the agency would prefer. And in asking for 30 days we are seeking to move quickly and offer the fastest possible time that we could.

After, um, you know plaintiffs identify 7 challenged directives that they say are the things that they are challenging, um, that the agency would presumably be looking at to compile administrative records for each of those purportedly-filed agency actions — and that will require looking at what a decision-maker considered, and some of the decision-makers are no longer with the agency, and this will take time and review, and we believe that 30 days

is reasonable for that.

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After that, we believe that the Court is correct, this case could be decided based on crossmotions -- well I won't say "correct." What I understood the Court was insinuating was that the case could likely be decided on cross-motions for summary judgment after that unless -- unless we were to provide a declaration or some additional justification that is not apparent in a document or on the face of the termination, in which case we understand the Court would want to allow for cross-examination. But if we did not do that, the Court would be able to review based on the record, and the termination and their justifications would rise and fall based on what is in the administrative record. And if the Court finds that it is insufficient, then, yes, we believe the Court could make its ruling based on that record.

But there is no need or justification for discovery, certainly not before an administrative record has been filed, certainly not before plaintiffs have demonstrated that the administrative record is incomplete, which we would say is a requirement.

In order to order discovery, there must first be a finding that the administrative record isn't complete and that one of the very limited circumstances that

allows for extra-record discovery exists, um, and that mostly -- that typically happens in the case of pretext. And I don't think there's any allegation that there's pretext for why these grants were terminated, it is clear on the face of the grants why the agency has said to terminate the grants.

And so we would propose that we could file the administrative record in 30 days and then the parties could file cross-motions for summary judgment thereafter, and then proceed to a prompt end and proper resolution of this matter in that way.

THE COURT: Well both of you are talking sensibly and I -- we're not going to, um -- neither one of you is going to prevail in their entirety, but that's not surprising.

This Court operates on an intentionally-practical and programmatic basis. I'm starting a significant MS-13 trial on the 2nd of June. I really think that case is going to go. I expect that it will go a couple weeks. That takes us up to the 14th of June, "Flag Day."

Whenever that case finishes, um, I'm prepared to address this case, or at least part of this case. I know the plaintiffs' allegations go further than what either one of us -- what anyone who has spoken is

talking about, and I'm not dismissing anything, though change could settle or throw it by the boards.

So if I'm going to look for you around the 16th of June, that's not for filing papers, that's for being ready to go. Clearly the NIH was prepared by March to send out these notices following these directives. So it does seem to me that I ought to have a -- now this is the 13th. I ought to have -- if we're going to have the appropriate administrative record, by Monday the 2nd of June, and briefs may be filed simultaneously with reply briefs thereafter.

And I'm getting ahead of myself, actually I work for Ms. Belmont. Let me ask her.

Assuming that the case on the 2nd of June runs two weeks, what do we have on the 16th?

THE CLERK: We're free.

THE COURT: Well we're not free now, we're --

I propose a hearing on the 16th. And I'm not one to micromanage. What the government says, um, makes sense to the Court. I want to encourage you to work out disputes, and all I can say is I'm not going anywhere. If I set this down for a hearing on the 16th of June, if that hearing is just on the record, because you've worked things out, so be it. If there's a dispute as to whether I should take evidence starting on the 16th of

June, you'll let me know. And, um, my effort will be -though whatever order happens will happen, and then to
follow it up with a written opinion just as rapidly as I
can.

list. I promise.

Now, um, if I left things like that, recognizing that there may be more to this case than we have discussed today, do the plaintiffs have any questions?

MS. DIRKS: Um, yes, your Honor. Um, not a long

One thing we haven't mentioned or focused on today is our unreasonable delay claim, and that does seem to be the one area that, um, would benefit most from, um, live testimony or where there was the most room for --

THE COURT: I couldn't agree more.

MS. DIRKS: -- and the most room for factual disputes.

THE COURT: But that's going to take some time.

So I was positing, um -- you know this idea of cross -
I know what the -- how these cases are handled. If we

get an agreed-upon record, I don't know that we -- it's

not strictly cross-motions for summary judgment where as

to each side I have to lean against their position, if

we had an agreed-upon record, then I draw the natural

and probable inferences from that record. I give both

sides an equal chance to argue the disputed -- it's a

mixed question of law and fact, the arbitrary and capricious issue. I'm not answering your question, I'm going back.

So the reason -- while I agree with you, that's going to take evidence, um, and we've got to start somewhere.

Do you want to start that this week or this month?

MS. DIRKS: I guess, your Honor, I -- I stand

corrected, with gratitude, that maybe I should ask the

more basic question.

When you say "briefs," your Honor, are you referring to specifically Rule 56 motions for summary judgment or a legal brief in support of --

THE COURT: A legal -- in support of a final decision on the issue, as you frame it, of whether these directives are unsupportable under the Administrative Procedure Act. And they will say, "Here is the record. Here are our reasons. They're all satisfactory reasons, under the Constitution, as the legal framework." And it's not for me, the Court, to make policy determinations, if policy determinations are permissible.

There are some statutory -- at least prior

Congresses have instructed the NIH, for example, to be sure that they include women in their research studies,

to be sure that they include children in their research studies, and I take it to encompass the science that, um, you want to capture the data on which proper health decisions can be made. But I don't mean to talk over you.

When do you want to go on the unreasonable delay? MS. DIRKS: Um, so if I -- I just want to make sure I understand the proposal that I'm reacting to, your Honor.

So with June 16th, it would be, um, briefing on the, um, the grant terminations piece of the case as to the challenged directives, and without the need to get into individualized, um, grants. Right?

THE COURT: Don't you characterize what I said. We'll see.

MS. DIRKS: All right, that's why I wanted to make sure I'm clarifying it, so I can understand what we're briefing.

THE COURT: I'm -- really, I'm trying to force you into -- both of you, into an agreed-upon record.

There's advantages to having an agreed-upon record. If you can't, I'll settle it. I'm not hesitant to settle it. But I'm always transparent about what I'm thinking.

So you've corrected me on my idea, my approach, and focused me more on the directives quite right. NIH

counsel properly says, "But really let's look at these directives." Work that out and, I expect on the 16th, if things work -- if things work on the 16th, I will have an agreed-upon record, I will have, um, briefs, I will hear argument, um, and if I can see my way clear to action -- but I don't promise anything on that day, but then I will take it under advisement. If I can't get my arms around it, I'll be saying, "But I want this witness" or "You can't really get there from here without something." I can't see now. But I respect you both -- I respect you all, and that's what I'm thinking.

You then say -- well let's focus on that piece. Without you characterizing it, the -- the terminations and the grant terminations piece, I hope to deal with on the 16th, to be followed by a decision, which is immediately appealable once I get the decision out, and it's based upon an agreed-upon record. That's where I'm hoping to go.

So still sticking with the plaintiffs. We haven't dealt with unreasonable delay, but are you -- do you understand that and can you work with that at least for today?

MS. DIRKS: Yes, your Honor, with one additional question. And we welcome this, your Honor, and I want to thank you for the June 16th date, because that

reflects our need for urgency.

One question. When the Court said that, um, briefs would be filed simultaneously, was that simultaneously with the administrative record, which would be due June 2nd, or simultaneous with each other?

THE COURT: No, no, no, not simultaneous with the administrative record. But it's not like you people don't know the other side. The lawyering has been, and I'm grateful, exemplary.

MS. DIRKS: Thank you, your Honor.

THE COURT: One thing that can be said about the NIH, whether it's the way they express it, I don't know the basis for that, but it's not like they're secretive about what they're doing. Okay?

MS. DIRKS: Um, that works very well, your Honor. But there's still the question pending about unreasonable delay? I'm happy to take that up now or later.

THE COURT: No, let's go now to the NIH.

My discussion with her is, um, can you work with her in that schedule?

MR. PORTS: Um, yes, your Honor, we will do our absolute best to have a record prepared by the 2nd.

THE COURT: All right. If you don't, I'm likely to, um, conclude that nothing exists. But that's

neither here nor there. But that's what I expect, on the 2nd.

Now unreasonable delay. How do you want to handle that?

MS. DIRKS: Um, your Honor, we think it makes sense to -- we could schedule it now or schedule it at another time, a second hearing on that case, your Honor. The reason why I hesitate from committing to doing -- to tackling that on the June 16th date is because there might be more need for fact-gathering there and more disputed facts that would not be contained within an administrative record because --

THE COURT: I have another hearing at 3:00.

MS. DIRKS: I'm sorry, your Honor.

THE COURT: Again, it's always the practicalities of each day. Are you suggesting I hold another status conference or are you suggesting that we go forward on the order I've entered now, and as you -- and you are working together, zealous advocates for their own position can work together, and I urge you -- I'm going to depend on it.

So what are you suggesting?

MS. DIRKS: Um, either we schedule a hearing now, your Honor, on unreasonable delay and the parties work backwards from there, the alternative would be for the

parties to propose a schedule, um, and an earliest date.

THE COURT: Why don't you -- why don't you do that and you don't have to agree on it. Your schedule may not be their schedule.

All I can say is I'm not insensitive to what I've done when I've collapsed further hearing on a preliminary injunction with trial on the merits. It's imperative that we all step up and give a reasoned, I hope to say, "brave, meticulous, and thoughtful opinion," that resolves what I am responsible for resolving at the earliest possible date. This wasn't "Okay, I collapse it with trial on the merits, when in the next year are we going to have the trial?"

So I'm going to leave you. I'm not going anywhere. Get Ms. Belmont, she's wonderful, and, um -- and it will be a status conference. It's not suddenly you come in here and I'm going to say "Well where are the witnesses?" We'll have a status conference when you know the issues that you think I need to address. But that can be as early as next week or at such other reasonable time.

MS. DIRKS: That works well, your Honor. Thank you.

THE COURT: The government?

MR. PORTS: Thank you, your Honor.

THE COURT: Good. It's good to see you. I look forward to working with you. And again, any case can be settled. If this case is settled, a simple phone call to Ms. Belmont is all that's required. We'll stand in recess. Thank you very much. (Ends, 2:50 p.m.) 

1	CERTIFICATE
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3	I, RICHARD H. ROMANOW, OFFICIAL COURT REPORTER, do
4	hereby certify that the forgoing transcript of the
5	record is a true and accurate transcription of my
6	stenographic notes, before Judge William G. Young, on
7	Tuesday, May 13, 2025, to the best of my skill and
8	ability.
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12	/s/ Richard H. Romanow 05-16-25
13	RICHARD H. ROMANOW Date
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Appendix G

1	UNITED STATES DISTRICT COURT
2	DISTRICT OF MASSACHUSETTS (Boston)
3	No. 1:25-cv-10814-WGY
<ul><li>4</li><li>5</li><li>6</li><li>7</li></ul>	COMMONWEALTH OF MASSACHUSETTS, et al, Plaintiffs vs.  ROBERT F. KENNEDY, JR., et al, Defendants
8	No. 1:25-cv-10787-WGY
9 10 11	AMERICAN PUBLIC HEALTH ASSOCIATION, et al, Plaintiffs vs.
12 13	NATIONAL INSTITUTES OF HEALTH, et al,  Defendants
14	*****
15	For Hearing Before: Judge William G. Young
16 17	Status Conference
18	United States District Court District of Massachusetts (Boston.)
19	One Courthouse Way Boston, Massachusetts 02210
20	Tuesday, June 3, 2025
22	*****
23	REPORTER: RICHARD H. ROMANOW, RPR
24 25	Official Court Reporter United States District Court One Courthouse Way, Room 5510, Boston, MA 02210 rhr3tubas@aol.com

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PROCEEDINGS

(Begins, 11:00 a.m.)

THE CLERK: Civil Matter 25-10787, the American Public Health Association, et al vs. the National Institute of Health, et al, and 25-10814, the Commonwealth of Massachusetts et al, vs. Kennedy, et al.

THE COURT: Well good morning counsel. We won't go through having everyone introduce themselves, but when you speak, if you could remember to introduce yourself, simply so that the Court Reporter's record is accurate. Let me tee up what I think I want to do here and, um, where we're going to go.

I wanted to have this status conference because there is the second of these two related cases, and I wanted to, um, have a conference where all parties could be present and, um, see the extent and the order in which they could be consolidated. So that was my purpose in calling this conference.

Or I should say, as I have in other such hearings, I have authorized internet access to this conference. Having done so, let me say, if you are attending this conference via the internet, have in mind the rules of court remain in full force and effect, which means there's no taping, streaming, rebroadcast, screen shots, or other transcription of these proceedings.

So, um, coincident with my scheduling the conference, um, various things have been done in the, um -- I've been given a proposed schedule for further proceedings in the first of the two cases and, um, in very large measure it makes perfect sense, though I want to make some comments about it, and emendations. But I am very grateful to the parties for the manner in which you're working together.

Second, consistent with the Court's order in the first of the two cases -- or at least in the first of the two cases, the government has, consistent with the Court's order, um, filed the administrative record.

Here it is. You will understand I haven't looked at it since the 2nd of June. But a question to government counsel.

Is this the record as you see it in both cases or just the first?

MR. PORTS: Thank you, your Honor. Tom Ports for the government.

This record is the -- it is the government's position that this is and will be the record for both cases. I will say that -- and we had some discussion about this earlier, um, all parties met at 9:30 today in the U.S. Attorney's Office. The United States believed, as the Court previewed the last time, that there are a

handful of discrete reasons why grants were terminated.

If you look at the different paragraphs, they tend to

line up across the various terminations.

We have compiled all -- everything considered directly and indirectly for those reasons. It does not include the actual termination documents for all of the PDFs in the, um, the related case. So the second-filed case, we don't have all of the actual termination documents. However we believe it is very unlikely that there will be any other reasons or justifications, and therefore this record is sufficient and contains everything directly or indirectly for that case as well.

I can represent that what I told the plaintiffs that I would suggest, in the second-filed case, is if plaintiffs would let us know or let the Court know, by the 5th, if there is any other justification that is not included in a termination record in that record, then we can promptly complete the record for the second case with anything in addition, and, um, then everything will be thoroughly complete and we'd be able to proceed with everything by the 16th. We think that's very unlikely that there are any different reasons. But, um, it is of course possible. And we think that is a way to proceed and resolve everything in Phase 1 together.

THE COURT: Thank you, that's a direct answer to

my question and I appreciate it.

Now, um --

MS. AKSELROD: Your Honor, um --

THE COURT: Yes?

MS. AKSELROD: May I respond on behalf of the APHA plaintiffs with regard to the completeness of the record or would you like me to wait on that?

THE COURT: I'd like you to wait.

MS. AKSELROD: Thank you, your Honor.

THE COURT: Saying I thank you, doesn't mean that's it. And let's jump right there.

In point of fact, um, I've been reflecting on what has been filed thus far and in two respects, um, if -if I don't have this in the record, I expect it by the

16th. So let me start with that. If it's there, fine.

But I read Footnote 1 on this schedule for further proceedings and respectfully, um, the defense either misunderstood or mischaracterizes the Court's view. I do think the very first issue to be considered is, um, the challenged directives, and so I need a record with respect to the challenged directives.

Specifically I expect -- I've come to understand that in this iterative process, the various universities were putting out algorithms about how to write grants and, um, "Stay away from this word," and "Don't say

that," and the like, "if you're seeking a grant." So one imagines, given the speed with which the defendants acted here, that there was guidance to the people who made the determinations, or the person who made the determination, and I expect it. I expect to see it. If there's an algorithm, if there's guidance, wherever it came from, I want to see what it is. The record to be supplemented in that respect.

"Grant Watch," which is really rather intriguing, um, and since everybody seems to look at Grant Watch for, um, the data concerning grants from the NIH, recognizing that this case, um, certainly in its Phase 1 is limited -- let me be very clear, is limited to grants terminated, not restored, not expired, that, um, in the first case, and the second case, the list with which we're working -- and to the extent we can pare that list down by settlement or otherwise, that's a good thing. But, um, I think Grant Watch may best qualify, um -- save the government's rights, they may want to brief this, but I think it qualifies under Federal Rule of Evidence 80317. This is like a, um -- like a "Physician's Desk Reference" or something.

So the parties are free, because the universe of grants of course goes well beyond the grant that, um,

whatever I have to say about the challenged directives, any relief, if any there is, has to do only with the, um, grants that are, at least the first phase, that are listed in the materials already filed.

So let me turn to this document now, which I do think is very helpful.

So the government, um, has filed its position on the, um, administrative record, um, and whether or not the defense agrees with it -- and that's the reason I cut counsel off, the proposal here sets forth very prompt time limits for challenging the completeness of the administrative record. I'm not going anywhere. It makes perfect sense. I seek to hold myself to the -- and hold you to the, um, what's set forth on Page 2 in Paragraph, um, 2 and 3 of the proposed schedule.

And again, the government has every right to contend that the record is complete and that the supplementation is either irrelevant or, um, it ought not be supplemented. But I've said what I'm looking for here.

Now we're on for the 16th. I propose to give you -- it's on at 10:00 on the 16th. I think we can thrash our way through the argument here in the morning, and the morning to me lasts till 1:00 -- um, from 10:00 till 1:00, I may need a brief recess, but I think we can

thrash our way through.

Now then we get to this proposed second phase.

And I agree that that will be heard thereafter, um, and here I see the parties differ markedly. Let me be as helpful as I can as to what I expect will follow.

You people have shown some amenability to resolving this partially or, one can always hope, wholly, um, with respect to certain or more of the challenged grants, so I want to know, at least in general -- and I recognize this is jury-waived, but I will start off the proceedings at 10:00 on the 16th.

And again, I'll do this at the sidebar. The parties can agree to private resolution, and I will say, "Well have you settled any of this, and if so, what?" And you'll tell me. And those conferences will be sealed. We won't get into substance at all. And then we'll spend the rest of the morning talking about, um, really the first phase of the case, the applicable law and what can be discerned from the administrative record.

Then close on to 1:00, I will say -- and maybe it will go faster than that, but maybe not, I will say,
"Well, um, now that you've heard me" -- and I've done -I've followed this technique in other cases, so I want you to know it now. "Now that you've heard my questions and my concerns and how I dealt with the answers and the

like, um, you tell me, do you want me to stay my hand for any particular period of time, because you could work out this part of it, or you could work out all of it, or" -- and you'd both have to agree, or you'd say, "No, we want the decision."

And then I will say, um -- but I'm giving a range here because I have no idea where we'll be at 1:00 on the 16th, I will say, um -- it goes from nothing, in which I will say, "I'll take the matter under advisement, thank you very much," and that's what you'll hear from me until, at minimum, some order comes out, and at maximum, the full opinion comes out. That's one end of the spectrum.

The other end of the -- well I'm not going to be able to -- I really am looking forward to the 16th. I have no preconceived notions about this case. I'm going to tell you the concern I have, but that's downstream.

So, um, all I'll say -- a combination like this, it won't be any opinion, but I'll say, "Well, you know I think" -- because I'm very sensitive that this started out with a preliminary injunction collapsed into trial on the merits, I'll say, "I think it's coming out, at least in this area, this way or that way or whatever." And, um, maybe I will be sufficiently confident to enter an order. Most likely I will not. But, um, the

likelihood probably will be that an order will precede
the full opinion, because I will have the full record,
I'll have the advantage of your briefs and your
arguments, and, um, cases don't -- unlike fine wine,
don't get any better with delay. So they'll be at least
a partial order, probably pretty fast, on the first
phase of the case. Unless you tell me the other, you
say, "No, stay your hand for a week, two weeks,
whatever, maybe we'll work it out."

Then, when you see the way I see this case, once that's out there, the rest of it is writing, and it implicates of course the second phase, because if it goes all the government's way, I don't see much to the second phase. And he tells me there isn't much to the second phase anyway. Maybe that's right, maybe that's not right.

If it goes significantly the plaintiff's way, the second phase is, in my mind, a different consideration. But the schedule that is posited here -- and I have full respect for the government saying that the administrative record is the, um, is appropriate, and only appropriate, um, actually the way you've written it is fully satisfactory to me, because it says -- and I'm now on Page 4 of the government's, I guess -- I take it it's the government's proposal? Yes, the defendants'

position. I think their schedule makes good sense.

And, um, at least -- and I propose then to adhere to it.

You said "the conclusion of the Phase 1," I propose to adopt it, and within 7 days, the motion to dismiss, within 10 days, etc., as it appears on Page 4.

Now let me stop there and ask for questions and I'll resolve whatever needs to be resolved, I hope, and then we'll move to the second of the two cases, which I hope you will tell me can be resolved on the same schedule, and the first case, we'll agree. But we haven't had everyone in court until today.

So here's my concern. And my concern is an unformulated concern, because it comes only -- I don't have the advantage of the administrative record, so candidly it comes from these, um, just looking at the initial spreadsheet and the subject matter of these various grants, um, I -- I have real concerns about evenhandedness here.

I have concerns about -- and about health care. I have concerns about black Americans. I have concerns about women. I have concerns about, um, legitimate gender issues having to do with health. But don't any of you take this as prejudging anything. It isn't. It's just the Court's attempt to be fully transparent and to grapple with the issues that the Court is duty-

bound to grapple with.

So -- and for the first round, questions? And we'll start with the plaintiffs, questions on those things? I had not thought of this as an argument session, which is not to foreclose argument, if it's necessary, but I came prepared for scheduling and not argument.

So the plaintiffs, please.

MR. CEDRONE: Good morning, your Honor, Gerard

Cedrone for the Massachusetts Attorney General's Office
on behalf of the plaintiffs in the states' case. I

wanted to raise two issues related to the scheduling on

Phase 2 and react to, um, your Honor's statements about
the schedule there. The first relates to the question
of discovery and the second relates to the schedule more
generally.

First, as we previewed here briefly, we do believe that discovery is appropriate on most claims and that they're not properly limited to the administrative record. I don't want to -- if your Honor's not expecting argument today, I don't want to launch into an argument, but we do stress that we think that's appropriate and are happy to brief that or argue that today or at another time, because we do think unreasonable delay claims, unlike claims under Section

7062, the essence of the claim is there is no final agency action, and so unlike --

THE COURT: You're now getting into --

MR. CEDRONE: I'm straying into argument, yes.

THE COURT: But I'm following, and so I think I can make a direct answer.

I'm not surprised by what you're saying. The schedule that now I've tentatively adopted, once we're concluded with the first phase, you can expect they'll move to dismiss. I'll entertain it. I'll rule on it.

But we'll assume you survive it. Though I express no opinion. And as part and parcel of that, one imagines I will hear fully the need for extra-record development.

And, um, again, that's his last paragraph in the proposal. So we will then, to the extent -- don't think I'm with you here, but we're trying to tease out an intelligent way forward, then we'll talk about the schedule to get at that.

Does that answer your question?

MR. CEDRONE: It does, your Honor. And that leads me to the second question or issue that I wanted to highlight with the schedule. We are concerned that this schedule here, especially for a claim that is grounded in undue-delay risks, moving the resolution of these issues close to the end of the government's fiscal year,

so this contemplates that after Phase 1 is completed, they'll be a week for them to move to dismiss, and then however long that takes to resolve --

THE COURT: You want it faster?

MR. CEDRONE: I do, I think we should walk and chew gum. If they have, you know, a motion to dismiss on those claims, they've had our --

THE COURT: You've got a -- (Laughs.) I think I can walk and chew gum, um, and I don't hear you to suggest otherwise.

What schedule do you suggest?

MR. CEDRONE: No, I'm suggesting that the federal government respectfully should walk and chew gum. We can litigate Phase 1 while I think they file any motion to dismiss that they have, you know, in short order, and produce any administrative record on the second phase in short order. They've had our complaint since April, they've had a --

THE COURT: Well the logic though is that I ought to hear and in my mind react to Phase 1. Now -- you know the truth is, now that we've engaged, I'm going as fast as I can, and when I say, "Well maybe I'll make an order" -- orders get revised in the discipline of writing full opinions. But I, at least conceptually, I'm prepared to take that risk however it comes out.

But, um, maybe I should say that, um, not within 7 days, but if they have a motion to dismiss as to Phase 2, the motion to dismiss must be filed, um, coincident with Phase 1, the 16th?

MR. CEDRONE: We think at least that would be appropriate. And I just want to be clear, I was not suggesting that --

THE COURT: Of course you were not. Of course you were not.

MR. CEDRONE: (Laughs.) We appreciate the dispatch with which this Court acts.

THE COURT: As in any case, we're all here together reaching out for justice. That's my concept of the thing.

So to be fair, I'll modify it. If they want to dismiss, um, the second phase, any motion to dismiss the second phase will be filed no later than -- filed, not entertained on the 16th, but filed no later than the 16th. The rest of it all stands.

Doesn't that make sense?

MR. CEDRONE: I think that would be appropriate.

And the other, I think, suggestion we would have is that

30 days --

THE COURT: If I knock that out, or to the extent I deny it, we'll give them 30 days to prepare the

97a

record.

How's that?

MR. CEDRONE: I think that's a bit long, respectfully, your Honor. It's longer than they were given to produce the record for Phase 1.

THE COURT: You said he didn't think -- well actually --

Mr. Ports, you said there wouldn't be much problem in producing the record for Phase 2, would there?

MR. PORTS: I believe I'm not -- I'm not sure what your Honor is referring to. We would request 30 days to file the Phase 2 record, um, as we've requested here. I can also respond to filing it coincident with the hearing on the 16th as well. If we can do that, if that's the Court's order, we believe there would be some benefit from going through the proceeding, hearing the Court's thinking, and having a sense of the resolution, before we file our motion to dismiss on Phase 2, which is why we propose 7 days, which is, we believe, a very short period of time that would allow us to focus on Phase 1 and get it resolved. I understand the Court's thinking, to perhaps get a preliminary ruling, um, get a better understanding of Phase 2 at the time we move to dismiss.

So we do think that there is a benefit to 7 days

or at least some period of days after the 16th. 1 2 THE COURT: Okay. How about this? How about 3 this? We'll have the hearing on the 16th. I'll do the best I can, whatever that is. But that's substantive, 4 5 that will be the findings and rulings. Any motion to dismiss need not be filed on the 16th, but must be filed 6 by the 20th. And then, rather than 30 days, we'll give 8 you until the, um, 9th of July to file the administrative record. 9 How's that? 10 11 MR. PORTS: Thank you, your Honor, we -- that 12 seems to be --13 THE COURT: You really --14 (Zoom interference.) 15 MR. PORTS: Yes, your Honor. THE COURT: Well that's an intelligent and 16 17 lawyer-like answer. 18 Now, Mr. Cedrone, I -- I'm trying to be fair. 19 That's acceptable to you? 20 MR. CEDRONE: Thank you, your Honor. It is. 21 THE COURT: And I'll again try, um, consistent with other obligations, to address it promptly. 22 23 Other questions? 24 MR. CEDRONE: I don't believe so for the state 25 plaintiffs.

THE COURT: Yeah.

MR. PORTS: For defendants, we just want to clarify that yesterday we received three deposition notices for next week, requests for production and interrogatory responses related to Phase 2, and we just wanted to make clear that the defendants need not respond to these until -- unless and until there's any motion to complete or supplement the record and a ruling on that in Phase 2 from the Court.

THE COURT: I think that makes sense, but then we're not going to be waiting, so you'd better line those people up, and you'd better be thinking about the answers to interrogatories, because I will give a very short time for discovery.

You understand?

MR. PORTS: If the Court orders that discovery is appropriate.

THE COURT: If we get there.

MR. PORTS: Understood, your Honor.

THE COURT: Right. They told you what they want. Be thinking about it.

MR. PORTS: Yes, your Honor.

THE COURT: All right.

Now let's turn to the second case. And my thought is, um, in view of Mr. Ports saying that but-for

individual notices on the specific grants that you have now filed, he doesn't anticipate anything else, can we treat the second case coincident with the first and hear you on the 16th?

MS. AKSELROD: Your Honor, Olga Akselrod with the ACLU on behalf of the APHA plaintiffs.

We are absolutely in favor of consolidating our proceedings with the June 16th hearing and believe that, um, the record as to the directives, um, may well decide many many of the issues in this case. But there is a difference in terms of the record that has been produced in the states' case and the record that has been produced in our case.

As you know, in the states' case the individual termination ARs have been produced, and those are set to be produced, um, by the defendants on June 16th in our case.

We have, um, proposed that the parties meet and confer on June 5th, um, which would give us enough time to review what has been, um -- what has been provided as to the ARs in the states' case. The defendants have proposed potential stipulations that may obviate the need for, um, submitting the individual terminations AR in our case, and we just need the parties to have a little more time for us to review the record, um, and

also to figure out whether such stipulations would be sufficient.

THE COURT: All right. Yeah, look, I gave them day for day what I gave the states from your start time.

MS. AKSELROD: Yes, your Honor.

THE COURT: I'm not -- I'm not going to revise that. I did that having thought it through. Having said that, there is so much to be gained by agreement.

And I urge -- but I am not ordering, and I'm not setting interim dates, further agreement.

I hear you say that you will -- however it works out, if you don't agree, you want to be heard and argue as to these directives, and, to the extent you can legally, you want to argue as to, um, grant terminations in your case on the 16th.

Right?

MS. AKSELROD: Yes, your Honor.

THE COURT: And I propose, in that 3 hours, to hear you. And I propose -- I intend to hold myself ready for argument in -- I'm calling it the "second case," but only that's because it -- how it emerged into my consciousness. It's not "second" in any way and I've spoken to it on an individual basis.

So I'm simply going to hold you to that. We'll do the first phase and then we'll see where we are.

MS. AKSELROD: Thank you, your Honor.

And we would propose that on June 6th, we would be able to provide the Court with a status report as to the parties' discussions and what if any additional ARs may need to be produced, and a proposed sort of supplemental, um, schedule for how to deal with those.

THE COURT: Well you're looking for a court order. You can file anything you want.

I do enjoy meeting with you all. Really that's not a personal thing, there's much to be said for the management and the joint efforts that everyone is putting into these two cases. At the same time, I'm not big on status conferences.

"what I want," but I will enter a due-appropriate order or no order. I have the case now entrained for argument on the 16th. I've got a lot of stuff to look at. I suggested other things I want to look at and I do want to look at them. And I have legal work to do. And I intend to give you a full and fair hearing on the 16th.

If I hear no other questions, I think we can -- MS. AKSELROD: Your Honor, I do have a few more questions.

THE COURT: Yes, go right ahead.

MS. AKSELROD: So -- well, first of all, I just

wanted to raise that the parties, um, did have some additional discussions over the course of the last two days on some modification to the schedule that was, um, proposed by the states and the defendants in that case. And I understand your Honor has adopted that schedule. We think that that schedule also makes a lot of sense in virtually every way. But the parties have agreed to a couple of modifications.

THE COURT: If you agree to them, put them in writing and let me know.

MS. AKSELROD: Perfect. Thank you, your Honor.

Secondly, um, I just wanted to clarify. So, first of all, of course to the extent that the parties are not able to reach stipulations, um, by June 5th, we would be arguing based on the directives AR, um, and wouldn't have the benefit of being able to make argument with regards to the grant termination AR, which we're not receiving until June 16th. So I just wanted to clarify that we will be prepared to argue as to the directives AR. We believe that the grant terminations can be resolved through the directives AR. If the Court finds that is unlawful, then relief would flow to those. But we just wanted to be clear that there may be a limitation as to what we argue.

THE COURT: You're making yourself clear.

MS. AKSELROD: Perfect. Thank you, your Honor.

And one, um, other clarification that I just wanted to raise with regard to the scope of Phase 2, um, and this is one of the ways that our case differs a little bit with regard to how I think this Court has framed Phase 2, which so far has been about unreasonable delay and 7061. And I just wanted to raise that in addition to 7061 claims, the APHA plaintiffs have also brought 7062 claims on behalf of the applicant.

THE COURT: I understand. I've ruled on -- I've treated their argument as a motion to dismiss and I've ruled on it. Believe me, I understand what your complaint raises.

MS. AKSELROD: Yes, your Honor, thank you. And that is of course also a difference in the schedule since, um, the motion to dismiss, as you've just noted, has already been heard in our case.

I just wanted to also raise that, from our perspective, the June 16th hearing as to the directives, um, could give relief not only as to the grant terminations, but also as to the suspension of applicant processes based on the directives.

THE COURT: I will tell you, in all candor, I had not thought of that. Now you may be arguing that, but I'm trying to get my hands around this case, and, um,

while relief as to people actually -- as to grants actually terminated is potential, that's why I wanted the list. So -- and that will be the Court's focus.

Obviously it's your complaint and you raise any claim you wish. I've ruled on a motion to dismiss.

It's my duty to adjudicate the claims. Um, but that's my response.

I think I'm -- the public officials are wrong to say we're only going to talk about the grant terminations, not these directives. I want to know all about these directives. I want to know where they came from. I want to know why there were no edits. And this business, which is fulsomely set forth in your complaint, we'll hear at least all about that. I want a full record as to those directives. And then I want to see how it plays out in cutting off funding for grants approved. That's what I thought we were talking about.

Now I guess all I can say is that's the Court's focus and it will be the Court's focus on the 16th. You can feel free to raise anything that the complaint raises. But when we talk about potential orders and the like, um, I'm limiting it to these plaintiffs, these grant -- Phase 1, these grant terminations. Now there is a Phase 2. I'm not expressing any opinion on that.

Is that helpful?

MS. AKSELROD: Yes, your Honor, it is. I think we may, um, with the Court's permission, still spend a bit of time explaining how the directives expressly require an applicant --

THE COURT: You will, on the 16th, and you will not think that I am, um, prejudging it if you spend that little time towards the end.

MS. AKSELROD: Thank you, your Honor.

THE COURT: All right.

Any other questions?

And again, hope springs eternal. If you resolve this matter or a significant portion of it, a simple call to Ms. Belmont is all that's necessary.

Yes, Mr. Ports?

MR. PORTS: Yes, your Honor. Thank you.

I wanted to clarify regarding the supplementing of guidance about what is contained in the administrative record.

Although it is the defendants' position that the grant terminations should be reviewed, the administrative record contains well-challenged directives, um, the -- where the challenged directives were considered, directly or indirectly, in the grant terminations, they're a part of that administrative record. Where they were not, we have provided separate

administrative records for the other, um, challenged 1 directives, to the extent we have had record IDs. 2 THE COURT: You'll appreciate that I haven't reviewed it, and so if I've misspoken, it's solely 4 5 because I have not yet had the chance to review it all. 6 All right. MR. CEDRONE: Your Honor --THE COURT: I have another obligation here. 8 9 MR. CEDRONE: I just want to clarify what was just 10 established, which is that, um, having heard your 11 Honor's views and admonitions, that the administrative 12 record in the states' case is complete, um, in the 13 government's view. 14 THE COURT: He said it was. 15 MR. CEDRONE: Okay, I just wanted to make sure of 16 that. 17 THE COURT: While I'm operating -- we talk about "clarifications," um, the question is, um, that 18 19 "clarifications" all, respectfully, have to go to me. 20 I'm telling you what I think Mr. Ports has represented, 21 that I have a complete administrative record as to the, 22 um, challenged declarations. That's what I heard him 23 And that -- well I'll stop there. say. 24 MR. CEDRONE: Thank you, your Honor.

THE COURT: Lest I clarify my own clarifications.

25

Thank you all. We'll stand in recess. (Ends, 11:45 a.m.) C E R T I F I C A T EI, RICHARD H. ROMANOW, OFFICIAL COURT REPORTER, do hereby certify that the forgoing transcript of the record is a true and accurate transcription of my stenographic notes, before Judge William G. Young, on Tuesday, June 2, 2025, to the best of my skill and ability. /s/ Richard H. Romanow 06-05-25 RICHARD H. ROMANOW Date 

Appendix H

1	UNITED STATES DISTRICT COURT
2	DISTRICT OF MASSACHUSETTS (Boston)
3	No. 1:25-cv-10814-WGY
4	COMMONWEALTH OF MASSACHUSETTS, et al,
5	Plaintiffs vs.
6 7	ROBERT F. KENNEDY, JR., et al, Defendants
8	No. 1:25-cv-10787-WGY
9	AMERICAN PUBLIC HEALTH ASSOCIATION, et al, Plaintiffs vs.
11 12	NATIONAL INSTITUTES OF HEALTH, et al, Defendants
13	****
14 15	For Hearing Before: Judge William G. Young
16	
17	Bench Trial, Phase 1 (Closings)
18	
19	United States District Court District of Massachusetts (Boston.) One Courthouse Way
20	Boston, Massachusetts 02210 Monday, June 16, 2025
21	
22	*****
23	REPORTER: RICHARD H. ROMANOW, RPR Official Court Reporter
24	United States District Court One Courthouse Way, Room 5510, Boston, MA 02210
25	rhr3tubas@aol.com

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PROCEEDINGS

(Begins, 10:00 a.m.)

THE CLERK: The Court will hear Civil Action

Number 25-10787, the American Public Health Association,

et al vs. the National Institutes of Health, et al and

25-10814, the Commonwealth of Massachusetts, et al vs.

Robert F. Kennedy, Jr., et al.

THE COURT: Good morning. These two cases I've authorized internet access, so it's appropriate that I say that if you are viewing these proceedings via the internet, the rules of the court remain in full force and effect, and that is to say there is no taping, streaming, rebroadcast, screen shots, or other transcription of these proceedings.

This is the final argument in Phase 1 of this

Administrative Procedure Act case. I'm pushing the

administrative record out of the way. (Moves pile of

documents.) Counsel will understand that I am prepared

for final argument. I do not claim to have read the

entire administrative record.

As we discussed, argument will proceed first with the plaintiffs, dividing an hour, should they take that long, and then with the defendants, dividing an hour. That isn't an invitation to use all that time. I am prepared for the final argument.

Mr. Cedrone, I will hear you. I assume it's you. Go ahead.

MR. CEDRONE: Good morning, your Honor, Gerard Cedrone from the Massachusetts Attorney General's office for the plaintiff states in the '814 case. We plan to divide our time roughly equally, so I will speak for no more than a half an hour.

We're asking the Court to set aside the challenged directives and the terminations that flow from those directives. With the time I have I'd like to address first the defendants' threshold arguments, then explain why the challenged directives violate the APA and the Constitution, and finally say a few words about remedies.

THE COURT: Maybe -- I want you to -- your argument organization makes sense, but you said "set aside the challenged directives," and one of the things I'll ask everyone, if I were to do that, if I were, under the Administrative Procedure Act, to set aside the challenged directives -- declare, for whatever imperfect reason that some or all were of no force and effect, um, life then, it seems to me, proceeds as though they did not exist, and I'm not clear for the need for injunctive relief as to the Administrative Procedure Act claim.

Get to that whenever it suits you.

Go ahead.

MR. CEDRONE: Understood, your Honor, and, um, I will be speaking to remedies and the injunctive relief piece.

THE COURT: Thank you.

MR. CEDRONE: Maybe before jumping into sort of the specifics, I also just wanted to take a step back.

We've been living with these facts for a while now, but I'd like to reiterate how unusual they are.

In the past few months, defendants have taken actions that are unprecedented in the history of the NIH, they issued directives that summarily ban research on 7 discrete topics, and they implemented those directives by canceling over 800 grants to the plaintiff states' institutions. And I can't emphasize enough just how extraordinary that is. In a typical year NIH cancels 1, maybe 2 grants, and here we have 800 and counting just to the plaintiff states, just in our case alone since January. That's 800 terminations affecting real people, including patients who lost critical medical treatments, researchers who lost years of work, and students who've seen their educational opportunities disappear.

Given that dramatic change and that dramatic departure from past-agency practice, you would expect to

see a robust administrative record, one with careful explanation, one that weighs various pros and cons, one that gives serious consideration to the real harms that happen to people when hundreds of studies are cancelled with no prior notice. Instead the record has none of that. There are obviously hefty binders, but what you have throughout those binders, over and over and over again, is repetition of the same paragraphs.

So with that said, let me speak first to the defendants' threshold arguments. The defendants' principal argument is that the Court should not even consider the legality of the directives because those directives are not final agency actions. That's incorrect. And the simplest way I can think to explain it is that between January and the termination of our grants, defendants clearly made a final policy decision to blacklist 7 discrete topics, that's the policy decision that we're challenging.

Now we think it's clear from the record that that policy decision is memorialized in, is consummated by, is distilled in these directives that we identified, but we don't think defendants can dispute the basic point that, before terminating our actual grants, they made a policy decision to blacklist certain topics, and that's what we're challenging.

And I would compare that action to the policy decision that your Honor currently has in front of you in the American Association of University Professors v.

Rubio case, where your Honor decided, as a preliminary matter, but recognized that even an unwritten policy in that case of targeting certain students for deportation can be a final agency action. Here we think we're in an even stronger position. It's not just that there's some unwritten policy in the ether, the defendants have actually reduced it to writing in the directives that we put in front of you.

And that's consistent with our challenging these policies as a final agency action. It's consistent with the statutory text, the Section 551 of the APA defines an "agency action" to include rules, which means "statements of general applicability with future effects." That's exactly what these directives are, they're directives that ban research into certain topics and direct agency personnel to act accordingly.

One final point on this final agency action question. We think it's clear that the challenged directives are final agency actions themselves. Even if we were wrong about that, there is no dispute, and the defendants concede at Page 12 of their principal brief, that the termination decisions are final agency actions,

and under Section 704 of the APA, final agency actions -- the review of a final agency action includes the review of any antecedent, interlocutory, or other decisions that merge into the final decision.

And so with all of that said, we think your Honor has already ruled on this in our case as a preliminary matter, we don't think defendants have given any reason to disturb your preliminary ruling that these -- that both the directives and the terminations that flow from them are final agency action.

I do want to address, before getting to the merits of the case, two more minor points on the defendants' threshold arguments that I just want to be sure are clear. One is that the defendants argued in their reply brief that a February 21st directive, that we've called the "Memoli directive," and I know there's different nomenclature floating around, but this is a February 21st directive at Page 2930 of the administrative record. The defendants argue in their reply brief that that's not properly in this case because we didn't call it out by name in our complaint, but that's wrong for two reasons.

The first is that our complaint makes clear, at Paragraphs 116 to 117, that the directives we're challenging -- that the directives we are challenging

include the universe of directives, including the directives that had been kept secret or that were not public at that point, um, that had the effect of blacklisting these certain topics. The February 21st directive falls squarely within that language.

And second, regardless of what we said in our complaint, defendants put this February 21st directive in the administrative record. So by their actions they've acknowledged that this February 21st memorandum is something that defendants considered or relied upon in reaching their decision. So they can't put that directive in the administrative record and then say it's not part of the case, that's not what the administrative record is.

The last minor point before pivoting to the merits relates to their argument that we lack standing to challenge the rescission of "NOFOs," which are "Notices Of Funding Opportunities" that announce grant opportunities. So defendants, um, haven't challenged the State's standing in general, um, but there's one minor piece, this rescission of NOFOs.

THE COURT: Well actually I have a question on that. What is it that you want with respect to those?

MR. CEDRONE: So just as, um, setting aside the challenged directive means, under the APA, you treat the

directives as if it never existed, because these notices of funding opportunity were pulled down based solely on the directives, um, the notices of funding opportunity should be restored.

THE COURT: I'm a pedestrian thinker, so help me here.

As I understand it -- and if I'm wrong, I want to corrected, the grants that are -- the grants that are at issue in this first phase are grants that had been funded by Congressional appropriation and were proceeding, but because of the challenged directives, were "terminated," um, an appropriate word.

I've got that right?

MR. CEDRONE: I think that's right, your Honor.

THE COURT: All right. And I think I understand that.

But even if the -- what do you expect? Should you prevail on that, I can -- I think I understand what should happen to -- if the challenges are gone, the money is there for this fiscal year, and the Congressional will is clear, they have provided the funds which the NIH has allocated and implemented, as it always has, so what about these NOFOs, um, what should happen?

MR. CEDRONE: Right, so I think there's two

things. One, I think it's largely relevant to the second phase of the case where we're talking about delays, but I wanted to address it today, as it's in the defendants' brief. But I think it's largely more relevant to the second phase of the case.

But the second point is that, um, the government, and the federal government produced a supplement to the administrative record on Friday, and at Page 6960, and the two pages that follow, there's a spreadsheet that lists NOFOs that have been "unpublished," in the language that they've used, with grants corresponding to them. At least some of those grants -- and these, as I understand it, are awarded grants, correspond to the plaintiff states. And we think we have standing, we think this is largely an issue for the second phase. But to the extent that the unpublishing of NOFOs has been a mechanism for terminating grants or part of terminating grants, we think that the Court can set it aside. But it is admittedly a very small part of this first phase, if it's relevant at all.

So turning then to the merits. The challenged directives violate, as we've explained, the Administrative Procedure Act and the Constitution. Let me start with the Administrative Procedure Act.

We obviously go through the various doctrinal

reasons in the brief why the directives are arbitrary and capricious. I think it's easiest to explain by looking at a particular example.

So in the brief we talk about a particular grant that was terminated, at Page 1364 of the record, it's a grant to the University of California entitled "Genetic and Social Determinants of Pharmacological Health Outcomes in Ancestrally-Diverse Populations." And admittedly I'm not scientist, but my understanding of this project is it's looking at how people of different genetic backgrounds might respond differently to pharmaceutical products, in the way it's absorbed by your body, in the way your body processes it, and so on. And that grant was cancelled. The cancellation language is at Page 1369 of the record.

Your Honor is very familiar with this paragraph by now, it's the standard DEI paragraph that reads: "It's the policy of NIH not to prioritize research programs related to DEI," and so on and so on. And ending with, you know, the assertion that "worse so-called 'Diversity Equity and Inclusion studies' are often" -- (Interruption by zoom.) "are often used to support unlawful discrimination on the basis of race and other protected characteristics." It's the same stock paragraph that repeats itself throughout the directives

and throughout the terminations. And what is stunning from the record is the lack of any support beyond those conclusory words.

So first, and perhaps most prominently, there is no definition anywhere in the record, despite repeated requests from this Court, for what the government even considers "DEI" to mean. I think -- I would have thought we could all agree that that term can have positive or, you know, laudable connotations. So the government never even defines what is so-called "prohibited DEI."

But even beyond that, the agency doesn't explain how that language, those conclusory statements, are consistent with statutes that Congress has enacted, very clearly expressing a preference and a priority for advancing research into health disparities, for understanding the health conditions of underrepresented groups. They haven't explained how that language in those conclusory statements are consistent with a strategic plan that NIH promulgated and that Congress requires NIH to promulgate.

And perhaps most, I think remarkably, they -- you know there's some, um, striking factual assertions in there. So that paragraph, as I mentioned, says -- asserts that DEI studies are, quote, "often used to

support unlawful discrimination on the basis of race."

That is a serious charge, and you would expect, with a charge of that magnitude, there would be some explanation somewhere in the record of how the agency came to that conclusion, what it relied on in reaching that conclusion, why it determined that one study, but not another runs afoul of that principle, and there is absolutely nothing like that.

When you strip away the hundreds of termination letters and the challenged directives from the binders that your Honor has in front of you, there is nothing left. And it is hard to reconcile that complete absence of explanation and evidence with the magnitude of the policy changes that the agency has enacted here. That's not what the Administrative Procedure Act requires.

And I would like to linger for a moment, before moving on to the other points on one particular aspect of the arbitrary and capricious nature of the Agency's decision, which is their failure to consider reliance interests.

The Supreme Court has said, again and again, that when an agency is changing its policies, particularly an entrenched policy, it has to consider reliance interests, it has to consider ways that the public and regulated parties have come to rely on the agency's

The Department of Homeland Security against Regents of the University of California, and Cena Motor Cars, SEC vs. Fox. Actually just a few months ago, this term, the Supreme Court reiterated the point in a case called Wages and White Lines --

(Interruption via zoom.)

THE COURT: Where does that come from?

THE CLERK: It's the zoom, Judge.

(Pause.)

MR. CEDRONE: Should I continue?

THE COURT: No, you continue.

MR. CEDRONE: Okav.

So the law is clear. When an agency is changing position, it has to at least consider and grapple with reliance interests. And we have gone through, in the briefing, some of the significant reliance interests that are at stake here.

So particularly close to home, Docket 7745,

"Walking through the Impacts on the University of

Massachusetts." UMass Chan Medical School has laid off

209 employees, it's cut the 2025 graduate program from

70 students to 10. It's frozen all hiring. And a

similar thing for UMass Amherst, rescinding funding from

100 accepted applicants and reducing admissions by half

for its School of Public Health.

And that's not to mention the harm to patients. We walk through in the briefing studies that support patients who are receiving treatment for risk of suicide whose programs have been closed down. We walk through in the briefing the lost data. One example from Docket 7725 is a Rutgers' study, it's a longitudinal study of alcohol abuse among youth and minors. And the declaration detailed how, when a study is interrupted, your ability to recruit participants and track them over time in a longitudinal study --

THE COURT: Don't let me throw you off, but I'm going to stick to the time, and you have about 10 minutes. And I have expressed a concern about straight-out discrimination here, racial discrimination, discrimination on the basis of one's -- how one lives out their sexuality, and possibly, and I'm much less certain about this, possibly discrimination against women's health issues.

Are you going to address any of those? Do you think they bear on this first, um, this first phase?

MR. CEDRONE: We haven't raised an expressed claim of racial or sexual discrimination. I think it's, um -- I think it's hard to look at what the agency has done here and, um, walk away with the view that it's

consistent with not only the values in the Public Health Service Act, which requires, um, thoughtful consideration and the promotion of minority health, um, women's health, and the health of sexual and gender minorities. And so I think that's -- that's the way we have seen it as being relevant to this case, is that not only are there these overarching constitutional and statutory principles and other statutes, but the Public Health Service Act itself states a Congressional priority for advancing the health of underrepresented groups, for advancing women's health, for advancing the health of sexual and gender minorities. And so that last statute in particular is Section 283(p), which we cite in our briefing.

I do not understand -- and that gets beyond the arbitrary and capricious point to the contrary-to-statute point, I don't understand how the agency can adopt these policies that it's adopted in these boilerplate paragraphs consistent with those Congressional policies. The defendants accuse us of trying to substitute our policy judgment for that of the agency? No, what we're arguing is that the agency has substituted its policy judgment for that of Congress.

The agency might believe, and the defendants might believe, as fervently as they like, that, um, that NIH

shouldn't be advancing the health of transgender

Americans, shouldn't be studying, um, you know

disparities in underrepresented communities, they might

believe that very fervently, but Congress chose a

different course in the statute and the agency is

required to carry it out.

And just on the reliance point, just to close out that point. It's important not only to walk through the reliance interests at stake, but the complete absence of any discussion of those interests in the record.

I would have thought that an agency that was taking seriously canceling, um -- banning research into certain topics and canceling projects that flowed from those topics would at least have considered those serious reliance interests and there is nothing to that effect in the record.

The defendants can say, "Well you can look at the termination letters and infer that the agency must have considered reliance interests, because obviously when you cancel a project, people had been relying on it, and they chose to do so anyway." But that is not how this works, that is not what the APA requires. The APA requires the agency actually to grapple with those issues in the record and explain why it's doing what it's doing. And it's a procedural requirement, but it's

not an empty formality. The reason the APA required that is because we think that agencies reach better substantive decisions when they're required to confront the things that they're doing, and they haven't done that here.

In the interests of time, I know I've addressed the contrary-to-statute point, we also argue in the briefing that the agency's decision is contrary to regulation. Um, I'll say on that briefly that obviously an argument that requires carefully parsing through the regulations, the regulatory history, um, the two basic points I would make on that argument is: Number 1, the defendants are arguing that we're trying to turn this into a contract case. It's been clear from the outset that we're not raising contract claims, we're asking the Court to construe a regulation that they invoke and directives that they promulgate. We're asking the Court to decide that that regulation doesn't mean what the defendants say it means. That is the ordinary business of a court hearing an APA claim.

And the second point on the contrary-to-regulation argument that I would leave the Court is, that at the end of the day, when you have all of these arguments walking through the statutory provisions, the regulation, um, cannot mean what the defendants say it

means because it would not be structured and worded and located in that way. They essentially read this regulation to say that an agency can cancel any project, at any time, with no prior notice. And if the regulation meant that, this would be a surprising way to grant that power, to say the least.

We also, as we've explained --

THE COURT: About 5 more minutes.

Go ahead.

MR. CEDRONE: Understood, your Honor.

We've also explained that the challenged directives violate the Constitution and are ultra vires.

Our constitutional claim -- I'll just address briefly to emphasize that --

THE COURT: It's a disfavored claim in light of the breathe of the Administrative Procedure Act, as I understand it, but I'll hear you.

MR. CEDRONE: I understand. And even with that, um -- even with that nature of, um -- even with that said, the one piece that the constitutional claim addresses that the APA claim doesn't is the failure to spend appropriated money. And I just would like to emphasize the constitutional claim and ultra vires claim, before moving on to remedies, that these claims span both phases of the case, we think there's a --

THE COURT: But that gets to the question I posed at the outset. So now, in the 4 minutes remaining, I really want an answer to that question.

Were you to prevail, assume you prevail, at least as to the grants, the NOFOs, we'll see, if that were to happen, isn't it enough simply to vacate the, um, challenged directives as arbitrary and capricious, say they're of no force and effect, illegal, and then, one would expect, that given the landscape, the undisputed landscape here, the appropriated grant-specific money would flow? You'd expect that, wouldn't you?

MR. CEDRONE: We would expect that. Let me explain I think one reason why I think an injunction is still appropriate and one other APA remedy that we're asking for.

So not only, in our view, should the Court set aside the challenged directives under the APA, it should also set aside the termination decisions that flow from it. As you see in the record, the termination decisions use the same boilerplate language, so one should follow from the other.

I agree with your Honor that that relief gets us much of what we are asking for and I agree that one would expect from that, um, would flow an appropriate result. The reason we think an injunction is still

appropriate is that the record, even though it demonstrates an underlying policy, it's been a bit of a game of Whac-a-mole, there are these different directives and defendants -- you know you point to one and defendants say, "That's not the directive that actually encapsulates this policy," so you point to another. And so the injunction gets at the idea that we're challenging these directives, but at its core we're challenging the policy that underlies it. And we think the plaintiffs need, especially given the harms at stake here, prospective relief, not just a set-aside of the directives and of the terminations that have flowed from them.

That's how we understand the defendants are requesting to take cross-examination of the witnesses that support our request for an injunction, so we don't want that piece of the case to delay what we think is appropriate relief that is currently ripe for decision, which is relief under the APA, um, that sets aside the challenged directives and the terminations.

And unless your Honor has further questions, I'm happy to yield the Court to my APHA colleagues. Thank you.

THE COURT: Thank you. And I appreciate it.

25 Counsel?

MR. PARRENO: Good morning, your Honor, Kenneth Parreno on behalf of the APHA plaintiffs.

THE COURT: Yes, Mr. Parreno, I'll hear you.

MR. PARRENO: It's good to see you again, your Honor. I'll be splitting argument today with Ms. Meeropol, um, and transition accordingly.

I want to start by, just very briefly, talking about who our clients are. Our clients are researchers and organizations of researchers who are dedicated to their work.

THE COURT: Well let me ask this question, which may be a little aside the point.

You have supplied, at the Court's direction, a finite list of the grants that we're talking about, very similar to that, um, put forward by the various states, and I've just been hearing about them. Whatever happens in this case -- well were anything to happen favorable to your clients, Rule 52 of the Rules of Civil Procedure require a written opinion. And so this is not -- it doesn't require a written opinion, but eventually in this case there's going to be a full written opinion.

I don't understand why those grants, should you prevail, ought not be listed in an appendix to that opinion? I don't understand why not?

MR. PARRENO: Your Honor, if I may? Ms. Meeropol

will address the remedy, the question of the -THE COURT: Fine. Go ahead.

MR. PARRENO: But we'll address that as well. I thank your Honor for that opportunity.

THE COURT: Yes, go ahead.

(Knocks over microphone.)

MR. PARRENO: Sorry about that.

Is that better?

THE COURT: Yes, go ahead.

MR. PARRENO: So these researchers comprise hundreds of individuals who are working on thousands of projects, some of which are at issue here, benefiting millions of Americans with their work on public health and advancing the scientific effort. That's what was disrupted by the defendants' actions. And I will focus first on the arbitrary and capricious nature of their actions.

Defendants' actions, the directives, both through their development and through their implementation, are arbitrary and capricious for three reasons. First, they do not represent the reasoned decision-making that is required of the Administrative Procedure Act. Second, they are unexplained, about-faced in policy. And third, they do not properly address the reliance interests that are at stake. They don't even consider them, much less

weigh them. I'll start with the reasoned decision-making.

My colleague, Mr. Cedrone, already emphasized the sheer stunning lack of analysis data, evidence underlying the directives themselves. No working definitions. No evidence establishing, for example, so-called "DEI studies" ultimately do not enhance health, lengthen life, or decrease illness. I won't belabor that point, um, for the sake of efficiency, we've argued that in our brief and Mr. Cedrone covered that point. But what I would like to do at this time, as to the reasoned decision-making, is to highlight what actually was in the record and how that further emphasizes the arbitrary and capricious decision-making that occurred here.

First, what is in the record shows a slap-dash decision-making process. What was revealed from a series of e-mails is that often NIH officials would take just minutes to make decisions that affected hundreds of researchers and millions of lives.

For example, and I know that your Honor is familiar -- is familiar with the record, but I do want to highlight a couple of examples to highlight this.

On March 11th, 2025, that's AR 3820, it took Matt Memoli 6 minutes to review 6 grants and to conclude that

all of them aren't aligned with agency priorities.

On May 9th, it took him just 2 minutes to review, quote, "several grants."

THE COURT: "Him" is who?

MR. PARRENO: I'm sorry?

THE COURT: "Him" is who?

MR. PARRENO: I'm sorry, your Honor, that's Matt Memoli, again, at AR 3452. These are just a couple of illustrative examples that reflect the slap-dash nature of how this review is occurring.

And as defendants acknowledge in their own certification in this case, in ECF Number 86-1, these grant files, for each of these grants, are hundreds if not thousands of pages long. It just strains credulity that any meaningful review can occur in a matter of minutes, much less 2 minutes.

Second, what also is in the record reflects that that slap-dash decision-making was in fact encouraged from the top down.

On June 13th, the defendants produced, um, in response with this Court's order on a motion to complete what is at AR 6963. That is a document that was provided to program officers to assess pending grant awards or actions for the purpose of alignment with the directives.

That document, like the rest of the record, reflects no working definitions of these forbidden topics, no guidance on how they actually analyze grants for these topics, and in fact includes the line, which is very telling, where when asked to provide or elaborate on the analysis, the document says explicitly, "No details are necessary." That's what the agency was saying from the top down.

Third, and still in the reasoned decision-making province, is that officials outside of NIH were calling the shots here. What's clear from the record is that the directives themselves are explicitly spelling out a process where HHS is directing and identifying these terminations, so that NIH officials are in turn just rubber-stamping them, not providing any review, and in fact are required to issue termination letters.

For example, on March 25th, the revised priorities directive at AR 3220, highlights that point, as does the May 7th directive at AR 3554.

In addition to that, the drafting and implementation of the directives also reflect this same sort of outside influence. Individuals outside of NIH were charged with identifying these grants, um, and that included individuals at HHS, for example, Rachel Riley, um, and in the record as well some individuals from the

so-called "Department of Government Efficiency," and that includes an individual named Brad Smith, and that's at AR 3752.

The point here is this isn't the sort of reasoned decision-making that we would expect and is required under the APA, what this is is a slap-dash harried effort to rubber stamp an ideological purge. That is not what the APA requires.

THE COURT: Well when you say an "ideological purge," what do you mean?

MR. PARRENO: What I mean here, your Honor, is that there had been statements in their directives that had been put out in a conclusory and boilerplate manner with no evidence and no data backing them up. What's missing here is that sort of reasoned analysis that is required of the agency.

Second, and I'll briefly discuss, um, the about-face nature, because I believe Mr. Cedrone addressed, in great detail, the reliance interests at stake.

So this is an improper about-face in agency policy. The issue here isn't that an agency can't change its policy, it's that the APA imposes specific requirements for such a change, especially where, as here, there are underlying facts that, um, contradict

the new priorities or policies.

So when defendants, in their briefing, are talking about this just boiling down to a policy-interest disagreement, that's just plain disingenuous, the issue here is that there's no explanation for why there was this about-face. Defendants are right, there needs to be an assessment and a reassessment, but there is neither here.

And in the interests of time, I will just turn very quickly to one question of jurisdiction, before turning this over to Ms. Meeropol. My, um -- Mr. Cedrone has made a number of points in the jurisdictional issue that we join as well, and it's highlighted in our brief, but I would like to emphasize that we still maintain that appeals of grant terminations do not strip this Court of its jurisdiction.

The terminations that were made pursuant to those directives and the directives themselves are final agency actions that are the consummation of decision-making and have legal consequences. And importantly, what the record shows repeatedly from these termination letters is the sheer utility of these terminations -- of, sorry, the appeal process of these terminations.

THE COURT: And in fact the letters themselves frequently say "No correction is possible," as I read it.

Is that correct?

MR. PARRENO: "No correction is possible," your Honor, and "The premise of this grant is incompatible with agency priorities," and "No modification of the project could align it with agency priorities." If that's not futility, your Honor, I don't know what is.

So I'll go ahead and -- and if there's no more questions about these two issues, your Honor, I will go ahead and turn it over to Ms. Meeropol, who will address the remedy issues.

THE COURT: Thank you.

Ms. Meeropol.

MS. MEEROPOL: Thank you, your Honor, Rachel Meeropol from the ACLU.

I want to cover the APA plaintiffs'

contrary-to-law claims, the withdrawal of funding

opportunities, and the scope of vacatur. Based on your

Honor's questions so far this morning, I'd like to

actually start at the end and talk about vacatur first.

THE COURT: So would I.

Go ahead.

MS. MEEROPOL: Perfect.

So I agree with the way my colleagues from the states have largely framed the issue, I'd like to take a minute to talk about exactly what the scope of vacatur looks like, um, should your Honor choose to set aside agency action.

Setting aside agency action is an indivisible remedy, and that means it necessarily benefits nonparties. If the Court finds that the directives --

THE COURT: Wait a minute. Wait a minute. It may have implications, but I've been clear from the beginning, that's why I wanted this list of grants.

Suppose that's right -- I misspoke. Forgive me.

At best -- at best you're here, you've listed these grants. If I accept these various arguments -- and we're just talking Phase 1 now, and I declare all of these directives, um, arbitrary and capricious, void and of no effect, this is -- I -- this is the United States District Court, that has an effect on these litigants who have standing who have challenged these grants.

Now once judgment enters under the -- the judgment -- again assuming that you're winning here -- and don't take anything from that, but assume that. If you win here, that's the judgment, because I -- either way I propose to enter a judgment on Phase 1 just as soon as I can to allow an appeal. So that -- well, um,

others who haven't sued, who haven't challenged their grants, may well have to deal with the defendants in other cases.

Is that legally incorrect?

MS. MEEROPOL: Your Honor has discretion to scope -- to design the scope of relief in this case just as you put forward.

THE COURT: All right.

MS. MEEROPOL: But give me 5 minutes for me to attempt to convince you --

THE COURT: Go ahead.

MS. MEEROPOL: -- that you may issue an order that is larger in scope. And here is why.

THE COURT: Go ahead.

MS. MEEROPOL: So first I would direct your Honor to Justice Kavanaugh's concurrence in *Corner Post* where he lays out the history of how the Supreme Court has, um, looked at what it means to vacate or set aside an agency action, and the degree to which even when individuals who are not before the --

(Interruption zoom.)

MS. MEEROPOL: -- even when individuals are not before the Court, they sometimes reap the benefit of setting aside that agency action, and that is because 7062 is authorization by Congress to set aside the

agency's action that is far broader in scope than what we think of as an injunction or sort of the concerns that we've heard from courts recently about possible nation-wide injunctions.

So if we look at the precedents that we've cited in our cases. Um --

THE COURT: I want to follow your argument, because I'm interested in it.

You're saying this is not a nation-wide injunction issue, this flows from the Congressional intent -- and you've cited a Supreme Court case, in passing the APA, the statute which governs here?

MS. MEEROPOL: That's correct, your Honor.

MS. MEEROPOL: Yes, we can look at the language of 7062 itself, which says to set aside agency actions that are arbitrary and capricious or contrary to law.

THE COURT: And that's the basis of your argument?

Looking at the leading D.C. Circuit case, um,

Allied Video v. U.S. Nuclear Regulatory Commission on

the question of whether a remand about vacatur is

appropriate, which is not an issue presented in this

case. When the D.C. Circuit actually looked to create

the, um, the various factors that courts should consider

about whether to remand about vacatur, one of the

factors was how disruptive is this decision going to be?

And the Court, in deciding in that case that vacatur would be too disruptive, said that's because vacating this rule would require the agency to refund all the fees it had collected in that case, not just the fees of individuals who were before the Court, but all of the fees.

The APA allows agency action -- allows the Court to set aside agency action that is unlawful and stops, and the Court is empowered through that, not just to set aside all of the unlawful terminations that our clients and a number of our client organizations have put before the Court, but that -- but if you look at how the Ninth Circuit has put it, "Agency action that" --

THE COURT: I'm not sure that -- wait a second. I just want you to use your time effectively, because I'm responsive to this argument.

MS. MEEROPOL: Yes.

THE COURT: Assume you win, as to these grants, et cetera, and you win in the manner that Mr. Cedrone, um, framed it, that the directives are declared arbitrary and capricious, have no force an effect, in essence are illegal, as are the terminations to these contracts -- to these grants, not contracts. All right, suppose that. Now -- and that's as far as we go.

I'm sensitive to the fact that this is an equity

case, that's why there's no jury sitting there, and whatever I do in a written opinion, or conceivably however I express myself today, or in the near future — and I say this with respect, you people aren't going away, we're going to be back here. Isn't that an issue that I need not reach today? But you're not giving it away if you answer "Yes." So as I would say, if it was a trial, "Your rights are saved." Well it is a trial, but if it was a jury trial.

Do you hear what I'm saying?

MS. MEEROPOL: I do. I do, your Honor. You need not reach it. My point is that you are empowered to reach it. And that is because agency action that is taken in violation of the law is void, it has no legal impact, and this Court can set aside all the actions that flowed from the directives.

And that's a good segue, if I may, because I see that I'm already short of time and I do want to make sure to talk a little bit about the withdrawal of funding opportunities. Unless your Honor wants to talk more about vacatur?

THE COURT: No, no, only on the part that I pushed back on him, on Mr. Cedrone. He says, "Look we live in the real world," he says "Now, if you're going to enter judgment on this part -- win or lose, if you're going to

enter judgment, if it goes our way, we want an injunction in the real world." And I'm saying, "Well wait a second, once I've explained the law, you know one can presume" -- I always did back when I was a Superior Court Justice and the executive was the Commonwealth of Massachusetts, I rarely entered an injunction -- and Mr. Cedrone, coming from that office, can go back and check, because once you've told them what to do, they'd appeal of course, and I welcomed it. But they do it. And he says, "Well, real world, Judge, that's not going to happen today, we need an injunction."

But what I'm asking you. If I were to stop short of an injunction, but, well, you win otherwise -- maybe not as far as I'm listing here, but for today, if that were to happen -- or when I get myself together, um, if that were to happen, um, don't you think they'll follow a reasoned opinion?

MS. MEEROPOL: I would hope so, your Honor.

THE COURT: Well more than that, you'd expect it.

MS. MEEROPOL: I would expect it last year, I don't know if I would expect it this year.

THE COURT: Well let's be clear, I do expect it.

Well enough on this, I do expect it. If that were to happen, I expect it. And again, nobody's going anywhere.

MS. MEEROPOL: We certainly aren't, your Honor.

THE COURT: Suppose it doesn't, we'll all be in this courtroom again and then I'll have that record before me. But that's not for today.

Go ahead as to what you want to cover.

MS. MEEROPOL: Um, before I move off vacatur, I would just ask your Honor to look at one of the cases we've cited in our briefs, um, Montana Wildlife

Federation vs. Holland, which is a case where the Court vacated a Bureau of Land Management policy around oil and gas leases, and then vacated all of the leases under that policy, not just the ones belonging to the parties that were before the Court. In fact the lease owners weren't before the Court at all, it was individuals challenging those leases who were before the Court.

And now I'll move on to the withdrawal-of-funding opportunities. I want to be clear on what we're challenging here and what we're not, um, because our perspective on this is slightly different than what I think we've heard so far this morning. And that's because the withdrawal-of-funding opportunities had several different legal consequences here.

First, the withdrawal-of-funding opportunities require -- the directives themselves require unpublishing these massive numbers of funding

opportunities, and they also require terminating multiyear grants by prohibiting noncompetitive renewals under
the unpublished notices of funding opportunities. And
we cited cases in our briefing, um, most notably *Policy*and Research LLC, which explains that a failure to
provide a noncompetitive renewal is tantamount to a
termination and must be reviewed by the Court in the
same way. And finally, because of the unpublishing, the
directives prohibit the award of new grants under
unpublished notices.

THE COURT: But that leads me to this. What is it you want me to do beyond declaring the directives and these non -- to take down these opportunities, void and of no effect, what more? Yeah, that's my question.

MS. MEEROPOL: Unwind all of the implementation of the directives. Require that NIH republish the funding opportunities that were unpublished in an arbitrary and capricious manner. Require that NIH vacate the terminations that occurred under those unpublished notices-of-funding opportunities through the failure to award competitive renewals. And order NIH to act on the applications that were pending before it when it unpublished the notices-of-funding opportunities.

THE COURT: Well if the bar to action is removed, isn't that what we've been talking about, one expects

they'll go on and do what they're supposed to do, which is act.

MS. MEEROPOL: Well certainly the regulations require them to do so. The regulations require that they evaluate every application that has been submitted taking into account scientific merit and through the peer-review process. But they have not done that for each of these unpublished, um, notices-of-funding opportunities. They haven't denied the application. They haven't delayed the application.

THE COURT: It's undisputed. It's undisputed, the record, of what's happened. Yes.

So again, suppose the directives are void and of no effect, suppose that, and, um, I agree with you, suppose these, um -- the effect of requiring competitive review year by year stifles multi-year grants, I understand that, so suppose I knock that out, um -- just suppose it, then things will go on, won't they?

MS. MEEROPOL: Yes, but in the interest of absolute clarity and to ensure NIH takes the steps it is regulatorily required to take -- and it is not doing so right now, despite the regulations require it, we think in the interest of ensuring that --

THE COURT: Well it's not doing it now because it's following the directives that, as we stand here

today, are in effect.

MS. MEEROPOL: Yes, that's certainly correct, your Honor, and certainly vacating the directives is the most essential component of the relief that we are seeking under the APA here. But the agency may need to be explicitly told that vacating the directives means unwinding all ways in which the directives have been implemented, and that includes their unpublishing of funding opportunities and their refusal, in violation of the regulations, to act on those applications through the peer-review process, through an evaluation of their scientific merit.

Now if I may, your Honor, I'd like to turn to our contrary-to-statute arguments briefly. And here, um, I would just start by saying that, you know, it is clear that Congress has mandated that NIH increase diversity in the biomedical research field, and that excludes through NRSA training grants and early-career investigator opportunities. So I want to highlight, um, a stark take away from the briefs and the record.

THE COURT: And the statute is the PSHA?

MS. MEEROPOL: The PSHA, but also, if you look at 288(a)(4), that sets forth, um, NRSA training requirements, and 283(0)(b)(2) talks about recruitment, um, in the context of early-career investigators.

THE COURT: These are statutory requirements?

MS. MEEROPOL: Statutory requirements, yes, your Honor.

THE COURT: Thank you.

MS. MEEROPOL: As we explained in our opening brief, every single program created by NIH specifically geared to increasing the diversity of the biomedical research field has been terminated.

THE COURT: 5 more minutes.

MS. MEEROPOL: Thank you, your Honor.

Because I have 5 minutes, I want to make sure I say one thing and then I'm going to come back to the statute, if you'll bear with me here.

THE COURT: Sure.

MS. MEEROPOL: I do want to say that defendants have challenged standing only with respect to the withdrawal of the notice-of-funding opportunities. And, um, on the other hand, they have never challenged the standing of our individual plaintiffs. But we have an individual plaintiff, Ms. Dee Mathis, who has explained that she applied for a mosaic grant, which is one of these unpublished opportunities, and she explains how -- because the opportunity was unpublished, even though she knows her application was reviewed, she never got the benefit of that review, and she's had no action on her

application.

So I just want to be clear that, to the extent their complaint about standing is about the failure to provide an individual who has, um, applied for one of these opportunities, we very clearly have one of those individuals.

Moving back to contrary-to-statute. We explained, in our opening brief, that every single program created by NIH specifically geared at increasing diversity has been cancelled, while the training programs that don't focus on increasing diversity have been retained. And the administrative record your Honor has just received bears this out.

I could read the record cites right now of a case that would be helpful to your Honor, because we weren't able to put that into our briefing, um, but I'm conscious of time, so I'm going to base that on -- your Honor told me not to, so I won't do it.

So, for example, the mosaic grant cancelled at AR 4309. The Mark program cancelled at AR 3741.

THE COURT: Just so you know, I'm not saying don't do it.

MS. MEEROPOL: Okay.

THE COURT: No one's going anywhere, no one has precluded post-hearing submissions.

MS. MEEROPOL: Should your Honor --

THE COURT: We talked about our procedure. You say -- the point you're making is the conclusory point, every single program designed to address or increase diversity is cancelled. That's what you're saying?

MS. MEEROPOL: That's what I said, and they have not disputed it, and the record bears it out. But we would also appreciate the opportunity, if it would aid your Honor, to provide a list of the citations for the new record.

THE COURT: I have not told you not to.

MS. MEEROPOL: Okay.

Finally, NIH also must prioritize research into health disparities and minority health issues.

Defendants insist that they're only prohibiting DEI, that they still fund health-disparities research. But the record shows that a grant about cervical cancer screening and follow-up delays among Latinos was terminated as being --

THE COURT: But Mr. Cedrone made the point that at least at the time of this action, DEI was nowhere defined, isn't that right?

MS. MEEROPOL: That's correct. And we know from the way they're implementing the directives, that NIH understands DEI to include medical research into who

bears the burden of disease in this country, which is precisely what Congress has mandated for research. They are targeting here exactly what Congress has required them to research.

And your Honor asked about the degree to which there's discrimination happening here. And I do think it is through the contrary-to-statute claim argument that your Honor can get at the way research that, um, is essential to ensure minority health -- not just majority health in this country, is being terminated.

If your Honor has no further questions, I'll sit down.

THE COURT: Thank you.

Mr. Ports.

MR. PORTS: Thank you, your Honor. Tom Ports from the United States Department of Justice.

Your Honor has asked some very practical questions and, um, defendants would like to walk through the case in a practical manner, and we believe that doing so leads to the conclusion that we should win. And so I'll walk through in five steps along the lines of what I think the Court will want to address and what it has shown interest in.

So the first thing that needs to be determined is what is the final agency action? We say it's the grant

terminations, they say it's something else, and that could be a couple of things, and we'll talk about that first.

Second, what was the agency's reasons for the terminations? Everyone agrees these are laid out.

There are a finite number of them. We've walked through them in our briefs. We say they're sufficient. They say they are not. And we can talk about that.

The question is -- or third, do those reasons analyze, examine the pertinent evidence, consider the relevant factors, and articulate a satisfactory explanation, including a rational connection between the facts found and the choice made? We believe it does.

Moving on to four. Assuming we survive those reviews, have plaintiffs proved that it's, for some other reason, in violation of the statute or regulation?

And then the last, if the Court nonetheless determines the defendants lose, what exactly should the order do here? And address remedy.

Starting at the top, which we believe is very very important and underlies the Court's questions and what the Court was driving at, um, if your Honor doesn't mind, we have printed each of the 8 so-called "challenged directives," we have them in a binder, and for convenient reference we think it's helpful to look

at each of them, um, because that's -- well it goes back and forth. There are, I guess, three ways to look at the terminations here -- or four really.

One thing as, um, I think the state plaintiffs are most explicit in saying, is the challenge here is to the agencies selecting a policy, setting a priority, a research priority. So that's Number 1, is just they challenge the agencies setting up research priorities that they don't agree with, and they think that it --

THE COURT: Well that's not how they frame it.

MR. PORTS: Your Honor, it's been a few different things. I believe Mr. Cedrone said that they're not necessarily challenging these 8 challenged directives, they are challenging, quote, "the underlying policy," "the underlying research priority decision," and that is exactly what Mr. Cedrone said, and that's one way to look at it. So we can look at these 8 documents or we can look at the challenge to the research priority. We think both of those would be inappropriate and we'll explain why.

Other options? I guess there's two more. We can look at the e-mails directing terminations that have a -- that collect a series of grants. Now those are directives to terminate. And then we have what we believe is the true final agency action, the

terminations themselves. This meets Stephanie Spears' two-prong test that represents the final decision of the agency, is the consummation of the decision-making process, and it has legal effect to terminate the grants. So that is what defendants believe you're ultimately looking at and these are listed on the spreadsheets the plaintiffs have presented here.

So starting at the top. These so-called "challenged directives" do not meet -- unlike the terminations don't meet the Stephanie Spears' test.

(Interruption zoom.)

If we look at Tab Number 1, the first tab, this is a policy directive. It says "Stop sending out miscommunications until the presidential appointee or some political appointee has reviewed a new publication." This is standard. It happens when a new administration comes in. It ended before the lawsuit.

We don't think this is a challenged directive that they care about so much here. Now it did lead to delays, we acknowledge that, and because meetings were cancelled for a time, meetings have since restarted.

Defendants mentioned in the status conference that we would ask the Court to take judicial notice of the Federal Register notices that we have cited that, um, say so. We have physical copies of those for all the

parties, if the Court would like them, otherwise they are cited in our brief, and they're simply Federal Register notices saying that NIH has scheduled meetings. So if the Court would like these --

THE COURT: So the record is clear, I'm prepared to take judicial notice of the Federal Register --

MR. PORTS: Thank you, your Honor.

THE COURT: -- that the Federal Register says what it says.

MR. PORTS: Yes, your Honor, thank you.

Moving on to the second so-called "challenged directive." This is the February 10th Secretarial Directive on DEI-related funding. It expresses a policy preference and it implements a review. It says "grants may be terminated."

So here we do know that NIH is setting a research priority preference and it's conducting a review. It hasn't made any decision to terminate -- well this document does not terminate or direct any terminations, that is not in here, it's conducting a review, we don't believe that to be final.

Next is the February 12th directive. This is the first so-called "Lauer memo." This directive says, based on various injunctions and Court orders, you know "Follow those directives, follow those orders, resume

issuing grants, and just make sure everything proceeds without -- without respect to, um, research priorities."

There's no harm from this directive to plaintiffs, this is not something that they, um, that we've been saying they could challenge and try to set aside.

The next document, Number 4, Challenge Directive

4, February 13th, it's a supplemental Lauer memo. This
says they're, um, "restricting funding where a program
takes part in DEI, which is to remain in place until the
review's complete." So again, this doesn't terminate
any grants, it places a temporary restriction. It was
subsequently terminated. This directive here was
superseded, this is no longer in effect. Instead, um,
it's been replaced and rescinded. So that is no more.
It didn't direct terminations in the first instance and
it has been rescinded regardless.

Number 5, we reach the February 21st, Dr. Memoli memo. This one expresses a need to ensure that NIH is not supporting low-value and off-mission projects. It does express a research priority.

THE COURT: It does not define "DEI"?

MR. PORTS: No, your Honor, it does not. And I'll touch on that in a moment.

It ultimately says that programs that do not meet priorities may be terminated. Similarly this directive

does not direct anyone to enter any terminations.

Moving on to Number 6. Importantly, before we move on to Number 6, it's important to note here that terminations occurred. Dr. Memoli directed the terminations after Number 6 -- or after Number 5, I apologize, and before Number 6. So after his memo, before any of the Bulls guidances started. So there are three guidances on -- signed by Michelle Gould and the terminations occurred before that.

So to the extent that any of these three are the challenged directives, terminations that preceded them cannot be affected by these. And we'll note that nothing before this had said "You must terminate anything," they just expressed priorities sadly to terminate and the termination occurs by an e-mail directive attaching a list of grants.

Looking at the Bull's directives.

MR. PORTS: Yes, your Honor, we're on Number 6.

This is labeled March 20, 2025. It's the first Bulls guidance. And it walks through not issuing a solely -- a grant solely based on a deprioritized filing and how -- well, first of all, it rescinded the February 13th

THE COURT: Well where are we now? We're at 6?

memo. But it walks through priorities on what to do to

adapt to make sure that research products that have

scientific value, in the judgment of NIH and its priorities, should be able to continue, while removing parts that, um, that NIH does not want to fund. And it is not directing any terminations, this is an entirely prospective guidance about future grants.

Number 7, the second Bulls guidance. This one here refers to essentially the language and other things and they refer to -- essentially Dr. Memoli made a decision, sent terminations, and this talks about the language to use when implementing the terminations, which are a separate directive from Number 7. So again this isn't telling anyone to terminate things, it's just saying "Where we have a decision, this is what to do."

And, um, the third of those Bulls guidances,

Number 8, um, this is -- it suffers the same problems as
the first two. So this one isn't helpful.

If we turn to the most --

THE COURT: I don't understand what you just said about 8?

MR. PORTS: I apologize, your Honor.

This is similarly not final, it does not direct any terminations, it's involved in a review, it's involved in like the agency's management of its process, so the terminations are --

THE COURT: So where do these thousands of the

terminations come from? 1 MR. PORTS: These terminations actually were made 2 3 by Dr. Memoli, your Honor. I get there's two -- the termination decisions are made by Dr. Memoli attaching 4 5 THE COURT: All of the ones we're concerned with 6 here? MR. PORTS: Any termination, yes. 8 THE COURT: All right. 10 MR. PORTS: So that if the challenge is to not 11 issuing a grant, issuing a future grant --12 THE COURT: And he did that over a short period of time, didn't he? 13 14 MR. PORTS: Your Honor, the plaintiffs do 15 challenge the amount of time that he took to actually review these spreadsheets after receiving them and argue 16 17 that that is arbitrary and capricious. And that is, we would say, your Honor, a question, a challenge to the 18 19 termination, the e-mail termination, whether that was 20 arbitrary and capricious, which is separate from the 21 research priority. And that is a more narrow ruling and 22 is appropriate -- is more appropriate to review than a 23 broader policy statement of what NIH will prioritize or

THE COURT: Wait a minute. Okay, now I'm

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will not prioritize.

appreciating your argument, and I want to appreciate it. Here's what I heard you just say.

If this Court were to vacate certain terminations or all of the terminations based on the conduct of Dr. Memoli, that result, from your point of view, is preferable to an opinion that takes issue with these challenged directives on the ground, as I hear your argument, that they either don't direct the terminations or state policies of HHS and NIH, which are beyond the purview of this Court, they have the right to their policies.

Do I understand?

MR. PORTS: Yes, your Honor. We're moving down a funnel essentially from a very broad statement of "These are policies" and then you have the e-mails directing terminations, and then we have the actual final agency action that represents the consummation and the agency's reasons, which are the termination letters which are sent pursuant to that e-mail. And so we believe that it's the letter that is the termination and it's the notices of awards that are amended that represent the final agency action.

THE COURT: So this Dr. Memoli, when he scurries around and does whatever he does, he does that, I take it -- but I have to review the record more thoroughly,

he does that pursuant to e-mails, right? 1 MR. PORTS: 2 Um --THE COURT: I mean where does he get his direction? 4 MR. PORTS: The decisions to terminate grants were 5 Dr. Memoli's decisions, is that what you're asking, your 6 Honor? He's making the decisions based on --THE COURT: I'm asking how it works, as a 8 practical matter, as an existential matter? 9 10 MR. PORTS: The record here shows that Dr. Memoli 11 received these lists of grants --12 THE COURT: That's a careful answer, but I'm 13 asking you -- to the extent that you know, and you're an 14 Officer of the Court, as a practical matter, how did we 15 get from these challenged directives to these -- and I'll focus just on the terminations that are before this 16 17 Court, and if it's Dr. Memoli who did it, what was he looking at when he made those determinations? 18 Beyond 19 the grants themselves, what instructions was he looking I'll ask that. 20 at? What was he looking at? 21 22 MR. PORTS: Sure, your Honor. 23 So to -- to answer the question as to the 24 challenged directives, how do we get from the challenged

directives to Dr. Memoli's directive to terminate grants

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that are attached to the e-mails? I will say, first of 1 all, that the last three challenged directives, 6, 7, 8, 2 the Bulls directives, they have nothing to do with Dr. Memoli's directive to terminate, these are sort of 4 5 instructions to ICs about their reviews and about any 6 future grants to --THE COURT: "ICs" are who? MR. PORTS: "Institutes and Centers." NIH is 8 divided into --9 10 THE COURT: Understood, they're the various 11 defendants here. 12 MR. PORTS: So these last three have nothing to do with that. 13 14 The February 21st Memoli memo states his 15 priorities. And now as far as the -- the details of --THE COURT: Well that's an order, isn't it? 16 17 MR. PORTS: It is a statement of his priorities 18 and a statement of things that may be terminated 19 pursuant to them, but it doesn't terminate anything, 20 it's a statement of research priorities, your Honor. 21 THE COURT: Which goes out to the various subinstitutes, the ICs? 22 MR. PORTS: Yes, your Honor, it informs them of 23 24 Dr. Memoli's priorities and states that they may be 25 terminated and --

THE COURT: And he's the man, I mean he's the -in a bureaucracy, he's the one who's giving the
directives?

MR. PORTS: He is the Acting Director of NIH, your Honor, yes, he has that authority.

THE COURT: I see.

MR. PORTS: And then the directives are sent -the determinations directed to terminate are sent by
him, they are his decisions, um, and that is my -- that
is my understanding, as an Officer of the Court, of the
statements. And otherwise the details of his review and
what he did, I can't speak beyond the record.

THE COURT: And I'm not asking you to. The record is what it is, the timing and the like. And I thank you.

Go ahead.

MR. PORTS: Um, thank you, your Honor.

So that was the -- what is the program. But what is the challenged -- if the Court is setting something aside, holding something to be arbitrary and capricious, that is, getting towards "What could be that be?"

Again, the defendants submit it is the ultimate terminations of, um, grants, not anything earlier, because all of the earlier things are --

THE COURT: I understand. You've made that point.

MR. PORTS: Thank you, your Honor.

Next we address what are the agency's reasons in any given termination?

As the parties recognize, there are a handful of reasons why Dr. Memoli directed the termination of grants. The language is provided, that is provided in each grant termination decision. And, um, we in our briefs walk through why we believe it doesn't meet the arbitrary and capricious standard.

And we will start by saying the standard of arbitrary and capricious, there is a presumption that it is valid. It need only be reasoned. A Court will uphold a decision of less-than-ideal clarity if the agency's path is discernable. And in our -- in our brief, um, we --

THE COURT: Looking at these letters, and I've looked at many of them, they're ipse dixit, there's no support. The action must be both reasoned, as I understand the controlling law, reasoned and reasonable. And in an earlier hearing I asked -- I looked at some of this conclusory language and I said, "Well I didn't understand that."

Is that so, that they are not, um, leading to valid results, they're not expending the money correctly? How do I know that? I know they say that.

MR. PORTS: 10. 1 THE COURT: And on Page --2 3 MR. PORTS: 10, which is 3226. THE COURT: Thank you very much. I'm on Page 10. 4 5 MR. PORTS: And just looking at the second bullet 6 point, your Honor. Now it does not say "Terminate DEI grants," and leave it without definition, the agency's stated reason 8 9 is, quote: "Research programs based primarily on artificial and nonscientific categories" --10 11 THE COURT: No, it doesn't say that, it starts saying, "DEI," and then your point is there's a colon? 12 13 MR. PORTS: Correct, your Honor. THE COURT: All right, I follow. I'm reading it. 14 15 MR. PORTS: "Research programs based primarily on artificial and nonscientific categories, including the" 16 17 18 THE COURT: Yes, and it has the language which so many of these -- go down to the sentence, "Worse, 19 20 so-called 'Diversity Equity and Inclusion,'" and then 21 comes the dread quote: "DEI are often used to support unlawful discrimination." Where's the support for that, 22 any support, any rational explanation? 23 You see I do understand. Believe me, I understand 24

that the extirpation of affirmative action is a -- is

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today a valid government position. I understand that. 1 Affirmative action had various invidious, um, calculus 2 based upon race. I understand that. But that's not a license to discriminate. 4 5 So I'm asking you, just explain to me, um, "often used to support unlawful discrimination," I see no 6 evidence of that? I mean in this record, point me to 8 anywhere in this record where it's pointed out that any 9 particular grant or group of grants is being used to 10 support unlawful discrimination on the basis of race. 11 From what I can see, it's the reverse. But, um, point 12 it out to me. 13 MR. PORTS: Thank you, your Honor. Beyond the 14 statement here, I -- there's nothing that I can point 15 the Court to as far as --16 THE COURT: I understand. All right. So that's 17 as close to a definition as we've got? 18 MR. PORTS: That is the agency's reasoning. 19 THE COURT: I do understand, that that's what's 20 proffered. 21 Go ahead. 22 (Pause.) 23 Thank you, your Honor. MR. PORTS: 24 Now moving on to the fourth topic then, the

terminations do not violate laws or regulations.

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the plaintiffs -- first of all, if the Court determines that these are arbitrary or capricious, or an abuse of discretion, there's no need to reach this question. But if the Court were to reach the question, um, we find the regulation does not violate -- the terminations don't violate the regulations because the, um, the relevant regulation, 45 CFR 75 at 372 is --

THE COURT: I'm more concerned -- actually forgive me for interrupting, but just to be transparent.

With respect to the interpretation of the regulations, I've got to reflect on the particular challenged regulation and the like. But how much is the statutory language that Congress has used? Don't -- don't these directives, and isn't the practical effect of these terminations flat-out violate what Congress, the people's representative, has, um -- who have enacted it into law, don't they violate it?

MR. PORTS: Respectfully, your Honor, no, they do not. And we'll start with, um, here plaintiffs have — at least the APHA plaintiffs, as we say in our response brief, admit that in order to construe these terminations as prohibiting research into health disparities, they need to be "recast," that is the word they use. And research into health disparities? NIH has renewed research into health disparities, including

research that requires that the researchers themselves be members of the health disparity communities.

And so we would submit, and I state it as well in the hearing, that the defendants intended to offer, um, examples of 13 grants that NIH has not terminated, that many of them have been renewed after the challenged directives that authorized research into health disparities, minority-related health, and topics along those lines. That, we would submit, clearly cannot be what the intent is here and that none of these laws --

MR. PORTS: To unlawfully discriminate, in some sort of way, um, is the -- is the question that was the concern.

THE COURT: What cannot be what the intent is?

THE COURT: The fact that you have allowed and reinstated 13?

MR. PORTS: I apologize, your Honor?

THE COURT: Is that what you -- is that your argument? I'm trying to understand. The fact that you've reinstated 13?

MR. PORTS: Well, your Honor, these are examples of other grants that have been renewed after the challenged directives that authorized research into health disparities and required that members of the health disparity community be researchers. And so the

assertion that this is a prohibition on that type of 1 research, which is favored by certain statutes, is 2 factually incorrect. THE COURT: But you agree that it's favored by 4 5 certain statutes. It's favored? It's required. It's not "favored"? 6 MR. PORTS: Well respectfully, your Honor, we would look at the statutes and I would argue that the 8 9 language and the terminations do not violate the 10 statutes. 11 So to take an example, um -- looking at the statutory language. So -- but before I do that, your 12 13 Honor, I would like to move into evidence, um, certified 14 records of the notices of award. 15 THE COURT: Well could you answer that question? You were about to and I'm very interested in the answer. 16 17 MR. PORTS: Yes, your Honor, I just didn't want to forget to --18 19 THE COURT: The statutory language. 20 MR. PORTS: Yes, your Honor. 21 So I'm looking at Page 26 of the States' brief, that's 126, it uses the language here: 22 23 "Challenged directives prohibiting research 24 related to gender identity runs headlong into a

provision instructing the NIH Director to, quote,

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'encourage efforts to improve research related to the health of sexual and gender minority populations,' 42 USC, Section 283(p)."

And I'll note that that is the section that -- my example is the section that the States called out in its opening remarks.

If we look at the -- if we turn back to the document that we were looking at before, Tab 8, Page 10, 3226, "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's the policy of NIH not to prioritize these research programs."

Your Honor, this statement here about the terminations is, in the judgment of NIH, "Improving research related to the health of sexual and gender minority populations." It is the judgment that this research is not -- is not scientifically valuable, and it is --

THE COURT: Wait. Wait a minute, please. And I'm truly trying to understand.

You just quoted to me, and I believe accurately, the statute, where you started, quote, "Encourage

efforts," and then you jumped from there to this language in your Tab 8, Page 10, which I'm looking at.

MR. PORTS: Yes, your Honor.

THE COURT: And you say somehow the language in Tab 8 encourages these efforts that Congress has required?

MR. PORTS: Your Honor, the key language is "to improve research." And this is a judgment that this research, although arguably related to sexual and gender minorities, is not good research to pursue.

THE COURT: Despite what Congress has said?

MR. PORTS: Your Honor, respectfully Congress has not said that research programs based on gender identity, it's not what this says, it says "improve research related to the health of sexual and gender minorities." And this -- the Secretary or the Director of NIH can make a judgment on what is an improvement of research and what is research that is not worth pursuing. And by not pursuing research that --

THE COURT: So Congress has -- in other words, I recognize that legislation is difficult, and it is, it's a difficult government endeavor, and so because of the language they have used -- of course the Congress has never dealt with an administration that has taken the positions that this administration has. So, um, they're

writing in a different milieu, I suggest to you.

But "encouraged efforts," you think that mandate

-- I read that as a mandate of the people's

representatives assembled in Congress, and they have now

made that law. The Director has decided that, um, in

his judgment, um, that this is not, um -- I want to be

fair to the specific language, he says, it's his

judgment that "Such, um, research, um, does not," I take

it, Dr. Memoli, in his judgment, um, "is not valid

research."

Is that correct?

MR. PORTS: The key language, your Honor, in the statute is to "improve research," and that leaves a -that leaves a great deal of discretion to HHS and NIH to say what is "improving research." And this is not valuable and it's a --

THE COURT: Thank you. Thank you, that answers my question, it's that language -- Congress's mandate, you point out, is to "improve research." And he decides this doesn't improve research?

MR. PORTS: Yes.

THE COURT: But it's not explained anywhere, um, how that's so, um, beyond the edict here? Correct me. It isn't explained? It's a judgment, but it's not explained?

MR. PORTS: Your Honor, I have nothing beyond the agency's stated reasoning for the termination.

THE COURT: Thank you. Understood.

Go ahead.

MR. PORTS: Moving on to other topics, um, immediately following that. This is the next line from the States' brief:

"The aspects of the challenged directives, the States' characterization of blacklisting research related to covid, cannot be squared with the statute mandating the NIH Director to advance the discovery and preclinical development of medical products for priority virus families and other viral pathogens with the significant potential to cause a pandemic."

First of all, your Honor, I'll note that, um, although I have not reviewed all of the recently-filed list of grants, at the time that we were writing a response brief, based on the initial list of grants, we didn't have any terminations for covid research. APHA said in their reply that they did. I would respectfully say that's mistaken, although a couple of them said "covid" in the name of the grant. The reason given by NIH for termination was "vaccine hesitancy."

But putting that aside, um, the reason for terminating these grants was:

"The end of the pandemic provides cause for terminating covid-related grant funds. These grant funds were issued for a limited purpose, to ameliorate the effects of the pandemic. But now that the pandemic is over, the grant funding is no longer necessary."

Again this is not inconsistent with the statutory language.

THE COURT: I heard -- and this is an expert record and it's not evidence, but I heard recently that 300 people die a week in the United States from covid. Of course probably an equal number die from the flu. I don't know.

Go ahead.

MR. PORTS: So the language for termination is not inconsistent with the statute here. Again, this is NIH's judgment about what is a priority virus family. Is covid still likely to cause a pandemic? And it says that the pandemic is over. And so this is a judgment call and it doesn't contradict the statute.

Again, with vaccines, just because a statute says the word "vaccine" doesn't mean that the NIH must prioritize research into vaccine hesitancy. The language of the statute quoted by the state is to, quote, "Support efforts" -- "Support efforts to," quote, "develop affordable new and improved vaccines." There's

nothing in any of these directives about prohibiting the development of affordable new and improved vaccines.

And that is so with each of these actions. They mention some of the same words, but the actions are -- they do not violate them.

The ultimate challenge is that the plaintiffs disagree with NIH's conclusions or that, cited in the conclusion, that NIH did this thing arbitrary and capricious. But there's no violation of statutes here, um, if we actually look at the statutes and look at the language that NIH provided.

And that moves us on to the fifth point, which I believe is the most, um, the one the Court just asked about, and, um, that is that if the Court rules against the defendants, what is the appropriate remedy here?

And, um, the ultimate question about what is the result of the Court's order turns a lot on what the Court determines to be the final agency action that it is vacating and remanding.

And so the 8 challenged directives that we went through have said -- none of them direct a termination, require a termination, they set priorities. And so, um, it's difficult to -- vacating them similarly doesn't reverse the termination, those are separate decisions, separate actions.

THE COURT: And that may be right. I mean

Mr. Cedrone made it clear that he was seeking, if that

was where the Court went, not to stop with any one or

more of these challenged records, but to vacate the

termination orders.

MR. PORTS: Yes, your Honor.

THE COURT: And your position?

Go ahead.

MR. PORTS: And our position is that if the Court vacates the termination orders, then that reinstates the grants. There's no need for a preliminary injunction.

If that's what the Court said it would do is what it would do, then the defendants would comply.

THE COURT: It is my duty to ask you, and I do so both with respect and the utmost seriousness, were I to do that, are you going to -- is the agency -- I'm not talking about you. Are the defendants here, starting with the Cabinet Secretary and other high officials, the now Director of the NIH and the individual ICs, are they going to -- preserving all their rights to appeal, if I were to do that, are they going to obey promptly?

MR. PORTS: Yes, your Honor, I would expect the defendants to comply.

THE COURT: You expect them to comply?

MR. PORTS: Your Honor, there is a presumption

that the defendants will comply.

THE COURT: There is a presumption they will comply. And you're telling me, as an Officer of the Court, you expect them to comply?

MR. PORTS: Yes, your Honor.

THE COURT: Thank you. All right.

MR. PORTS: I began moving in the certified records that show the notices of awards that have been not terminated that deal with the various topics that plaintiffs say are prohibited. If I may move them into evidence? They have a certification, a record of regularly-conducted activity attesting to their authenticity.

THE COURT: No objection to my receiving these?
(Silence.)

THE COURT: I hear none. They may be received and they will be part of the record.

MR. PORTS: Yes, your Honor.

I will say that APHA had asked that -- so this is a subset of the 16 initial grants that were listed as, um, active at the time of the opposition to the PI. So this is 13 that continue to be active. And they asked to be moved in -- or they requested 26. This is 13 of 26. They requested the opportunity to move in the rest as different documents. We do not object if they were

going to move for that, just to put that on the record.

THE COURT: So I'll take all 26.

All right.

MR. CEDRONE: No objection to them being received into evidence preserving all arguments to the weight they should be given, if any.

THE COURT: I understand that.

MS. MEEROPOL: And the same for the APHA plaintiffs, your Honor.

THE COURT: In a multi party case the objection or statement of one is the statement of the others, on that side of the "versus," unless you want to take a different position. They are received and part of the record.

Thank you very much.

All right, now as we discussed, here's what's going to happen. I'm taking this matter under advisement.

At 2:00, Ms. Belmont is going to ask you whether you want me to stay my hand, because you're talking. If you both agree, you can be sure that the Court will agree.

I've said, and I reiterate, that this case warrants a thorough written opinion. I recognize that we've only talked about Phase 1 and indeed we've talked

about the contours of Phase 1, and when I say a "thorough written opinion," it's focused on Phase 1.

And at an appropriate time, however it comes out, I would enter an order that the interests of justice are that there be a separate judgment so it can be immediately appealed by whoever wants to appeal.

If you say you want to -- if you tell her you want me to stay my hand, the Court will honor it. If any of you want to hear if I have anything to say, she'll tell me that. I don't need to know who. It's up to me whether I see my way clear to say anything at all today.

It goes without saying that I am very grateful both for the briefing and the extraordinarily fine oral arguments made by counsel. We'll take the matter under advisement.

We'll recess.

(Recess, 12:50 a.m.)

(Resumed, 2:00 p.m.)

THE COURT: This case warrants and will receive a full written opinion. At the same time, this case commenced with a request for a preliminary injunction, and the Court takes that very seriously. And the parties, and I include all the parties, have stepped up to afford the Court the chance to make findings and rulings upon an adequate record.

I have worked on the case really since the day it was filed. I still must further reflect upon the extensive record, the extensive administrative record before the Court, and I intend to do so.

But there are some findings and rulings that the Court's efforts, aided by you all, and aided by the Court's law clerks, that I'm able to make today, and in the interests of justice, I'm going to do it, right now.

These are -- well let me start really by saying what I'm not going to address, and nothing I say now should, um, implicate or suggest any finding yet to be made, though the Court reserves its right to make such findings upon a more thorough review of the record or, as we will see, as the record comes to be more fully developed.

So I am not -- well I have limited today's remarks, at least the first phrase, because I'm going to stop and let you ask questions, and then I have something else to say. But the first-phase remarks this afternoon are limited entirely to the claims under the Administrative Procedure Act, and nothing else.

Even as to the claims under the Administrative

Procedure Act, the Court makes no rulings. I have the

data on which I could make them, but I do not today make

any ruling on conflicts with the challenged directives

or terminations and the governing statutes and regulations save -- that is the Administrative Procedure Act itself is a governing statute. Likewise, um, I am not today going to endeavor to interpret any of the governing regulations.

There is evidence here that, um -- that these directives are at least a part of the process that led us to the terminations that, um, we are dealing with in this case, there was some input of some sort by some representative of DOGE. The Court makes no finding either way -- either way as to that, but reserves its right further to consider that matter.

The Court has expressed a concern, a very real concern about discrimination here. I'll have more to say about that after our break.

One of the things that concerns the Court is that there is more than a little evidence here of, um, discrimination on issues of women's health. I make no such finding. I reserve the right to make that finding should I come to be satisfied, by a fair preponderance of the evidence, that such discrimination exists. So those are the things I'm not making any findings on.

As to my remarks today, they are necessarily conclusory. I've challenged the defendants for making conclusory statements, and perhaps I'm going to make

some, but I do so only in the interests of justice and for expedition, I am satisfied that everything I say now is fully supported by the evidentiary record, and, um, in the full written opinion I will, um, have ample recourse to that record. And I reserve my right to make further subsidiary, um, factual determinations, and draw further legal conclusions. But what I say now decides the points to which I speak, having in mind there's going to be a full written opinion that will follow. So let me address the first part of what I want to say.

The Court, on the administrative record, rules that the parties before it have standing. The Court, having carefully considered the briefs and the oral arguments, treats the challenged directives as a whole, as a process, does not break them down into discrete paragraphs, and rules that when treated as a whole, these directives constitute final agency action under the Administrative Procedure Act, Sections 551 and 704.

When you look at these directives, 7 different explanations are offered for agency action. The law, as to the adequacy of such explanations, I -- I would take it, though there are many cases, but the one I want to refer to specifically is Judge Gorsuch's opinion for the Court in *Ohio vs. Environmental Protection Agency*, found at 603 United States at 279, um -- well the PIN cite

will be 144 Supreme Court 2040 at 2024. And there, speaking for the Court, Justice Gorsuch says:

"An agency" -- and I'm omitting citations. "An agency action qualifies as, quote, 'arbitrary' or, quote, 'capricious' if it is not, quote, 'reasonable' and 'reasonably explained.' In reviewing an agency's action under that standard, a Court is not, quote, 'to substitute its judgment for that of the agency,' closed quote, but it 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. Accordingly, an agency cannot simply ignore an important aspect of the problem."

This Court finds and rules that the explanations are bereft of reasoning virtually in their entirety.

These edicts are nothing more than conclusory,

unsupported by factual development.

Moreover, in -- as presented to this Court, there is no reasoned argument as to the reliance interests of the many parties affected. It's well to have recourse precisely to the statute under which this Court -- the Act of Congress under which this Court draws its authority for the conclusions and rulings that the Court makes.

I quote paragraph -- not paragraph, Section 706,

"Scope of Review of the Administrative Procedure Act."

This -- this defines, in this aspect of the case, the powers of this United States District Court in circumstances. This power is derived directly from the statute enacted by the people's representatives in both Houses of Congress. It trumps any regulation. It trumps any order, directive, or edict. Here is what it says:

"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 an agency action."

Then, in Paragraph 2, it empowers the Court to "Hold unlawful and set aside agency action, findings, and conclusions, found to be" -- and I here have reliance on Subparagraph A, "arbitrary and capricious."

This Court rules that the determinations -- that the challenged directives, excuse me, taken as a whole are -- and each of them are, when taken as a whole, arbitrary and capricious, they are of no force and effect, they are void and illegal. And so are each of the terminations before this Court declared arbitrary and capricious, void, and of no effect, they are illegal

and they are vacated and set aside.

I looked up and spotted Ms. Meeropol and I should be specific.

I am not now deciding anything beyond the ruling I just made. That does not mean that in further consideration of the NOFO claims, I could not, or I could not further analyze the argument that was made by those plaintiffs. All I'm saying is I am not now doing that, I'm not ready, nor am I sufficiently confident to do it. I'm speaking only to those things about which I -- a careful review satisfies me that on that ground -- on the grounds I have announced, I am confident in the action that the Court takes.

Having done that, the Court, um, at least sitting this afternoon, accepts the representation of the government counsel, I'm sure made after careful consideration, that he expects that the defendants promptly will comply with the, um, decisions as to the law made by this Court, and I'm relying on that. The Court -- because the case goes on, the Court has continuing jurisdiction. And if these -- this vacation of these particular grant terminations, the vacation of these directives, taken as a whole, um, does not result in forthwith, um, disbursement of funds both appropriated by the Congress of the United States and

allocated heretofore by the defendant agencies, if that doesn't happen forthwith, the Court has ample jurisdiction.

But as I stated earlier, I do come from a kindler, gentler period of jurisprudence when, if a Court of competent jurisdiction -- and this Court is such a court, declares the law authoritatively, executive agencies are presumed to put that declaration into effect, that's the authorization of the Congress in the Administrative Procedure Act. And based on the representation of counsel, I have every reason to believe that will be done.

Now to give effect to the few conclusory findings

I have made and the rulings I have thus-far made, the

plaintiffs are charged with, forthwith, tomorrow will be

soon enough, um, preparing a partial but final judgment

as to these issues. I will enter that final judgment,

um, under Federal Rule of Civil Procedure 54(d), in the

interests of justice so that there is a basis for an

immediate appeal, should anyone wish to appeal.

There is more to this case. I very much understand that. I both welcome any such appeal, but it is my duty to move as rapidly as careful and conscientious analysis permits, and I believe I have given it to so much of this action as I have just spoken

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I have more to say on another topic, but this is a good time to stop and simply go around and see if there are any questions. This is not a time to argue or seek to reargue, just are there any questions about what the Court has found and ruled. Questions. And we'll go in the order of the argument.

Mr. Cedrone?

(Pause.)

MR. CEDRONE: No, your Honor, I think it's clear.

THE COURT: Fine.

Mr. Parreno?

MR. PARRENO: No, your Honor, no questions.

THE COURT: And, Mr. Ports, any questions?

MS. PORTER: I want to make sure that we're clear that this -- the order applies to all grants listed by the plaintiffs, that's both sets of plaintiffs, as most recently updated, um, any orders to set them aside and terminate them, to vacate them, and set them aside.

So everything on that list?

THE COURT: That is the list to which I have referenced. Your question is perfectly appropriate. That's what I'm speaking about.

MS. PORTER: Okay, thank you, your Honor.

THE COURT: All right.

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Any other questions? 1 MS. PORTER: Does this apply to, I guess, the 2 3 status of, um, grants listed where there have been no action, no affirmative action by the agency other than 4 5 maybe, um --THE COURT: I think I've made myself clear. 6 have a list and I've acted on it. MS. PORTER: Okay, thank you, your Honor. 8 9 THE COURT: All right. 10 Now I have something else to say. 11 MR. PARRENO: Your Honor, if I may? THE COURT: Yes. 12 13 MR. PARRENO: What, um, just to make it clear, 14 what counsel on the other side has addressed has raised 15 another question for us, and perhaps if I may raise it with the Court? 16 17 We wish to ask the Court for the opportunity to provide one additional list of plaintiff members, grants 18 19 of plaintiff members that have not yet been provided to 20 the Court, and we're prepared to, um, provide that. 21 THE COURT: Work it out with them. If they oppose, I will take that into account. But work it out 22 23 with them. 24 MR. PARRENO: Yes, thank you, your Honor.

THE COURT: Now there's another aspect of this

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case, a darker aspect, one that I take very seriously, and it's this.

I could not -- I cannot, as a United States

District Judge, read this record without coming to the conclusion, and I draw this conclusion -- I am hesitant to draw this conclusion, but I have an unflinching obligation to draw it, that this represents racial discrimination and discrimination against America's LGBTQ community, that's what this is. I would be blind not to call it out. My duty is to call it out. And I do so.

Now clearly I have no hesitancy in enjoining racial discrimination, I said during the course of the argument, and it is the law and I must uphold it, and I have no hesitancy in upholding it. The extirpation of affirmative action is a legitimate government policy. It is not a license to discriminate on the basis of color. It simply is not. That's what the Civil War amendments are about. Any discrimination, any discrimination by our government is so wrong that it requires the Court to enjoin it, and at an appropriate time I'm going to do it.

Having said that, I welcome -- if the parties wish, though I don't require any extension of the record, evidence as to harm so that I may more carefully

and accurately frame such an injunction. That's racial discrimination.

It is palpably clear that these directives and that the set of terminated, um, grants here also are designed to, um, frustrate, to stop research that may bear on the health -- we're talking about health here, the health of Americans, of our LGBTQ community. That's appalling. Having said it, I have very real questions about whether this Court has the power to enjoin it. I do not assert such a power, though I find the record will be clear to anyone that it has and is occurring under this, um, under what's going on.

Now I'm speaking only of health care, I'm speaking only of the parties before me, nothing else. I don't have a record as to that. It's not the province of this Court just to invade against discrimination. But on this record, these two aspects of discrimination are so clear that I would fail in my duty if I did not note it.

And so the parties are invited, as to those two aspects and -- though I make no finding with respect to it, any harm to the issues involving women's health.

Gender differences are an appropriate area of research and research and, um, trying to advance the frontiers of science so that all Americans have the best health care that we can afford.

You will meet and inform the Court as to when -if any party wishes -- I am bound by case-incontroversy, I say what I will receive evidence on, but
I do not require anything. I've said everything that I
am able to say. And while there's another phase to this
case, on this discrimination issue, I am prepared to
receive evidence, but I do not require it.

If the parties wish to present evidence, you'll inform me as to when you're prepared to begin such evidentiary -- because defense counsel is correct, they have the right to cross-examine as to that, and at least as to any discrimination as to LGBTQ people, they -- it may very well be that while I can recognize it and call it out, I have no power to enter injunctions with respect to it. But I'm certainly open to considering that.

But let me say something about racial discrimination here. I've never seen a record where racial discrimination was so palpable. I've sat on this bench now for 40 years, I've never seen government racial discrimination like this. And I confine my remarks to this record, to health care. And I ask myself, how -- how can this be, because on this record anyway, I don't see anyone pushing back against it?

I don't -- take a look at the people who have been

named as defendants here, one of them is a cabinet-level officer. The other one is, not the same individual, but is now the Director of the National Institutes of Health. And though I needed help as to what an "IC" is, there are other distinguished, um, at the National Institutes of Health level and their subsidiary institutes, these are distinguished doctors, they are people whose profession has been devoted to the American people, to our society. All our society. They are all American citizens.

Now I don't claim any high moral ground here. I'm a United States District Judge, I have the protections that the Founders wrote into the Constitution, along with imposing upon me a duty to speak the truth in every case, and I try to do that. And so I've asked myself, what if I didn't have those protections? What if my job was on the line, my profession, all the career to which I have devoted whatever poor skill I have, would I have stood up against all of this? Would I have said, "You can't do this, you are bearing down on people of color because of their color. The Constitution will not permit that." I see nothing in this record.

And, you know, when I ask myself that question, without the protections of --

(Phone rings.)

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THE COURT: I was going pretty well there.
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            (Laughter.)
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            THE COURT: Okay.
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            -- without the protections of an independent
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     judiciary so necessary to our society, as I know my own
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     heart, I do not have an answer to that question, for
     myself, and that makes me unutterably sad.
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           And so we're going to recess. But is it true of
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     our society as a whole, have we fallen so low? Have we
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     no shame?
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           We'll recess.
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            (Recess, 2:35 p.m.)
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1	CERTIFICATE
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3	I, RICHARD H. ROMANOW, OFFICIAL COURT REPORTER, do
4	hereby certify that the forgoing transcript of the
5	record is a true and accurate transcription of my
6	stenographic notes, before Judge William G. Young, on
7	Monday, June 16, 2025, to the best of my skill and
8	ability.
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12	/s/ Richard H. Romanow 06-23-25
13	RICHARD H. ROMANOW Date
14	RIGHTIND II. ROTHINGW BAGG
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