UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN PUBLIC HEALTH ASSOCIATION; IBIS REPRODUCTIVE HEALTH; INTERNATIONAL UNION, UNITED AUTOMOBILE, AEROSPACE, AND AGRICULTURAL IMPLEMENT WORKERS (UAW); BRITTANY CHARLTON; KATIE EDWARDS; PETER LURIE; and NICOLE MAPHIS, *Plaintiffs*, v. NATIONAL INSTITUTES OF HEALTH; JAY BHATTACHARYA, *in his official capacity as Director of the National Institutes of Health*; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; and ROBERT F. KENNEDY, JR., *in his official capacity as Secretary of the United States Department of Health and Human Services*, *Defendants*.	Case No. 1:25-cv-10787-WGY

APHA PLAINTIFFS' RESPONSE TO DEFENDANTS' MERITS BRIEF ON PHASE 1

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Defendants' scant reference to the administrative record in their Opening Brief is both notable and telling. Without evidence that might explain or justify their actions, Defendants are left with jurisdictional arguments this Court has already rejected, and a startling claim that the conclusory, boilerplate language pulled from the Directives themselves *is* the "reasoning" that satisfies the APA. ECF No. 125 at 30-39.[1] Defendants' effort to recast their unprecedented attack on science as a matter of routine is similarly untethered from the facts. *Id*. at 10-11. But the reality of what is unfolding at the NIH does not seem to matter: Defendants persist, for example, in invoking a smattering of ongoing grants on "certain minority-related topics," *id*. at 32, to claim they are acting in accordance with Congressional mandates—even though *APHA* Plaintiffs[2] demonstrated *weeks* ago that many of these grants have been terminated. ECF No. 71 at 12-14; *see also* ECF No. 103 at 32.

ARGUMENT

I. *APHA* Plaintiffs' Claims Are Justiciable.

Defendants' primary arguments are jurisdictional. They insist that the Directives are merely "part of the process of making the decision to terminate grants" and thus not final agency action, ECF No. 125 at 15—a mischaracterization this Court has already preliminarily rejected. Case No. 1:25-cv-10814, ECF No. 105 (D. Mass. May 12, 2025) ("SMJ Order") at 25. They go on to attack *APHA* Plaintiffs' challenge to the withdrawal of Notices of Funding Opportunities ("NOFOs") and resultant denial of applicant Plaintiffs' ability to compete for NIH grants pursuant to a regulated process on three grounds: final agency action, agency discretion, and standing. They

[1] Because Defendants filed a single Merits Brief on Phase 1, *see* ECF No. 101, citations to Defendants' Opening Brief herein are to ECF No. 125 in *Massachusetts v. Kennedy*, Case No. 1:25-cv-10814.

[2] "*APHA* Plaintiffs" refers to the Plaintiffs in the above-captioned matter (including members of Plaintiffs APHA and UAW, *see* ECF No. 103 at 1 n.1), as distinct from those in *Massachusetts, et al. v. Kennedy, et al.,* No. 1:25-cv-10814-WGY.

insist a few of the Directives are moot. And finally, while they seem to concede that some terminations are final agency actions, they argue that the voluntary appeals process renders the terminations—that had immediate effect—non-final. They are wrong on every count.

A. The Directives Constitute Final Agency Action.

Defendants claim the Directives are "parts of the interlocutory process to review grants." ECF No. 125 at 16. In contrast, the record shows that the Directives reflect a completed decision to defund research on disfavored topics, while providing instructions as to *how* grants that match these topics must be terminated. *See*, *e.g.*, AR0004[3] ("[G]rants that support DEI and similar discriminatory programs . . . are inconsistent with the Department's policy."); AR2135-36 ("NIH will no longer prioritize research and research training programs that focus on Diversity, Equity and Inclusion (DEI)"); AR3229 ("ICs must use the exact language provided").

That certain Directives were periodically revised and updated does not make them interlocutory. *See* ECF No. 125 at 18. The record shows that revisions to the Directives merely expanded the list of disfavored topics and elucidated the procedures to use when issuing terminations; the agency's *decision* to purge verboten topics did not change. *Compare* AR2135 - 36 *with* AR3516-17. Indeed, the timeline and process of the terminations confirms the final, and legally consequential nature of the Directives: hundreds of bulk terminations followed each one, all employing the boilerplate termination notices each Directive set forth. ECF No. 103 at 11-17; *see also* Appendix A (Timeline of Directives and Terminations).

Defendants' insistence that the Directives merely provide for a *review* of grants is equally belied by the record. It is true that the Secretarial Directive—one of the few that appear intended for public disclosure—tells agency personnel to review grants to determine if they are consistent

[3] References to the administrative record produced by Defendants on June 2, 2025, matches the page numbers in the record (*e.g.*, "AR0004" corresponds to "NIH_GRANTS_000004").

with agency priorities. AR0004. But the balance of the Directives show that ICs were *instructed* to terminate hundreds of grants without any review whatsoever.[4] To the extent any review happened at the IC level, the Directives mandated termination of any grant associated with the disfavored topics. And Defendants concede that the Directives instruct NIH employees "about *what to do* if all or a portion of a grant no longer effectuates agency priorities." ECF No. 125 at 12 (emphasis added). *See Biden v. Texas*, 597 U.S. 785, 808–09 (2022) (noting memorandum was final agency action because it "bound [agency] staff by forbidding them to continue the program"). The Directives are thus distinguishable from the manual at issue in *Whitewater Draw Natural Resources Conservation District v. Mayorkas*, which did "not prescribe any particular option in any particular way." 5 F.4th 997, 1008 (9th Cir. 2021).

Cases cited by Defendants concerning "investigatory measures," ECF No. 125 at 17, are also inapposite. In *Harper v. Werfel*, the First Circuit held that an IRS summons seeking certain financial records "is a preliminary investigative step, far upstream of any potential [] enforcement" and thus is not final decisionmaking. 118 F.4th 100, 116 (1st Cir. 2024). Here, the Directives identified grants that *required* termination. *See, e.g.*, AR3452 (Memoli responding *2 minutes* after receiving list of grants: "Please terminate . . . for being inconsistent with agency priorities.").

B. Appealed Grant Terminations Are Final Agency Action.

Defendants' Opening Brief does not bother to distinguish between *APHA* Plaintiffs and State Plaintiffs and thus it is difficult to tell whether Defendants concede that *APHA* Plaintiffs'

[4] *See, e.g.*, AR2352, 2353, 3512, 3820; *see also* AR3454 ("To avoid issuing awards, in error, that support DEI activities ICs must take care to completely excise all DEI activities"); AR1957 ("Guidance for IC staff to use when *terminating awards* identified by HHS or the IC due to DEI or other agency priorities" (emphasis added)); AR3216-30 ("Prior to issuing all awards (competing and non-competing) or approving requests for carryover, ICs must review the specific aims/major goals of the project to assess whether the proposed project contains any DEI, gender identity or other research activities that are not an NIH/HHS priority/authority" and if determined that "[t]he sole purpose of the project is related to an area that is no longer an NIH/HHS priority/authority," then "ICs must not issue the award (competing or non-competing)").

separate challenge to the grant terminations (as opposed to the Directives) is a proper assertion of final agency action. *See* ECF Nos. 1 (Complaint) at ⁋ 200, 125 at 25 (referring to "forty-four terminations under appeal"). Regardless, a researcher's (or their institution's) choice to appeal a grant termination does not prevent this Court from considering their claims.[5]

First, the terminations are final agency actions regardless of any pending appeal because they have "an actual or immediately threatened effect." *Greater Bos. Legal Servs. v. United States Dep't of Homeland Sec.*, No. 21-CV-10083-DJC, 2023 WL 2540892, *2 (D. Mass. Mar. 16, 2023), and are actions from which "legal consequences flow," *Bennett v. Spear,* 520 U.S. 154, 177-78 (1997). Most obviously, the terminations result in an *immediate* loss of funding.

Second, Defendants have plainly stated that any administrative appeal is futile: termination letters provide that "no corrective action [to the grant] is possible" because the "premise of [the grant] is incompatible with agency priorities, and no modification of the project could align [it] with agency priorities." *See, e.g.*, ECF No. 38-24 at Ex. D. It is "utterly unclear… how a terminated Grant Recipient might mount such an appeal," and "the Termination Letter effectively and practically renders meaningless the right to appeal." *Am. Ass'n of Colleges for Tchr. Educ. v. McMahon*, No. 1:25-CV-00702-JRR, 2025 WL 833917, at *21 (D. Md. Mar. 17, 2025), *reconsideration denied*, No. 1:25-CV-00702-JRR, 2025 WL 863319 (D. Md. Mar. 19, 2025).

Third, there appears to be no express deadline for NIH to rule on an administrative appeal. *See* 42 C.F.R. Part 50, Subpart D. Without such a guardrail, prohibiting a judicial challenge until

[5] The *APHA* Plaintiffs have not yet received the administrative record on individual grant terminations that *APHA* Plaintiffs identified on May 27, 2025. While the Court ordered Defendants to produce that record by June 16, at the final pretrial hearing on June 12, counsel for Defendants indicated that it would instead be produced the following day—Friday, June 13. *APHA* Plaintiffs will review the record to the best of their ability prior to June 16, and will plan to address the record to the best of their abilities, to avoid any unnecessary delay in a Court ruling on all Phase 1 merits issues. While *APHA* Plaintiffs address Defendants' argument that appealed terminations are not final agency action, *APHA* Plaintiffs do not waive the right to provide supplemental briefing on their claims concerning individual grant terminations following the Phase 1 Proceedings if necessary, including as to any supplemental list of grant terminations *APHA* Plaintiffs provide to Defendants.

resolution of an administrative appeal places Plaintiffs in perpetual limbo, and perversely incentivizes Defendants to delay ruling on any appeal. Nor is the Court's consideration of the appealed grant terminations "an invitation to waste judicial resources," ECF No. 125 at 25, as analysis of Plaintiffs' APA claims does not require analysis of any individual termination. NIH issued boilerplate justifications for the terminations, and the record does not contain any evidence of review of grants to see whether the justifications applied on a grant-by-grant basis. *See* ECF No. 103 at 22-26. The Court will determine whether this categorical termination violated the APA. That any single, or even a few, grants may be reinstated is of no moment.

Finally, even if *some APHA* Plaintiffs and Members have pending appeals, and the Court finds that renders *their* individual grant terminations non-final, the Court can still grant relief to all by vacating the Directives, *see* Section IV, or *APHA* Plaintiffs and Members should be given the opportunity to withdraw their appeals.

C. None of the Directives Are Moot, and Each Harmed Plaintiffs.

Defendants contend that the Lauer Memorandum, AR0009, did not cause direct harm, and the Supplemental Guidance which modified it, AR0016, has since been rescinded and thus is moot.[6] ECF No. 125 at 22-24. These arguments fail. The Lauer Memorandum initiated the present wave of Directives by announcing that "NIH is in the process of reevaluating the agency's priorities" and counseling that "[a]dditional details on future funding actions" would be forthcoming. AR0009. Those future funding actions began the very next day with the issuance of the Supplemental Guidance. AR0016. Therein, Defendants ordered that funds for awards deemed to serve the "sole purpose" of furthering "DEI" were to be "fully restricted." *Id.*

[6] Defendants also raise arguments as to the "January 21, 2025 Secretary's Memorandum," which is at issue in the States' case, but has not been directly challenged by the *APHA* Plaintiffs.

Defendants purportedly repealed the Supplemental Guidance *twice*, AR3457, 3217, which in itself calls into question the effectiveness of any recission. Regardless, the record clearly shows that multiple terminations were made pursuant to the Directive, prior to the alleged rescissions, *see* AR2469-70, 2296—concrete harms which must be unwound. Moreover, the record shows that Defendants have not rescinded the *underlying policy* announced in the Supplemental Guidance: fully restricting funding for awards deemed "DEI." *See, e.g.*, AR2930-31. Defendants cannot implement binding policies that result in grant terminations, purport to "rescind" those policies by issuing nearly-identical ones weeks later, and avoid judicial review of any actions by asserting that the challenged policies were either non-final or moot. *See New York v. Trump*, 764 F. Supp. 3d 46, 53 (D.R.I. 2025) (where "policies in [rescinded OMB Directive]" were still "in full force and effect," issues were not moot).

D. This Court Has Jurisdiction over Claims Regarding Withdrawn NOFOs.

As discussed *supra*, the Directives are final agency action, and the record shows that dozens of NOFOs were unpublished pursuant to the Directives. AR3823, 3752-53, 3810, 2353, 3752. Thus, withdrawal of NOFOs can be challenged as implementation of the Directives regardless of whether the NOFO withdrawal is itself final agency action.

i. Withdrawal of NOFOs is final agency action.

Even if this were not the case, NIH's unpublishing of NOFOs has direct and immediate consequences for both applicant Plaintiffs and *APHA* Plaintiffs whose non-competitive renewals were denied. *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997); *Franklin v. Mass.*, 505 U.S. 788, 797 (1992). The Directives prohibit issuing awards for applications to unpublished NOFOs. *See* AR003517 ("I[nstitutes,] C[enters,] O[ffices]'s must not issue the award (competing or non-competing)" for "application[s] received in response to a NOFO that has been unpublished due to

its focus on activities that are no longer an NIH/HHS priority"). NIH regulations require that all applications "shall be evaluated" through the peer review process and that NIH "will" reach a disposition on their applications. 42 C.F.R. § 52.5, 42 U.S.C. §§ 289a, 284a. Yet NIH has simply refused to act on pending applications for a funding opportunity that has now been unpublished.

Applicants who spent months completing onerous applications have lost the regulatorily mandated opportunity to receive feedback through the peer review process and action on their application.[7] This "eliminat[ion] of an application from contention amounts to the agency's 'last word on the matter.'" *Multnomah County v. Azar*, 340 F.Supp.3d 1046, 1057 (D. Or. 2018).[8] Similarly, individuals who expected to receive annual non-competitive renewals, or the next phase of one of the NIH's two-phase training grants, have had their reasonable expectations of future funding extinguished in a manner that is indistinguishable from a termination.[9] *See Pol'y & Rsch., LLC v. U.S. Dep't of Health & Human Serv.*, 313 F. Supp. 3d 62, 76–78 (D.D.C. 2018).

Defendants argue that agency action is not final prior to an award of funds, ECF No. 125 at 19-20, but the cases they rely on do not support this categorical approach. In *Rattlesnake Coalition*, for example, the court declined to find congressional appropriation of funds to the Environmental Protection Agency final agency action, but separately found the agency's interim

[7] *See* ECF No. 38-21 at ¶¶ 7-12 (Nicole Maphis describing 70 weeks of work on MOSAIC application, that members of a study group evaluated her application, but that "all review related data was deleted from the system" such that she received no feedback on her proposal); ECF No. 38-37 at ¶¶ 12-15 (UAW Member 3 describing that the study group assigned their MOSAIC application a "perfect score" yet the Advisory Council set to later consider the same proposal was cancelled without notice and emails to NIH seeking an explanation went unanswered); ECF No. 38-40 at ¶¶ 9-11 (UAW Member 11 describing 150 hours of work on F31 Diversity application, that they were congratulated by NIH for receiving a "fundable score," but that an NOA never issued).

[8] S*ee also Planned Parenthood of New York City, Inc. v. U.S. Dep't of Health and Human Serv.*, 337 F. Supp. 3d 308, 327 (S.D.N.Y. 2018) (Funding Opportunity Announcements that directly affect parties constitute final agency action); *Arizona v. Shalala*, 121 F.Supp.2d 40, 48–49 (D.D.C. 2000).

[9] *See* ECF Nos. 38-35 at ¶¶ 7, 11-14 (MOSAIC grantee received notice MOSAIC program "terminated" after successfully competing one portion of five-year program); 38-36 at ¶¶ 4, 9-11 (same); 38-41 at ¶¶ 4, 10-14 (same).

decision not to issue an environmental impact statement final, even though it preceded any award of funds. 509 F.3d at 1103–04.[10]

ii. Defendants' withdrawal of NOFOs is not "committed to agency discretion."

Next, Defendants argue withdrawal of NOFOs is committed to agency discretion and thus unreviewable, but "an agency is not free simply to disregard statutory responsibilities." *Lincoln v. Vigil*, 508 U.S. 182, 193 (1993). This Court has already rejected Defendants' similar arguments, observing that *Lincoln* "stands for the unremarkable proposition that review is precluded so long as the agency allocates funding from a lump-sum appropriation to meet permissible statutory objectives." SMJ Order at 27 (internal citations omitted). This Defendants have not done. Instead, they have systematically eliminated entire granting programs related to diversifying the profession and health disparities, removing associated NOFOs and administratively withdrawing or refusing to review applications, despite congressional mandates. ECF No. 103 at 18 n.15 (providing record citations). The APA's waiver for action committed to agency discretion does not leave agencies "free to disregard legislative direction in the statutory scheme that the agency administers." *Heckler v. Chaney*, 470 U.S. 821, 833 (1985).

Defendants correctly note that "Congress may overcome the presumption against review by providing '*guidelines for the agency to follow* in exercising its enforcement powers,' by '*setting substantive priorities*, or by otherwise circumscribing an agency's power.'" *Holbrook v. Tenn. Valley Auth.*, 48 F.4th 282, 293 (4th Cir. 2022) (emphasis added) (quoting *Heckler*, 470 U.S. at 833). Congress has done just that. *See* ECF No. 103 at 29-31 (describing numerous congressional

[10] Both *Planned Parenthood of Wisconsin, Inc. v. Azar*, 316 F. Supp. 3d 291, 300–01 (D.D.C. 2018) and *Karst Environmental Education and Protection, Inc. v. U.S. Environmental Protection Agency*, 403 F. Supp. 2d. 74, 81(D.D.C. 2005), stand for the basic premise that an immediate impact on a plaintiff is needed for a change in award funding to constitute final agency action. Defendants also cite *Delta Data Systems Corporation v Webster*, 744 F.2d 197, 206 (D.C. Cir. 1984), but the court there did not consider whether a grant procurement constituted final agency action.

mandates that NIH promote diversity in the biomedical field and support research into health disparities). Defendants once again invoke 42 U.S.C. § 284(b)(2)—which states NIH "may" issue grants to *support* programs and activities under the PHSA—and § 282(b)(3)—which only requires the NIH Director to coordinate across ICs in setting priorities, to reduce redundancies, and to encourage collaboration—as supposed evidence of discretionary authority. But these cherry-picked clauses do not overcome Congress' "plain statutory commands" that "provide meaningful standards for judicial review." *Holbrook*, 48 F.4th at 293.

iii. *APHA* Plaintiffs have standing.

Defendants also argue that *APHA* Plaintiffs lack standing to challenge the unpublishing of NOFOs and resulting refusal to consider applications, claiming that non-receipt of "expectant funding" is not a cognizable harm. However, it is well-established that "a plaintiff suffers a constitutionally cognizable injury by the loss of an *opportunity to pursue a benefit* . . . even though the plaintiff may not be able to show that it was *certain to receive* that benefit had it been accorded the lost opportunity." *Teton Historic Aviation Found. v. Dep't of Def.*, 785 F.3d 719, 724 (D.C. Cir. 2015) (citation omitted) (emphasis in original). The unpublishing of NOFOs and refusal to consider applications also mean that researchers who rely on the well-established NIH grant application system have lost the benefit of having their applications and research, which required significant energy and resources to prepare, reviewed in an appropriate and lawful manner. *See* 42 C.F.R. § 52.5 (requiring applications properly submitted to be reviewed); *see also* ECF Nos. 38-21; 38-37 (discussing harms from withdrawal of NOFOs). And while Defendants argue, citing only the *States'* filings in support, that Plaintiffs have not identified harm from specific NOFOs being withdrawn, ECF No. 125 at 22, the *APHA* Plaintiffs' filings in this case show otherwise. *See, e.g.*, ECF No. 38-37 at ¶¶ 6-8, 11-19; ECF No. 38-40 at ¶¶ 5-11; ECF-No 38-39 at ¶¶ 6-11.

Additionally, Defendants' argument that Plaintiffs lack standing to challenge Directives restricting funding for grants related to China and COVID is unavailing. *APHA* Plaintiffs *do* have members who have had grants terminated related to COVID,[11] the organizations are continuing to collect information on their members' harms, and such harms continue to accrue daily while the Directives remain in effect.

II. The Record Confirms that the Directives Are Arbitrary and Capricious.

Turning to the merits of *APHA* Plaintiffs' claims, Defendants attempt to recast bald, political boilerplate language as "reasoned decisionmaking." They cannot, and do not, point to actual analysis, reasoning, or evidence in the record supporting their conclusory rejection of previously peer-reviewed research—because none exists. Instead, Defendants again parrot the conclusory justifications that appear across the Directives to make a conclusory argument that these justifications are reasoned.

For example, to show that the Directives provide a "rational explanation" for the purge of massive amounts of pre-approved research, Defendant just rely on their boilerplate language:

> 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.

ECF No. 125 at 30; *see also id*. at 33, 34. Even after repeated prompts by the Court and compiling a record, *see* ECF No. 84 at 35 n.4, Defendants *still* fail to point to any working definition of "DEI studies" or any evidence to explain their disfavor. But that is just one of many flaws. On what basis

[11] These appear on the May 27, 2025 List of Grants Impacted by the Directives that *APHA* Plaintiffs previously provided to this Court, and which they will shortly supplement.

have they concluded such studies are often "used to support unlawful discrimination"? ECF No. 125 at 30. What is a "gender identity" study according to Defendants? *Id*. at 33. How have they determined that "[r]esearch programs based on gender identify are often unscientific" and "have little identifiable return on investment?" *Id*. And how did Defendants conclude that "vaccine hesitancy" research does not "benefit the American people and improve their quality of life?" *Id.* at 34. Defendants point to no answers in the record—because none are there.[12]

This Court and others have emphasized that such "conclusory and vague" boilerplate "untethered to the specific terminated grants" will not do. ECF No. 84 at 31–35. That the Directives and the balance of the record contains "no discussion" of any data shows that NIH "entirely failed to consider important aspect[s] of the problem." *DHS v. Regents of the Univ. of California*, 140 S. Ct. 1891, 1913 (2020). Defendants do not muster anything to the contrary, and the record confirms that there is no "reasoned explanation for [Defendants'] action." *Id.* at 1916. For instance:

- On February 22, Acting Director Memoli spent no more than **25 minutes** to purportedly review and conclude that 18 NOFOs "need[ed] to come down." AR3752, AR3810;
- On March 11, **6 minutes** after Memoli received an email with 6 grants, he responded: "All of these grants can be terminated for being unaligned with current NIH/HHS priorities." AR3511, AR3820; and
- On May 9, Memoli spent **2 minutes** reviewing a list of "several additional grants" and directing termination "for being inconsistent with agency priorities." AR3452.

Defendants do not explain how lightning speed implementation of the Directives could possibly reflect reasoned decisionmaking.

[12] Defendants make no arguments as to several of the other forbidden topics *APHA* Plaintiffs have challenged—including climate change and influencing public opinion. They have therefore waived the arbitrary-and-capricious issue on those topics. *See Ministeri v. Reliance Standard Life Ins. Co*., 523 F. Supp. 3d 157, 174 (D. Mass. 2021) ("except in extraordinary circumstances, arguments not raised in a party's initial brief and instead raised for the first time at oral argument are considered waived." (internal citation omitted)).

Defendants' attempt to characterize *APHA* Plaintiffs' challenge as a "policy disagreement" is a red herring. ECF No. 125 at 33. Agencies can change their policies, but Defendants omit that they must "supply a reasoned analysis for the change." *See Ark Initiative v. Tidwell*, 816 F.3d 119, 127–28 (D.C. Cir. 2016) (quoting *State Farm*, 463 U.S. at 42); *see also* ECF No. 103 at 26-27. Put another way, an "about-face" must "be addressed explicitly by reasoned explanation for the change of direction." *NLRB v. Lily Transp. Corp.*, 853 F.3d 31, 6 (1st Cir. 2017) (Souter, J.). Further, because Defendants' "new policy rests upon factual findings that contradict those which underlay its prior policy," the record must "show that there are good reasons for the new policy," *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009). There is no evidence in the record of this kind of explanation, *see* ECF No. 103 at 26-27, and Defendants' reliance on a single dissenting opinion to assert that a change in administration (ECF No. 125 No. 31), without more, can satisfy this standard runs afoul of bedrock and longstanding APA requirements of agencies needing to show their work. *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 222 (2016).

In addition, Defendants implicitly concede what the record makes clear—that they failed to consider reliance interests. Without record citation, they argue that NIH "necessarily understood" reliance interests when it made its determinations. ECF No. 125 at 31. But Defendants cannot "rely upon reasons absent from [their] original decision[s]." *DHS*, 140 S. Ct. at 1909–10. There is no evidence in the record showing any consideration of reliance interests. *See* ECF No. 103 at 27-28; *NIH*, 2025 WL 702163 at *20. And Defendants cannot, *post hoc*, recharacterize what is missing from the record and their contemporaneous analysis. *DHS*, 140 S. Ct. at 1909–10.

And finally, contrary to Defendants' assertion otherwise, applicant Plaintiffs also have reliance interests NIH must consider. *See* ECF No. 41 at 38–39, 42–43. There is no evidence in

the record that NIH considered the impact on applicants who have lost the mandated opportunity to receive feedback through the peer review process and action on their applications.

III. The Directives Are Contrary to Statute and Regulations.

Defendants largely miss the point of *APHA* Plaintiffs' **contrary to statute** arguments. First, they ignore the wholesale elimination of NIH granting programs designed to fulfil Congress's mandate to "recruit[] women, and individuals from disadvantaged backgrounds (including racial and ethnic minorities)." 42 U.S.C § 288(a)(4); ECF No. 72-3 at ¶9-10; ECF No. 38-37 at ¶¶ 19-25. That some training programs, like NRSAs, continue to be funded while they are stripped of any plan to increase recruitment of underrepresented communities does not suffice. *See* ECF No. 84 at 36. Defendants cannot terminate programs *because* they do the very thing Congress has mandated: diversification of the biomedical research field.

Second, Defendants insist that they have terminated "DEI grants that it determined did not enhance health, while preserving grants into health disparities." ECF No. 125 at 32. They once again provide no record cite for their assertion. Instead, they rely on a Declaration from the Acting Deputy Director for Extramural Research at NIH attaching a list of the 26 grants addressing minority health disparities Defendants insist "HHS is continuing." *Id.* Of this list, NIH records show that five were terminated and two ended before the brief was filed. ECF No. 103 at 32.[13] Even were this not so, continuing a few grants on health disparity work cannot change that terminating other projects *because they somehow involve race or ethnicity* directly conflicts with

[13] Indeed, of the four grants Defendants highlight in their brief, *Elucidating the high and heterogenous risk of gestational diabetes among Asian Americans,* MD018459 has been terminated; *Understanding cancer and comorbidities among American Indian and Alaska Native people*, MD018641 ended on April 30, 2025; *and Health Promotion in the Prevention of Anxiety and Depression: The Happy Older Latinos are Active (HOLA Study)*, MD012610 has a project end date of July 31, 2025. ECF 72-4 at ¶3.

"giv[ing] priority to . . . minority health disparities research," 42 U.S.C. § 285t(f)(1)(D), and thus violates Defendants' statutory mandate.

Defendants insist they have complied with the statutory directive to develop a strategic plan. ECF No. 125 at 33 (citing 42 U.S.C. § 282(m)(1)). But Defendants are also required to "ensure" funding is "sufficiently allocated for research projects identified in strategic plans," *id.* at 282(b)(6), and they are not doing so. ECF No. 103 at 30-31. Finally, Plaintiffs have, in fact, identified statutes directing NIH to support research into "transgender issues." ECF No. 103 at 30 (*citing*, *e.g.,* 42 U.S.C. § 283(p)); *see also* 42 U.S.C. §285f-5(a) (statutory mandate that NIH prioritize products for viruses with a significant potential to cause a pandemic); 42 U.S.C. § 283d (instructing ICs to develop new and affordable vaccines).

With respect to Plaintiffs' **contrary to regulation** arguments, Defendants first contend that the grounds for termination set out in 45 C.F.R. § 75.372 are non-exhaustive. ECF No. 125 at 27. This contradicts the holding of multiple courts. *See* ECF No. 103 at 34. If Plaintiffs and these courts are correct, this ends the inquiry: an agency may not violate its own regulations, and it is undisputed that HHS has not yet formally adopted 2 C.F.R. § 200.340. ECF No. 84 at 30.

Only if the Court disagrees need it proceed to Defendants' argument that they were entitled to terminate grants based on a change in "agency priorities" under 2 C.F.R. § 200.340 as incorporated into the NIH Grants Policy Statement ("GPS"). But this argument also fails on its own terms. First, although Defendants repeatedly argue that the GPS controls because it is a "contractual term" in the grants, *but see* ECF Nos. 41 at 20-21 (addressing mischaracterization of NIH grants as contracts), this Court has already determined that it "need not decide" that issue, because under § 200.340 "whether the 'award no longer effectuates agency priorities' can *still* be challenged under the APA …[for] failure to provide a reasonable explanation." ECF No. 84 at 31

(emphasis in original). Second, Defendants are incorrect that § 200.340, as incorporated in the GPS, *would* authorize the challenged Directives and terminations, because § 8.5.2 GPS refers to "Remedies for Non-compliance" (none is alleged here), and "[200.340] only allows agencies to terminate . . . agreements 'to the extent authorized by law." *Id*. at 30. Finally, Defendants' invocation of 42 C.F.R. § 52.6(c)(3) does not change that analysis. That regulation in fact constrains HHS's ability to freely terminate grants by its own properly promulgated regulations. *See Policy & Rsch. LLC*, 313 F. Supp. at 76-78.

IV. The Remedy that Plaintiffs Seek is Appropriate and Necessary.

Both vacatur of the Directives and a permanent injunction to redress Plaintiffs' injuries are warranted. Defendants concede that vacatur is an appropriate remedy and can reverse grant terminations. ECF No. 125 at 37. But they muddy the remedial waters in suggesting remand. Remand without vacatur may be appropriate to allow an agency to correct a misstep. *See Brown v. U.S. Dep't of Educ.*, 640 F. Supp. 3d 644, 667 (N.D. Tex. 2022), vacated on other grounds and remanded sub nom. *Dep't of Educ. v. Brown*, 600 U.S. 551 (2023). But here, Defendants engaged in multiple *violations* of the APA that have caused irreparable harm to Plaintiffs and the public. *See Massachusetts ex rel. Div. of Marine Fisheries v. Daley*, 170 F.3d 23, 32 (1st Cir. 1999) (describing remand as "less attractive" than vacatur because of, *inter alia*, impacts on the plaintiff).

Defendants also oppose an injunction, but although it is a "drastic remedy," *Monsanto Co.*, 561 U.S. at 165, it exists to remedy equally drastic harm, which is why it should be ordered when each of the four equitable factors are satisfied, *id.* at 157, as they are here. ECF No. 103 at 39-40.

CONCLUSION

For the reasons discussed here and in Plaintiffs' prior briefing, ECF Nos. 41, 71, 103, Plaintiffs respectfully request that the Court grant their requested relief. *See* ECF 103-1.

Dated: June 13, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on June 13, 2025 a true and correct copy of the above document was filed via the Court's CM/ECF system and that a copy will be sent automatically to all counsel of record.

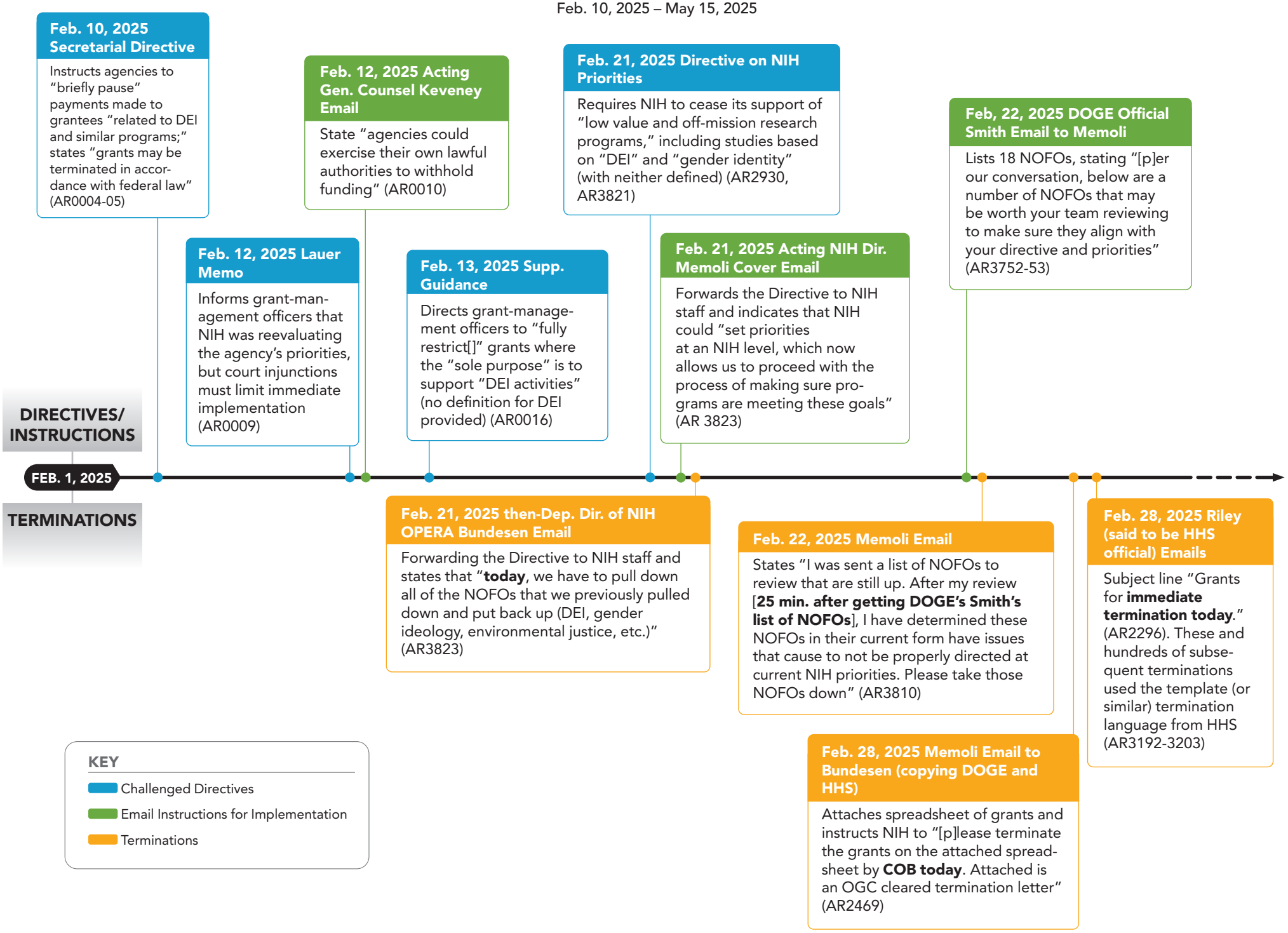
June 13, 2025

/s/ Jessie J. Rossman
Jessie J. Rossman

APPENDIX A

TIMELINE OF DIRECTIVES AND TERMINATIONS

Feb. 10, 2025 – May 15, 2025



TIMELINE OF DIRECTIVES AND TERMINATIONS

Feb. 10, 2025 – May 15, 2025