IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS, *et al.*,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., *et al.*,

Defendants.

No. 1:25-cv-10814-WGY

Leave to File Reply Granted
April 9, 2025 (ECF No. 59)

REPLY IN SUPPORT OF PLAINTIFFS'
MOTION FOR A PRELIMINARY INJUNCTION

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INTRODUCTION

NIH's recent actions are without historical precedent. Before the events giving rise to this suit, NIH terminated less than one grant per year—usually for instances of gross misconduct. Ex. 37 ¶¶29–31; Ex. 41, at 44:7–45:23.[1] Since January, however, NIH has abruptly cancelled over 800 projects.[2] And the termination letters continue to roll in. The agency has also slow-walked its review of applications for new grants, moving at a glacial speed that will prevent it from allocating all the money that Congress has appropriated this year. These delays and terminations—and the policies driving them—are illegal: they flout the standard of reasoned decisionmaking that the APA demands and violate the agency's constitutional obligations.

Defendants identify no reason why this Court should tolerate the irreparable harm these unlawful actions are causing plaintiffs and the American public. Defendants attack this Court's jurisdiction at length, but their central jurisdictional contention—that plaintiffs are bringing dressed-up breach-of-contract claims—recasts plaintiffs' complaint into something it is not. When they do eventually turn to the merits, defendants offer breezy assurances that their new policies are lawful. But the Challenged Directives barely pretend to engage in reasoned decisionmaking or to comply with the agency's legal obligations. And although defendants' opposition makes various factual assertions—for example, that any delays have now ended—defendants do not submit any actual evidence to back them up. As for the equities, defendants' insistence that plaintiffs have suffered no harm from the single largest mass termination of grants in NIH history beggars belief.

Plaintiffs have demonstrated a need for prompt relief. The Court should grant their motion.

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[1] "Ex." refers to exhibits to the Pappavaselio Declaration (ECF No. 77). "Mem." refers to plaintiffs' memorandum of law (ECF No. 78). "Opp." refers to defendants' opposition (ECF No. 95). "Reply Ex." refers to exhibits to this reply.

[2] Alfonsi, *Scientists Fear Trump Administration Cuts to NIH Could Impact the Health of Americans for Generations*, CBS News (Apr. 27, 2025), https://cbsn.ws/4iMte0y.

ARGUMENT

I. This Court has jurisdiction.

A. The Tucker Act does not deprive this Court of jurisdiction.

Defendants try (Opp. 7–11) to shunt a portion of this lawsuit into the Court of Federal Claims under the Tucker Act. But defendants misread both the Act and the relevant case law.

As an initial matter, even by their own terms, defendants' Tucker Act arguments apply only to a subset of plaintiffs' claims. Defendants do not argue that the Claims Court must hear plaintiffs' constitutional claims (Counts 4–5), *ultra vires* claims (Count 6), or declaratory-judgment claims (Count 8). *See* Mem. 18–19 (arguing that the Tucker Act does not apply to the constitutional and *ultra vires* claims); Opp. 7–11 (not contesting the point). Nor do defendants argue that the Tucker Act bars this Court from hearing plaintiffs' unreasonable-delay claim (Count 7); after all, that claim arises out of defendants' failure to take steps *preceding* the entry of any agreements with grantees. Thus, there is no dispute that this Court has jurisdiction over Counts 4 through 8.

As for Counts 1 through 3—plaintiffs' §706(2) claims—defendants' arguments rest on a creative recasting of plaintiffs' complaint. Defendants insist that the Tucker Act applies because plaintiffs have brought contract claims in disguise. But as another court recently put it, in rejecting the same argument that defendants now advance, plaintiffs' claims do not sound in contract because "the Court could decide this case without ever reading the grant agreements." *S.F. Unified Sch. Dist. v. AmeriCorps*, No. 25-cv-2425, 2025 WL 1180729, at *9 (N.D. Cal. Apr. 23, 2025) (brackets and quotation marks omitted). Under the well-established test for assessing whether a claim fails within the Tucker Act, courts look to (1) "the source of the rights upon which the plaintiff bases its claims" and (2) "the type of relief sought." *Albrecht v. Comm. on Emp. Benefits*, 357 F.3d 62, 68 (D.C. Cir. 2004) (cited at Opp. 8). Here, those factors favor plaintiffs: they assert rights under the APA (not their contracts) and request an order vacating unlawful agency directives

(not money damages or specific performance).[3]

In these ways, plaintiffs' claims resemble the Commonwealth's claims in *Bowen v. Massachusetts*, 487 U.S. 879 (1988). *See* Mem. 20–21. Defendants do not grapple with *Bowen*'s analogous facts, relegating any discussion of that thorough, binding, and on-point Supreme Court decision to a footnote. Opp. 8 n. 5. Instead, defendants argue that the Supreme Court's motion order in *California* controls this case. But that is incorrect for reasons already explained (Mem. 21–23), including that the Supreme Court understood the plaintiffs in that case—unlike plaintiffs here—to be asking "the Government to pay out past-due grant obligations." *Dep't of Education v. California*, 145 S. Ct. 966, 968 (2025). Just a few weeks before *California*, the Supreme Court declined the federal government's invitation to apply the Tucker Act to a case involving a freeze on the payment of certain foreign-aid funds—thus demonstrating that each case must be evaluated on its own terms. *Dep't of State v. AIDS Vaccine Advoc. Coal.*, 145 S. Ct. 753, 753 (2025). And in recent weeks, numerous courts have rejected the federal government's efforts to expand the *California* order beyond the facts of that case.[4] This Court should do the same.

The other cases defendants cite do not compel a different result. In *Albrecht*, the Court

[3] Defendants' own conduct belies the assertion that this case is contractual. Defendants terminated grants without any advance assessment of individual projects. Reply Ex. 1 ¶¶20–23 (describing termination of NCATS grants without input from director or staff); *see* 42 U.S.C. §287a(e)(1)–(2) (describing NCATS director's authority). In other words, the terminations clearly stem from an across-the-board policy, and *that* is the focus of the plaintiffs' APA claims.

[4] *See S.F. Unified*, 2025 WL 1180729, at *6–11; *Cmty. Legal Servs v. HHS*, No. 25-cv-2847, 2025 WL 1168898, at *3 (N.D. Cal. Apr. 21, 2025); *Climate United Fund v. Citibank, N.A.*, No. 25-cv-698, 2025 WL 1131412, at *9–12 (D.D.C. Apr. 16, 2025); *Woonasquatucket River Watershed Council v. USDA*, No. 25-cv-97, 2025 WL 1116157, at *12–15 (D.R.I. Apr. 15, 2025); *Chi. Women in Trades v. Trump*, No. 25-cv-2005, 2025 WL 1114466, at *8–10 (N.D. Ill. Apr. 14, 2025); *New York v. Trump*, No. 25-cv-39, 2025 WL 1098966, at *1–3 (D.R.I. Apr. 14, 2025); *Maine v. USDA*, No. 25-cv-131, 2025 WL 1088946, at *19–20 (D. Me. Apr. 11, 2025); *but see Widakuswara v. Lake*, No. 25-5144, 2025 WL 1288817, at *3–5 (D.C. Cir. May 3, 2025) (holding 2–1, on motion for stay, that Tucker Act likely applied). The minute order dissolving a TRO in *Mass. Fair Housing Center* does not suggest a different result. Unlike plaintiffs here, the plaintiffs in that case were not challenging the legality of agency policies antecedent to the challenged terminations. *See generally* Compl., *Mass. Fair Hous. Ctr. v. HUD*, No. 25-cv-30041 (ECF No. 1). Regardless, to the extent that minute order relied on the view that a challenge to a grant termination is a *per se* request to "enforce a contractual obligation to pay money," Minute Order, No. 25-cv-30041 (ECF No. 42), it overreads the Supreme Court's order in *California*.

held that the Tucker Act applied where "appellants' claim turn[ed] *entirely* on the terms of a contract." 357 F.3d at 69. Similarly, in *American Science & Engineering, Inc. v. Califano*, 571 F.2d 58 (1st Cir. 1978)—which predated *Bowen*'s controlling decision—the court held that the district court lacked jurisdiction because the "plaintiff's own prayer for relief ma[de] it clear" that the plaintiff sought "enforcement of the license agreements or money damages." *Id.* at 63; *see also Diaz v. Johnson*, No. 19-1501, 2020 WL 9437887, at *1–2 (1st Cir. Nov. 12, 2020) (noting that complaint expressly invoked Tucker Act and sought damages). The contrasting facts in those cases only confirm why the claims here are *not* contract claims.

Defendants might prefer to litigate this case in an Article I tribunal that offers fewer protections than this Court, but they cannot achieve that result simply by rewriting the complaint.

B. Plaintiffs are not seeking specific performance of a contract.

Defendants' contention (Opp. 12–13) that this Court lacks jurisdiction to order specific performance of a contract collapses into defendants' flawed Tucker Act argument. To be sure, *if* a plaintiff seeks relief for breach of contract, it can only pursue money damages, as defendants' cited cases hold. *See Coggeshall Dev. Corp. v. Diamond*, 884 F.2d 1, 5 (1st Cir. 1989) (plaintiff "sue[d] for breach of contract and ask[ed] [for] specific performance"); *Imaginarium LLC v. SBA*, 618 F. Supp. 3d 1225, 1232 (D. Utah 2022) (similar). As already discussed, however, plaintiffs are *not* seeking contractual relief. Instead, their §706(2) claims ask the Court to set aside unlawful policies that operate at a higher level—and to vacate or enjoin actions enforcing those policies. That kind of request is the bread and butter of the APA. The fact that defendants might need to undertake discrete, actions to comply with a judgment in plaintiffs' favor does not change the nature of plaintiffs' claims: as *Bowen* explained, a request "for specific relief" under the APA is "within the District Court's jurisdiction." 487 U.S. at 910; *see also Nat'l Ctr. for Mfg. Scis. v. United States*, 114 F.3d 196, 198–99 (Fed Cir. 1997) (Tucker Act did not apply because plaintiff asserted statutory

violations and right to payment was contingent on future events).

C. Plaintiffs are not pursuing an impermissible programmatic challenge.

Defendants are also wrong to argue (Opp. 13–15) that sovereign immunity bars this suit because plaintiffs are bringing "an impermissible programmatic challenge." As an initial matter, the notion that plaintiffs are pursuing a "wholesale" overhaul of NIH's operations is inconsistent with defendants' insistence that plaintiffs have brought workaday breach-of-contract claims; both things cannot be true. Regardless, plaintiffs' claims are nothing like the programmatic challenges that courts have rejected elsewhere. In *Lujan v. National Wildlife Federation*, 497 U.S. 871 (1990), plaintiffs' claims failed because they did not pursue a challenge "to a single [agency] order or regulation, or even to a completed universe of particular [agency] orders and regulations." *Id.* at 890; *see Ala.-Coushatta Tribe v. United States*, 757 F.3d 484, 490 (5th Cir. 2014) (complaint was "structured as a blanket challenge to *all* of the Government's actions with respect to *all* permits and leases" for certain land). Here, by contrast, plaintiffs challenge a bounded universe of discrete directives. Mem. 8–11; *see infra*, pp. 6–8. The fact that defendants have enforced these directives against hundreds of projects does not make this lawsuit *programmatic*, even if it is *large*. As the First Circuit did in *New York v. Trump*, 133 F.4th 51, 68 (2025), and as this Court did in *AAUP v. Rubio*, No. 25-cv-10685, 2025 WL 1235084, at *21 (Apr. 29, 2025), the Court should once again reject the federal government's attempt to use *Lujan* to block run-of-the-mill APA claims.

Defendants' contrary arguments are unpersuasive. They take issue (Opp. 15 & n. 6) with the fact that plaintiffs have included certain "nonpublic or undisclosed directives" within the definition of the "Challenged Directives." But in this respect, too, plaintiffs' claims are bounded: the relevant nonpublic directives are those requiring specific actions (*i.e.*, "curtail[ing] NIH support for previously advertised funding opportunities and previously awarded grants") on specific grounds (*i.e.*, because they "relate to one or more of" several discrete blacklisted subjects).

Proposed Order ¶(i)(i), at 3 (ECF No. 76-1).[5] More generally, defendants argue (Opp. 15) that "[p]laintiffs' claims are not saved by their identification" of the documents constituting the Challenged Directives. But it is not clear what defendants mean by this: the very thing that distinguishes a programmatic challenge from a routine APA claim is the identification of specific agency actions. Nor is it clear why defendants fault plaintiffs (Opp. 14) for supporting their unreasonable-delay claim with statistics: courts often consider statistics in applying §706(1). *See, e.g.*, *Kennedy v. Dep't of State*, No. 24-cv-11556, 2025 WL 662566, at *3 (D. Mass. Feb. 28, 2025).

D. Plaintiffs' §706(2) claims challenge final agency actions.

Defendants acknowledge (Opp. 17) that an agency action is final if it marks the consummation of the agency's decisionmaking and carries legal consequences. That standard does not require a particular measure of formality: as this Court recently explained, even an "unwritten" policy compelling agency officers to "consider" certain "factor[s]" in their decisions can be reviewed under the APA. *AAUP*, 2025 WL 1235084, at *21 (brackets and quotation marks omitted); *see also Army Corps of Eng'rs v. Hawkes Co.*, 578 U.S. 590, 599 (2016) (analysis of finality is "pragmatic"). The Challenged Directives easily pass this test: they memorialize defendants' view that certain research topics are off-limits, and they detail the specific steps that NIH officials must take to operationalize that policy. Mem. 23 n. 19. In this way, the directives are like the agency memorandum the Supreme Court recently found reviewable in *Biden v. Texas*,

[5] Importantly, *defendants' own conduct* creates the need to guard against the likelihood that NIH is making decisions based on nominally "internal" or "draft" directives that have been withheld from the public. That is exactly what happened with the Priorities Directive and Revised Priorities Directive: although those directives bear all the hallmarks of final agency policies, the public learned of them only through press reports. Courts have long made clear that an "agency will not be permitted to develop a body of 'secret law' . . . hidden behind a veil of privilege because it is not designated as 'formal,' 'binding,' or 'final.'" *Coastal States Gas Corp. v. Dep't of Energy*, 617 F.2d 854, 867 (D.C. Cir. 1980). But defendants have sought to do just that. Defendants' related contention (Opp. 15 n. 6) that they "cannot defend" a claim based on unpublished directives is not well-taken. Defendants know whether they have issued any other internal directives that (1) "curtail NIH support for previously advertised funding opportunities and previously awarded grants" because they (2) "relate to one or more of" the specific blacklisted subjects plaintiffs have identified.

597 U.S. 785, 793, 808–10 (2022) (allowing review of policy that "direct[ed] [agency] personnel to take all appropriate actions to terminate [a program], including taking all steps necessary to rescind implementing guidance").

To support their argument, defendants reimagine the Challenged Directives. They argue (Opp. 17–19) that the directives merely initiate a review process, but that misstates the directives' effect. On their face and in practice, the directives are the written distillation of defendants' determination that certain research topics are now taboo—and that any projects connected with those topics must be defunded. Mem. 8–11; *see* Reply Ex. 1 ¶¶21, 25–26 (describing fallout at NIH center following sudden terminations). To be sure, defendants have enforced those directives against hundreds of individual projects nationwide. But the APA allows plaintiffs to challenge the overarching policy itself: the types of "agency action" that can be reviewed under the APA include "rule[s]," which the statute defines broadly to encompass "agency statement[s] of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency." 5 U.S.C. §551. The Challenged Directives easily satisfy that definition. In the end, defendants' own conduct confirms that the directives are not "interlocutory": if they were, defendants would not be implementing them by terminating hundreds of grants around the country.

Regardless, defendants do not dispute (and could not dispute) that the grant terminations *themselves* are final agency actions. As part of its review of those terminations, the Court clearly has the authority to review the overarching agency policies that compelled them. *See* 5 U.S.C. §704 ("A preliminary, procedural, or intermediate agency action or ruling not directly reviewable is subject to review on the review of the final agency action."); *see also see* Am. Compl, Prayer

for Relief I(d), at 88 (ECF No. 75) (asking the Court to set aside the terminations).[6]

E. The challenged actions are not "committed to agency discretion."

Finally, defendants are incorrect to argue (Opp. 20) that plaintiffs cannot pursue their APA claims because "[a]ny NIH actions to terminate existing grants or to award future grants" are committed to agency discretion. *See* 5 U.S.C. §701(a)(2).[7] Here again, defendants mischaracterize plaintiffs' claims as raising programmatic challenges to NIH's "discretionary funding decisions" or "grant administration." But plaintiffs challenge specific directives and subsequent actions implementing those directives. The Supreme Court has "read the exception in §701(a)(2) quite narrowly, restricting it to those rare circumstances where the relevant statute is drawn so that a court would have no meaningful standard against which to judge the agency's exercise of discretion." *Weyerhaeuser Co. v. FWS*, 586 U.S. 9, 23 (2018) (quotation marks omitted). This case does not present one of those "rare circumstances."

To support their argument, defendants rely on two decisions finding certain funding matters committed to an agency's discretion. Opp. 19–21 (citing *Lincoln v. Vigil*, 508 U.S. 182 (1993); *Milk Train, Inc. v. Veneman*, 310 F.3d 747 (D.C. Cir. 2002)). From these decisions, defendants appear to extrapolate the principle that all questions related to fund allocation are committed to agency discretion. Neither decision supports that sweeping proposition. Again, plaintiffs seek review not of the agency's discretionary funding decisions but of defendants' adoption and

[6] Defendants argue (Opp. 15–17) that a subset of directives—specifically, the Notice Pause Directive, Lauer Memorandum, Supplemental Lauer Memorandum, and Climate Change Directive—are irrelevant because they have expired and/or cause no injury. Perhaps the administrative record will bear this claim out. But what the current record shows is that plaintiffs have experienced significant injury from a series of overlapping and interlocking blacklisting directives that have caused unprecedented delays and disruptions. The secretive and slapdash nature of these directives, which makes it hard to know which are effective at any given time, is hardly a defense.

[7] While defendants do not expressly limit this argument to plaintiffs' APA Claims, *see* Opp. 19–21, it cannot plausibly apply to plaintiffs' constitutional, *ultra vires*, or declaratory-judgment claims. The committed-to-agency-discretion limitation is found in §701(a)(2), a provision of the APA; it obviously does not govern non-APA claims.

enforcement of the overarching Challenged Directives. These directives directly conflict with authorizing statutes and applicable regulations, *see infra*, pp. 9–14, which "circumscribe [the] agency['s] discretion to allocate resources" and provide "meaningful standards" for a court to employ when reviewing the agency's decisions. *See Pol'y & Rsch., LLC v. HHS*, 313 F. Supp. 3d 62, 76 (D.D.C. 2018) (K.B. Jackson, J.) (collecting cases); *AMA v. Reno*, 57 F.3d 1129, 1134–35 (D.C. Cir. 1995) (discretion over resource allocation does not bar review of whether agency gave a reasoned explanation and complied with statutory requirements). For these reasons, the cases defendants cite are inapposite: they preclude review only so "long as the agency allocates funds from a lump-sum appropriation to meet *permissible statutory objectives*." *Lincoln*, 508 U.S. at 193 (emphasis added).

To the extent defendants advance their committed-to-agency-discretion argument not only with respect to plaintiffs' §706(2) claims, but also with respect to plaintiffs' undue-delay claims under §706(1), they are on even weaker footing. The law requires defendants to hold study-section and advisory-council meetings and to issue final decisions on grant applications. Mem. 34–35. Neither *Lincoln* nor any other case defendants cite suggests that Congress has committed to NIH the discretion to unreasonably delay those actions—or to forgo them entirely. In other words, even if defendants have the discretion whether to issue a particular grant, they do not have the unreviewable discretion to delay a decision indefinitely. Mem. 35 n. 22.

II. Plaintiffs are likely to succeed on the merits of their claims.

A. The adoption and enforcement of the Challenged Directives violated §706(2).

1. Defendants fail to reconcile their actions with the relevant statutes.

As plaintiffs have explained (Mem. 23–25), the Challenged Directives violate the APA because they conflict with congressional directives, including statutes requiring NIH to support the health of certain minority populations and to formulate a periodic strategic plan.

Defendants counter (Opp. 26–27) that they have acted consistently with congressional directives because they have not terminated every single grant pertaining to minority health. But the fact that defendants have not engaged in *more* unlawful conduct does not justify the unlawful actions they *have* taken. For the reasons discussed (Mem. 23–24), defendants' decision to blacklist research with perceived equity aims is inconsistent with Congress's judgment. That is true even if defendants have not canceled *every last grant* with an equity dimension.[8]

As for the strategic plan, defendants argue (Opp. 27) that the plan is merely "aspirational" and is not a "strait jacket." But that argument sidesteps the problem with defendants' conduct: even if defendants have some discretion to depart from the plan from time to time, they cannot toss entire portions of the plan out the window at a moment's notice. Mem. 24. Doing so effectively renders Congress's carefully crafted strategic-planning statute a nullity. *Id.*

2. Defendants misread and misapply 2 C.F.R. §200.340.

The Challenged Directives instruct NIH officials to terminate grants under 2 C.F.R. §200.340 even though that regulation does not allow terminations based on *sua sponte* changes in agency priorities. As plaintiffs have explained (Mem. 27–28), the most natural reading of §200.340(a)(2)[9] is that an agency can terminate a grant only if it no longer effectuates agency priorities for reasons external to the agency—*e.g.*, if new evidence shows that the project is

[8] Defendants claim (Opp. 26) that their Exhibit A shows they are not hostile to *all* "research into certain minority-related topics." But the exhibit raises more questions than it answers. According to the exhibit, defendants have maintained programs called "Church Wellness Coordinator-led Intervention to Improve Hypertension Control in the Black Community" and "Engaging Partners in Caring Communities (EPICC): Building capacity to implement health promotion programs in African American churches." But during the same time period, NIH cancelled a grant for "Faithful Response II: COVID-19 Rapid Test-to-Treat with Kansas City Missouri Health African American Churches" on the ground that it involved DEI objectives. Ex. 15 (at Ex. 31, p. 1). How these decisions are consistent is anyone's guess—because defendants have provided no explanation aside from their boilerplate letters. *See* Reply Ex. 1 ¶¶11, 14–17, 23–26 (describing how NIH has departed so far from the agency's prior practice and understanding of "DEI" that IC staff could not reliably flag grants at risk of termination under the Challenged Directives).

[9] Defendants' terminations cited the 2020 version of §200.340, in which pertinent no-longer-effectuates language appears in subsection (a)(2). Defendants' opposition now cites the 2024 version, in which the language appears (as amended) in subsection (a)(4). Plaintiffs continue to cite the 2020 version that NIH itself cited in terminating grants.

ineffective or no longer feasible. *See* AAMC Amicus Br. 12–13 (ECF No. 86). Defendants respond (Opp. 23) that the text of the regulation does not *expressly preclude* the agency from terminating grants based on unilateral changes in its priorities. But defendants' reading contravenes the regulatory structure and history. *See* Mem. 28; AAMC Amicus Br. 11–15. If defendants' argument were correct, most of the regulations relating to grant terminations would be superfluous, because §200.340(a)(2) would give NIH absolute and unreviewable authority to cancel a project at any time for any reason. Defendants have no response.

Regardless, the precise meaning of §200.340(a)(2) is irrelevant because that provision does not govern NIH grants. Defendants do not dispute that §200.340, by its terms, is nonbinding. Mem. 25–26. Nor do they dispute that HHS adopted its own, HHS-specific regulation that rejected §200.340's "priorities" clause. Mem. 26–27.[10] Still, defendants argue (Opp. 22) that §200.340 applies because NIH incorporated that provision into its agreements with award recipients by way of a document called the Grants Policy Statement (GPS), *see* Ex. 11. As discussed above, however, plaintiffs are not bringing contract claims. The question is whether the Challenged Directives comply with the agency's controlling regulation, and the answer to that question does not turn—and could not turn—on the terms and conditions of grant awards. *Pol'y & Rsch.*, 313 F. Supp. 3d at 82 (holding that the GPS "does not, and cannot, trump the agency's formal regulations")

Even if the Court were to indulge defendants' efforts to inject the terms and conditions of grant awards into this case, defendants' arguments still fail. Defendants contend (Opp. 21) that plaintiffs' "notices of award" cross-reference the GPS, which in turn cross-references §200.340.

[10] Defendants say (Opp. 22) that the grounds for termination in the HHS regulation, 45 C.F.R. §75.372(a), are not exhaustive. But that is inconsistent with the text and structure of §75.372(a), which establishes a comprehensive termination framework and does not contemplate other, unspoken grounds. Defendants' argument also makes little sense of the history: if they could rely on §200.340 all along, why did HHS promulgate §75.372, and why did the agency later repeal it and *expressly adopt* the OMB regulations starting this October? Mem. 26–28 & n. 20.

But a federal agency must "clearly and unambiguously specify termination provisions applicable to each Federal award." 2 C.F.R. §200.340(b) (2020); *see id.* §200.211(c)(1)(v) (2020). A single cross-reference to §200.340 in the 400-plus page GPS—embedded in a section discussing "remedies for *noncompliance*" (*see* Ex. 11 §8.5.2, at IIA-15)—hardly provides unambiguous notice that NIH can terminate grants for "changed priorities." Indeed, a different section of the GPS suggests the exact opposite, incorporating by reference an NIH policy that says:

> **IV. Non-Adoption of 2 CFR 200.240(a)(2) [sic] Termination Clause**
>
> a. NIH does not adopt 2 CFR § 200.240(a)(2) [sic], stating that the Federal awarding agency may terminate a Federal award if the award no longer effectuates the program goals or agency priorities. . . .

Research General Terms and Conditions at 2 (Apr. 8, 2021), https://bit.ly/NIH-Terms; *see* Ex. 11 §3.1, at IIA-2 (incorporating the April 2021 document by reference). Thus, even if the GPS could be read to incorporate §200.340 *generally*, it does not incorporate subsection (a)(2) *specifically*.[11]

3. Defendants' actions were unreasoned and unreasonable.

As plaintiffs have explained (Mem. 28–31), the Challenged Directives are arbitrary and capricious because they did not (1) acknowledge or provide good reasons for the agency's changes in longstanding priorities, (2) explain why the blacklisted topics were chosen (or allow for individualized consideration of projects touching on those topics), or (3) consider grantees' reliance interests. Defendants fail to resuscitate the agency's reasoning on any of those fronts.

Defendants argue (Opp. 24–26) that "a change in administration" is a "reasonable basis" for changed agency priorities. But their only support for that proposition comes from a dissent.[12]

[11] Defendants' opposition states (at 23) that plaintiffs relied on the NIH Grant Policy Statement to argue that NIH may terminate a grant "only if a recipient has failed to comply with the award's terms and conditions." It is not clear what defendants are referring to; the page they cross-reference, Mem. 26, contains no argument about the GPS.

[12] Justice Rehnquist concurred in part and dissented in part in *State Farm*; the language that defendants quote comes from the portion of his opinion addressing the one issue on which he *disagreed* with the majority. *See Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 58 (1983) (Rehnquist, J.); Opp. 24–25.

And even if a presidential transition can, in some circumstances, provide grounds for changed priorities, an inauguration is not a quadrennial APA hall pass: an agency must still acknowledge that it is changing positions, identify the transition as the reason for the change, and grapple with the implications of its new stance. *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009); *Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983); Mem. 28–31. Defendants failed to do any of that. Nowhere do the Challenged Directives or termination letters acknowledge that NIH is changing its priorities at all, let alone make any effort to tie those changes to the change in administration. *See* Mem. 28–30. Pointing to a change in administration also fails to explain defendants' new and unsupported positions on *empirical* matters—*e.g.*, defendants' contention that certain programs "do not enhance health, lengthen life, or reduce illness," Ex. 10, Appx. 3—which do not depend on who occupies the Oval Office.

As for the agency's failure to consider plaintiffs' reliance interests, defendants now assert (Opp. 25) that "NIH necessarily understood that it was terminating funding on which the grantee relied" but decided those interests "were outweighed." But the Court must judge the Challenged Directives by the agency's "contemporaneous explanations," not the "*post hoc* rationalizations" that counsel offer for the first time in litigation. *DHS v. Regents of the Univ. of California*, 140 S. Ct. 1891, 1909 (2020). And nothing in the Challenged Directives or termination letters gives even a hint that defendants thought about reliance interests before cutting programs mid-stream. *See Massachusetts v. NIH*, No. 25-cv-10338, 2025 WL 702163, at *21 (D. Mass. Mar. 5, 2025) (identifying a failure to consider reliance interests in reducing NIH funding).

As a fallback, defendants appear to argue (Opp. 25) that if the Court agrees with plaintiffs on these questions, their remedy is limited to "remand back to NIH for a follow up, not an injunction." But "vacatur is the normal remedy" under the APA, and a bare remand is inappropriate

given, among other things, "the seriousness of the [Challenged Directives'] deficiencies." *Env't Def. Fund v. FERC*, 2 F.4th 953, 976 (D.C. Cir. 2021) (brackets and quotation marks omitted).

B. Defendants violated §706(1) by delaying and withholding required action.

Defendants do not meaningfully argue that the unprecedented and ongoing delays of the past several months have been reasonable. Instead, they contend that plaintiffs cannot prevail on their undue-delay claim under §706(1) because (1) the actions that NIH failed to take in recent months—convening study sections and advisory councils and issuing final award decisions—are not "discrete and mandatory agency action that the agency failed to take," and (2) "the agency is presently taking the very actions that plaintiffs seek to compel." Both arguments fail.

1. Defendants are delaying required agency actions.

Defendants do not dispute that the PHSA and its implementing regulations require study sections and advisory councils to hold meetings, or that those meetings are "discrete." Nevertheless, defendants maintain (Opp. 29) that §706(1) does not allow a court to compel "[m]eetings—even meetings established by statute." But nothing in the provisions they cite supports that categorical rule. As defendants acknowledge, §706(1) allows a court to compel an "agency action." And under 5 U.S.C. §551(13), an agency action includes "the whole or part of an agency . . . sanction [or] relief." A "relief," in turn, includes the "taking of other action on the application or petition of, and beneficial to, a person," while a "sanction" includes the "withholding of relief." 5 U.S.C. §§551(10)(B), (11)(C). Study-section and advisory-council meetings fall within those capacious definitions: they are formal meetings at which an arm of the agency evaluates, grades, and votes on each application.

The case defendants cite, *Texas Health & Human Services Commission v. United States*, 193 F. Supp. 3d 733 (N.D. Tex. 2016), underscores the point. There, the plaintiffs sought to compel action under a statute that requires federal agencies to consult with state and local governments at

least quarterly regarding certain refugee programs. *See id.* at 742. Those "consultations," which the court described as "an ongoing process of communication," *id.*, look nothing like study-section or advisory-council meetings, at which NIH and its instrumentalities take concrete steps to decide whether an application advances to the next stage—or not. Indeed, the *Texas Health* court contrasted the consultative communications at issue there with communications that would be triggered by *specific* applications. *Id.* Here, plaintiffs' claims are of the latter variety.

Regardless, even if the court lacked the power to compel study-section and advisory-council meetings, it certainly has the power to compel a final decision on plaintiffs' pending applications; that decision is plainly an "agency action." *See Tang v. Chertoff*, 493 F. Supp. 2d 148, 156, 158 (D. Mass. 2007) (compelling adjudication of pending application for immigration relief). Defendants respond (Opp. 29) that 42 C.F.R. §52.5(b)(2) allows the agency to "defer [a decision on an application] because of either lack of funds or a need for further evaluation." But defendants have not purported to defer any applications for lack of funding or further evaluation—and they certainly have not presented evidence of any such deferrals. Defendants' argument also ignores 5 U.S.C. §555(b), which requires the agency to "proceed to conclude a matter presented to it" "within a reasonable time." *See Tang*, 493 F. Supp. 2d at 155–56; *Rezaii v. Kennedy*, No. 1:24-cv-10838, 2025 WL 750215, at *5 (D. Mass. Feb. 24, 2025). In short, the agency does not have unbridled discretion to sit on an application forever, as defendants seem to suggest.

2. Defendants have not shown that the delays have abated.

Defendants next argue (Opp. 30–31) that they have resumed ordinary business, so there is nothing left for the Court to compel. In particular, they argue (Opp. 28) that their delays in adjudicating grant applications are—or were—merely "a brief pause that NIH took on processes shortly following the change in administrations [that] is over." But they offer no actual evidence to support that bald assertion. And the evidence in the record shows that unreasonable delays

persist—with significant consequences for plaintiffs and their institutions. *See* Reply Ex. 2 ¶¶3–10; Reply Ex. 3 ¶¶5–10; Reply Ex. 5 ¶¶9–16.

Defendants cite the Federal Register to show that *some* study-section and/or advisory-council meetings have occurred or are now scheduled to occur. *See* Opp. 30 (citing Opp. 6 nn. 3–4). But that does not address the problem, which is that defendants have failed to resume meetings "at a pace that will allow them to meet the timelines that NIH has published and consistently met in the past." Mem. 12; *see* Reply Ex. 5 ¶12. Defendants thus attack a straw man in asserting (Opp. 28) that "[p]laintiffs do not and cannot dispute that NIH has resumed reviewing and deciding applications." What plaintiffs *have* disputed is whether NIH has resumed its operations in a way that will allow it to discharge its statutory and regulatory obligations. All the evidence in the record shows that it has not, and defendants do not meaningfully contest the point.

To avoid that problem, defendants assert (Opp. 31) that because NIH delayed *all* applications, plaintiffs are raising an impermissible "programmatic" challenge. As explained above, defendants are confusing a large lawsuit with a programmatic one. *See supra*, p. 5. The fact that defendants have engaged in *widespread* delays—rather than delaying a single application here or there—does not strengthen their position. Defendants also fault plaintiffs (Opp. 31) for comparing the current delays to the timelines followed in previous years. As explained, however (Mem. 36), courts often consider typical processing times in evaluating §706(1) claims.

C. Defendants have violated separation-of-powers principles by failing to spend appropriated funds.

Defendants do not dispute that the Constitution does not expressly authorize their actions in this case. *See* Mem. 32–33. And their claim (Opp. 32) that Congress "explicitly" authorized NIH to systematically terminate grants vastly overreads the statutes they cite. Whatever generic authority agency officials have to set the agency's "overall direction" or conduct "priority-setting

reviews," Opp. 32 (quoting 42 U.S.C. §282(b)), those statutory grants do not go so far as to permit the Executive Branch to effectively "impound" congressionally appropriated funds. Instead, if the President and his appointees "want[] to spend less than the full amount appropriated by Congress," they "must propose the rescission of funds [under the Impoundment Control Act (ICA)], and Congress then may decide whether to approve a rescission bill"; the Executive Branch, in other words, "does not have unilateral authority to refuse to spend the funds." *In re Aiken County*, 725 F.3d 255, 261 n. 1 (D.C. Cir. 2013); *see* Mem. 32–33. Defendants have not invoked the ICA's procedures; as a result, they have overstepped the Executive's discretionary authority to set priorities and usurped congressional spending power.

Defendants argue (Opp. 33) that no money has been rescinded or withheld because they have taken steps to repair the damage caused by the delays and terminations. As discussed above, however, there is no evidence that these meetings are happening at a pace that will allow the funds to be expended by the end of the year as mandated by Congress. *See supra*, pp. 15–16. After a jump in the number of meetings scheduled for April, there is a plateau of meetings scheduled from now through the summer. Reply Ex. 2 ¶¶9–10; *see also* Reply Ex. 3 ¶¶8–10 (analyzing funding obligated to date). Moreover, plaintiffs presented unrebutted evidence that grants subject to blacklisted topics were pulled entirely from study-section review. *E.g.*, Ex. 18 ¶¶18–19. Accordingly, it is unlikely NIH will close the gap its delays have created.

III. Plaintiffs have demonstrated irreparable harm.

"District courts have broad discretion to evaluate the irreparability of alleged harm and to make determinations regarding the propriety of injunctive relief." *K-Mart Corp. v. Oriental Plaza, Inc.*, 875 F.2d 907, 915 (1st Cir. 1989). Irreparable harm exists whenever "a plaintiff stands to suffer a substantial injury that cannot adequately be compensated by an end-of-case award of money damages." *Rosario-Urdaz v. Rivera-Hernandez*, 350 F.3d 219, 222 (1st Cir. 2003). Here,

plaintiffs have introduced detailed evidence establishing exactly that kind of harm—*i.e.*, numerous irreparable injuries that have already occurred and will continue to occur absent injunctive relief.

Defendants respond (Opp. 34–35) that these harms are not irreparable because plaintiffs' injuries involve "delayed payment of money." But plaintiffs have put forward unrebutted evidence of substantial and irreparable *non*-monetary harms. For example, defendants' actions have led—and will continue to lead—to the discontinuation of vital research initiatives and programs, *e.g.*, Ex. 17 ¶51; Ex. 20 ¶45; Ex. 36 ¶20, including longitudinal studies whose data will be irretrievably invalidated, *e.g.*, Ex. 25 ¶22; Ex. 33 ¶18; Ex. 65 ¶9, and animal studies whose subjects will need to be euthanized, *e.g.*, Ex. 34 ¶46; Ex. 59 ¶38. Defendants' actions have likewise required—and will continue to require—that plaintiffs' universities lay off or fire highly specialized and trained personnel, *e.g.*, Ex. 15 ¶41; Ex. 31 ¶18; Ex. 45 ¶10, cut enrollment and rescind offers of admission, *e.g.*, Ex. 45 ¶10; Ex. 59 ¶31, and withdraw funding offers for accepted applicants, *e.g.*, Ex. 45 ¶15. A session of this Court recently found that these exact harms are irreparable when they arise from a mere reduction in NIH funding. *See Massachusetts*, 2025 WL 702163, at *28–31. It follows *a fortiori* that these harms are irreparable when they stem from outright terminations.[13]

Defendants are wrong to suggest (Opp. 35) that plaintiffs can avoid this irreparable harm by shifting resources. States typically set their budgets for the upcoming year in advance, *see, e.g.*, Mass. G.L. c. 75, §8, and so could not possibly have budgeted in anticipation of the unprecedented delays and terminations at issue in this suit. In any event, the question is not whether the state as a whole suffers irreparable harm, but whether the relevant institution does. *See Massachusetts*,

[13] Even if plaintiffs' harms were "primar[il]y" monetary in nature (Opp. 34), they are still irreparable, because sovereign immunity would bar plaintiffs from suiting the federal defendants for all the economic losses they will incur. *See Rosario-Urdaz*, 350 F.3d at 222; *Chamber of Commerce v. Edmondson*, 594 F.3d 742, 770–71 (10th Cir. 2010) ("Imposition of monetary damages that cannot later be recovered for reasons such as sovereign immunity constitutes irreparable injury."); *California v. Azar*, 911 F.3d 558, 581 (9th Cir. 2018) (same); *Concord Hosp., Inc. v. NH Dep't of Health and Human Servs.*, 743 F. Supp. 3d 325, 362–63 (D.N.H. 2024) (same).

2025 WL 702163, at *30 (analyzing the issue at the institution level). And the unrebutted evidence shows that plaintiffs' institutions do not have the funds to weather this assault without incurable losses, *e.g.*, Ex. 45 ¶13; Ex. 60 ¶11, and any "glide path" funding to ease the impacts to research strips funding from other vital areas, *e.g.*, Ex. 45 ¶¶9–15; Ex. 59 ¶27; Ex. 17 ¶¶39, 51 (interim funding pulled from other needs not "sustainable"); Reply Ex. 4 ¶¶2–3.

Defendants also argue (Opp. 35–37) that the evidence of plaintiffs' harms is "speculative' and "conclusory." Not so. Plaintiffs have offered numerous declarations detailing the concrete injuries they face from both terminations and delays. *See* Ex. 45 ¶¶10–15 (documenting rescission of offers from incoming graduate classes because of delays and terminations); Ex. 50 ¶10 (loss of essential senior researcher attributable to delays). In response to this and other evidence of harm, defendants have offered *no* competent evidence whatsoever.

IV. The public interest favors an injunction.

Courts have consistently held—including in the context of NIH funding—that the public interest favors an injunction where harm to health and safety would otherwise result. *E.g.*, *Massachusetts*, 2025 WL 702163, at *32. Here, plaintiffs have presented unrebutted evidence that defendants' actions will result in "diminished access to healthcare" for at-risk populations, *see, e.g.*, Ex. 17 ¶44 (termination of study providing screening for certain high-risk cancers with no other comparable screening in-state); Ex. 20 ¶45 (termination of funding providing resources for suicide prevention). None of defendants' alleged fiscal injuries outweigh these interests.

V. The injunction should provide relief to the plaintiff states and their institutions.

Defendants argue (Opp. 37–38) that any preliminary injunction should be limited to plaintiffs and their public institutions, not "unaffiliated institutions in their states." Plaintiffs do not disagree: they seek relief only for themselves and their own public institutions, including their

universities, instrumentalities, and subdivisions. *See* Proposed Order ¶¶(v), (vii) (ECF No. 76-1).[14]

VI. Defendants' stay request is premature.

Defendants argue (Opp. 38–39) that if the Court enters a preliminary injunction, it should stay the injunction pending the disposition of an appeal. Defendants do not meaningfully develop any argument on this point. That is unsurprising: their request is premature. The Court should deny it without prejudice to renewal at the appropriate juncture.

VII. The Court should exercise its discretion not to require a bond.

"By providing that the bond should be in an amount that the court considers proper," Rule 65(c) "vest[s] the district court with wide discretion." *Axia NetMedia Corp. v. Mass. Tech. Park Corp.*, 889 F.3d 1, 11 (1st Cir. 2018) (quotation marks omitted). Courts typically have not required bonds (or have required only a nominal bond) in actions between states and the federal government.[15] In this case—where the federal government has withheld previously awarded research funding and defendants will suffer no individual monetary harms—a bond is especially unwarranted. *See, e.g.*, *Nat'l Council of Nonprofits v. OMB*, No. 25-cv-239, 2025 WL 597959, at *38 (D.D.C. Feb. 25, 2025). Requiring a bond in those circumstances would, in essence, "hold Plaintiffs hostage for the resulting harm." *Id.*

CONCLUSION

The Court should grant plaintiffs' motion for a preliminary injunction.

[14] In discussing the injunction's scope, defendants refer (Opp. 38) to "these cases" and "the members of the plaintiff organizations." But the only plaintiffs in this action are states, and the case has not been consolidated with any others (although it has been deemed related to *APHA v. NIH*, No. 1:25-cv-10787-WGY).

[15] *See, e.g.*, *Maine*, 2025 WL 1088946, at *30 ($1,000) (citing other cases); *Maryland v. USDA*, No. 25-cv-748, 2025 WL 973159, at *40 (D. Md. Apr. 1, 2025) ($100 per plaintiff state); *Washington v. Trump*, No. 2:25-cv-244-LK, 2025 WL 659057, at *28 (W.D. Wash. Feb. 28, 2025) (no bond); *Colorado v. HHS*, 1:25-cv-121, 2025 WL 1017775, at *6 (D.R.I. Apr. 5, 2025) (no bond).

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