

**UNITED STATES DISTRICT COURT  
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.

Civil Action No. 1:25-cv-10787-WGY

Leave to file excess pages granted  
May 5, 2025 (ECF No. 62)

**DEFENDANTS' OPPOSITION TO PLAINTIFFS'  
MOTION FOR PRELIMINARY INJUNCTION**

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## I. INTRODUCTION

Plaintiffs request a preliminary injunction for two sets of claims: (1) contract-based grant-termination claims; and (2) claims of unreasonable delay in processing grant applications. The Tucker Act requires that contract-based grant termination claims be brought in the Court of Federal Claims. *See* 28 U.S.C. § 1491(a)(1). Plaintiffs frame these claims as constitutional, statutory, and regulatory challenges and invoke the Administrative Procedures Act, but, at its heart, Plaintiffs seek to undo the National Institute of Health’s (NIH) grant terminations and require the United States to specifically perform the agreements. Plaintiffs’ claims are rooted in those grant agreements, and whether the terms of those agreements allowed termination to effectuate agency priorities. The APA thus confers no jurisdiction upon this Court to review plaintiffs’ claims or to restore previously awarded grants.

The Court also lacks jurisdiction for additional independent and alternative reasons. *First*, plaintiffs’ claims are prohibited programmatic challenges rather than challenges to identified final agency actions. Plaintiffs attack the Executive’s authority to alter the government’s course after a change in administration, and impermissibly call upon this Court to supervise agency operations.

*Second*, even considering the identified actions individually, which Plaintiffs misleadingly call “Directives,”<sup>1</sup> the Court lacks jurisdiction to review them. Indeed, the challenge to each Directive fails either because it has already expired, it did not harm plaintiffs, or it is not a final

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<sup>1</sup> For the sake of clarity, Defendants use the same naming conventions used by Plaintiffs in their Memorandum in Support of Motion for Preliminary Injunction (ECF No. 41). Use of this terminology should not be construed as agreement with any of Plaintiffs’ allegations.

Moreover, despite claiming otherwise, ECF No. 41 at 6 n.2, Plaintiffs definition of the “Directives” differs from the defined “Challenged Directives” in the related matter. *Compare* ECF No. 37-1 ¶ 1 *with Massachusetts v. Kennedy*, No. 1:25-cv-10814-WGY, ECF No. 76-1 at 2.

agency action subject to APA review. *Third*, grant termination decisions are not subject to APA review. Although a grant recipient may seek recourse in the Court of Federal Claims under the Tucker Act, for purposes of APA review, the awarding and termination of grants is committed to agency discretion by law. For all these reasons too, the Court lacks jurisdiction.

Plaintiffs next claim that the National Institutes of Health (NIH) has unlawfully delayed the review and decision of grant applications. But the APA does not authorize a district court to review day-to-day program operations of federal agencies, and the “delay” claims are moot as NIH is now expeditiously reviewing and deciding applications.

All of Plaintiffs’ claims are also unlikely to succeed on their merits. The terms and conditions of Plaintiffs’ grant agreements provided that a change in agency priorities is a valid basis for the agency to terminate the grants. Defendants’ grant terminations were based on the agency’s new priorities, well-reasoned, and complied with applicable statutes.

Plaintiffs’ claims of irreparable harm from the grant terminations and delays also fail as the harms they claim are monetary, speculative, or described so generally that the description cannot satisfy plaintiffs’ high burden of proof. Nor can plaintiffs show that the public interest favors them. On the contrary, the public has a substantial interest in the federal government’s responsible stewardship of the public fisc. A preliminary injunction risks loss of federal funds that would likely be difficult or impossible to recover if NIH ultimately prevails.

For these reasons, plaintiffs’ motion for a preliminary injunction should be denied.

## **II. BACKGROUND**

NIH’s mission is to “seek fundamental knowledge about the nature and behavior of living



systems” in order to enhance health, lengthen life, and reduce illness and disability.<sup>2</sup> To further this mission, NIH spent more than \$35 billion in Fiscal Year 2023 on almost 50,000 competitive grants to more than 300,000 researchers at more than 2,500 universities, medical schools, and other research institutions across all 50 states and the District of Columbia. *See* Supplemental Guidance to the 2024 NIH Grants Policy Statement: Indirect Cost Rates, NOT-OD-25-068 (Feb. 7, 2025).

In awarding grants, NIH has been given broad discretion by Congress. 42 U.S.C. § 241(a)(3); 42 U.S.C. § 282(b)(3), (12). The Health and Human Services (“HHS”) Secretary awards grants “to those applicants whose approved projects will in the Secretary’s judgment best promote the purposes of the statute authorizing the grant and the regulations of this part.” 42 C.F.R. § 52.6(a). NIH also has broad discretion in grant administrations. *See, e.g.*, 42 C.F.R. § 52.6(f).

When NIH awards a grant, it enters an agreement with the grantee by issuing a Notice of Award (“NOA”), and the terms of that NOA govern the contractual relationship between the grantee and NIH. The terms of the grant agreements include the terms identified in NIH’s Grant Policy Statement (“NIHGPS”), including 2 C.F.R. § 200.340, which permits NIH to terminate a grant agreement if it “no longer effectuates the program goals or agency priorities.” 2 C.F.R. § 200.340(a)(4); *See* NIH Grants Policy Statement (“NIHGPS”) at Part II, Subpart A: General, ch. 3<sup>3</sup>; *see also, e.g.*, ECF No. 38-24 at 15-16 (listing “all other requirements described in the NIH Grant Policy Statement” under “Standard Terms and Conditions”). Importantly, while a grant agreement permits the grantee to draw funds, it does not “commit[] or obligate[] the United States

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<sup>2</sup> NIH, Mission and Goals, available at <https://www.nih.gov/about-nih/what-we-do/mission-goals> (last visited Feb. 14, 2025).

<sup>3</sup> <https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf>



in any way to make any additional, supplemental, continuation, or other award with respect to any approved application or portion of an approved application.” 42 C.F.R. § 52.6(c)(3).

Following the 2024 Presidential election, NIH’s priorities shifted. NIH exercised its broad discretion and authority to make and administer grants in alignment with those priorities, including by terminating certain grants. It conducted a comprehensive review of outstanding grants to determine which ones departed from its current priorities. To effectuate this review, from January 21 to February 1, the Administration issued a temporary freeze on the publication of any documents in the Federal Register until they were reviewed by a presidential appointee. *See* Lorsch Decl. ¶ 18. Because NIH must post a notice to the Federal Register every time it schedules a meeting to review grants, it scheduled no meetings for the duration of the temporary pause. 5 U.S.C. § 1009(a)(2). *Id.* ¶¶ 19, 21. NIH also cancelled all peer reviews for that period. *Id.* ¶ 20.

“[T]o provide the Administration time to review agency programs and determine the best uses of the funding for those programs consistent with law and the President’s priorities,” on January 27, the Administration announced a “temporary pause on all . . . disbursements of Federal financial assistance, and other relevant agency activities that may be implicated by executive orders.” ECF No. 38-7 at 3. This included a “pause [on] all activities associated with open [Notice of Funding Opportunities], such as conducting merit review panels.” *Id.* The temporary pauses have ended, and NIH is now in the process of holding 578 peer review meetings between March 24 and May 31.<sup>4</sup> Lorsch Decl. at ¶ 22, 24. NIH is moving expeditiously and anticipates that by the end of May, it will have completed over 100% of the peer review meetings for the current advisory council cycle (Cycle III), and it will have completed review of 100% of the Cycle III

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<sup>4</sup> *See, e.g.*, 90 Fed. Reg. 11175; 90 Fed. Reg. 11324; 90 Fed. Reg. 11323; 90 Fed. Reg. 11422; 90 Fed. Reg. 12333; 90 Fed. Reg. 12325; 90 Fed. Reg. 13187; 90 Fed. Reg. 13182.

applications. *Id.* ¶ 25. The NIH institutes and centers (ICs) have also held or scheduled the advisory council meetings that were delayed as a result of the pause, and NIH will meet its obligations pursuant to 42 U.S.C. § 284a(e).<sup>5</sup> *Id.* ¶ 26. Additionally, from the date of the pause (Jan. 21, 2025) until May 12, 2025, NIH had issued 11,362 new non-competitive grants and issued 1,971 new competitive grants. *Id.* ¶ 27. Beginning in late February, NIH identified 689 grants for termination and sent termination letters explaining its decision. *See, e.g.*, ECF No. 38-33 at 56-57.<sup>6</sup> The letters also notified grantees of their appeal rights. *Id.* at 57. There are currently 431 appeals of grant terminations through NIH’s appeals process. Lorsch Decl. ¶ 13.

### III. RELEVANT PROCEDURAL HISTORY

Plaintiffs filed this suit on April 2, 2025, over a month after grant terminations started. *See* Compl., ECF No. 1. More than three weeks after filing their Complaint, on April 25, 2025, Plaintiffs filed a Motion for a Preliminary Injunction (PI). ECF No. 37.

### IV. LEGAL STANDARD

“A preliminary injunction is an extraordinary and drastic remedy that is never awarded as of right.” *Peoples Fed. Sav. Bank v. People’s United Bank*, 672 F.3d 1, 8-9 (1st Cir. 2012) (internal quotation omitted). A movant may be awarded such an extraordinary remedy only “upon a clear showing” that it is “entitled to such relief.” *Winter v. Nat. Res. Def. Counsel, Inc.*, 555 U.S. 7, 22 (2008). “A plaintiff seeking a preliminary injunction must establish that [it] is likely to succeed on the merits, that [it] is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in [its] favor, and that an injunction is in the public interest.” *Winter v. Nat.*

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<sup>5</sup> *See, e.g.*, 90 Fed. Reg. 14267; 90 Fed. Reg. 13755; 90 Fed. Reg. 13175; 90 Fed. Reg. 14454; 90 Fed. Reg. 13376; 90 Fed. Reg. 15009; 90 Fed. Reg. 14143; 90 Fed. Reg. 13379; 90 Fed. Reg. 13604.

<sup>6</sup> Including competitive and non-competitive grants, NIH had 91,482 active grants between January 21, 2025, and May 12, 2025. Lorsch Decl. ¶ 14.

*Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). The moving party “bears the burden of satisfying each of these four elements,” using evidence to support its contentions. *Akebia Therapeutics, Inc. v. Azar*, 443 F. Supp. 3d 219, 225 (D. Mass. 2020). The last two factors “merge when the Government is the party opposing the preliminary injunction.” *Nken v. Holder*, 556 U.S. 418, 435 (2009). Irreparable harm “constitutes a necessary threshold showing for an award of preliminary injunctive relief,” *Gonzalez-Droz v. Gonzalez-Colon*, 573 F.3d 75, 79 (1st Cir. 2009), and is “the basis for injunctive relief.” *Voice of the Arab World, Inc. v. MDTV Med. News Now, Inc.*, 645 F.3d 26, 32 (1st Cir. 2011). As a threshold matter, the court must have jurisdiction to order such relief. *Lowenthal v. Massachusetts*, No. 14–13631, 2014 WL 5285615, at \*2 (D. Mass. Oct. 14, 2014).

## **V. ARGUMENT**

### **A. This Court Lacks Jurisdiction over Plaintiffs’ Claims**

The Court must first assess whether it has subject matter jurisdiction. *See Acosta Ramirez v. Banco Popular de P.R.*, 712 F.3d 14, 18 (1st Cir. 2013) (“Federal courts are obligated to resolve questions pertaining to subject-matter jurisdiction before addressing the merits of a case”). As a general rule, the federal government is “immune from suit in federal court absent a clear and unequivocal waiver of sovereign immunity.” *Crowley Gov’t Servs., Inc. v. GSA*, 38 F.4th 1099, 1105 (D.C. Cir. 2022). Thus, to sue a federal agency, a plaintiff must identify an express waiver in the text of a federal law and show that its claim falls within the waiver’s scope. *See FAA v. Cooper*, 566 U.S. 284, 290 (2012) (“a waiver of sovereign immunity must be ‘unequivocally expressed’ in statutory text”). Here, Plaintiffs seek to rely on the APA, which includes a limited waiver of sovereign immunity for claims “seeking relief other than money damages.” 5 U.S.C. § 702. That limited waiver does not extend to this action for several independent reasons.

**1. The Court of Federal Claims has exclusive jurisdiction over Plaintiffs’ grant-termination claims.**

When a party seeks to access funding that it believes the government owes under a contract or grant, the proper remedy is typically suit under the Tucker Act, not the APA. *See Burgos v. Milton*, 709 F.2d 1, 3 (1st Cir. 1983). The Tucker Act confers exclusive jurisdiction on the United States Court of Federal Claims to hear cases involving express or implied contracts with the United States which exceed \$10,000. 28 U.S.C. § 1491(a)(1). Therefore, “the Tucker Act impliedly forbids” the bringing of “contract actions” against “the government in a federal district court” under the APA. *Albrecht v. Comm. on Emp. Benefits of the Fed. Rsrv. Emp. Benefits Sys.*, 357 F.3d 62, 67-68 (D.C. Cir. 2004); *see also Glaskin v. Klass*, 996 F. Supp. 67, 72 (D. Mass. 1998). This ensures that contract claims against the government are channeled to the court that has “unique expertise” in that area. *Ingersoll-Rand Co. v. United States*, 780 F.2d 74, 78 (D.C. Cir. 1985).

Plaintiffs contend the Tucker Act does not apply because their claims are “not rooted in contract with the government, but rather statutory, regulatory, and constitutional law,” Pls.’ Mem. (ECF No. 41) at 14; they do not seek money damages but “declaratory and injunctive relief aimed at the unlawfulness of the Directives [and] terminations,” *id.* at 16; and the Court of Federal Claims “is unable to remedy any of these [claimed] ongoing injuries,” *id.* Despite Plaintiffs’ artfully disguised contract-based claims, “[p]ainting a pumpkin green and calling it a watermelon will not render its contents sweet and juicy.” *Arruda v. Sears, Roebuck & Co.*, 310 F.3d 13, 24 (1st Cir. 2002).

*Ingersoll-Rand Co. v. United States* is directly on point. *See* 780 F.2d 74 (D.C. Cir. 1985). There, plaintiffs sued the United States in federal district court after the government terminated its contract. Like Plaintiffs here, *Ingersoll* alleged that the court had jurisdiction because its claims were rooted in regulation, not contract; sought only declaratory and injunctive relief and did not

specifically allege a breach of contract claim; and argued that the relief available in the alternative court was inadequate. *Id.* at 76-80. The D.C. Circuit disagreed, holding that the district court lacked jurisdiction over Ingersoll’s contract-based claims. *Id.* at 80. In doing so, the *Ingersoll* Court noted that “a plaintiff may not avoid the jurisdictional bar of the [Act] by alleging violations of regulatory or statutory provisions rather than breach of contract,” *id.* at 77, that the “essence of I-R’s claim is a request for specific performance of the original contract,” *id.* at 79-80, and that Ingersoll had not established that a damages award was an inadequate remedy, *id.* at 80. Like *Ingersoll*, this Court should see through Plaintiffs’ attempt to cloak their contract-based grant termination claims under the guise of regulatory or constitutional claims. Plaintiffs may not sidestep the Tucker Act’s jurisdictional bar simply by avoiding a request for damages.

Moreover, in *Department of Education v. California (California)*, the Supreme Court addressed this issue in the same context: termination of grant awards that no longer aligned with agency priorities. 604 U.S. \_\_\_, 145 S. Ct. 966 (2025). There too, plaintiffs asserted APA claims, *and sought only declaratory and injunctive relief, and not money damages*, after the Department of Education terminated certain grants that no longer aligned with agency priorities. *See* No. 1:25-cv-10548, Compl. (ECF No. 1) ¶¶ 3, 14, pp. 51-52; Proposed TRO Order (ECF No. 2-1) at 2; 2025 WL 725103 (D. Mass., filed March 6, 2025). After the district court issued a temporary restraining order (1) enjoining the government from terminating those grants and (2) requiring the government to “restore Plaintiff states to the pre-existing status quo prior to the termination [of the grants],” *id.* at TRO (ECF No. 41 at 9) —the same relief the Plaintiffs here request—the Supreme Court stayed that order, explaining that the government is “likely to succeed in showing the District Court lacked jurisdiction to order the payment of money under the APA.” *Id.* at 968-69. According to the Supreme Court, suits seeking relief like that sought by the *California* plaintiffs, and like those

asserted in this case, belong in the Court of Federal Claims. *See id.*<sup>7</sup> Plaintiffs’ arguments here mirror those made by the *California* plaintiffs and rejected by the Supreme Court. 145 S. Ct. at 968-69; *see California Pls.’ Opp’n to Application*, 2025 WL 963588, at \*20-27 (March 28, 2025).<sup>8</sup>

The Plaintiffs grant-termination claims arose only when NIH terminated the grants pursuant to the terms of the grant agreement. “The question presented by the complaint could be phrased as whether the contract forbids termination under these conditions.” *Ingersoll*, 780 F.2d at 78. Though Plaintiffs contend that “HHS regulations do not authorize Defendants to terminate grants based on [2 C.F.R. § 200.340],” ECF No. 41 at 27, “[t]hat the termination also arguably violates certain other regulations does not transform the action into one based solely on those regulations.” *Ingersoll*, 780 F.2d at 78. That Plaintiffs’ argument as to alleged irreparable harm is based on financial loss shows the contractual nature of the claims. *See* ECF No. 41 at 33-37.

Nor does Plaintiffs’ attempt to disguise their claims as ones for “equitable relief setting aside Defendants’ actions” change the result. *See* ECF No. 41 at 16. *Diaz v. Johnson*, No. 19-1501, 2020 WL 9437887, at \*2 (1st Cir. Nov. 12, 2020) (holding that plaintiff “cannot manufacture an

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<sup>7</sup> Like the First Circuit’s decision, the Supreme Court’s decision in *California* concerned only whether the government was likely to succeed (on its Tucker Act arguments) in the context of a stay pending appeal. On the question of likelihood of success — *the same standard at issue in this PI motion* — the Supreme Court abrogated the First Circuit’s ruling and found the government likely to succeed on the merits and would suffer harm absent a stay. 145 S. Ct. at 968. Neither the Supreme Court’s ruling nor the First Circuit’s decision is binding on the merits themselves. *See* 132 F.4th 92, 96 (1st Cir. 2025) (“[O]ur discussion at this point assesses only the likelihood of success on the merits as the record now stands *and does not constitute a holding on the merits.*” (emphasis added)).

<sup>8</sup> Plaintiffs rely on *Bowen*, but the Supreme Court held in *California* that *Bowen* does impact the Tucker Act’s grant of exclusive jurisdiction to the Court of Federal Claims for claims to compel the payment of money under grants, such as this one. Nor did *Bowen* involve a claim for breach of contract; rather, in holding the Tucker Act inapplicable to a State’s claim under the Medicaid Act, the Court stressed both the statutory nature of that specific cause of action and the intricate features of the Medicaid Act. *Bowen*, 487 U.S. at 900 n.31. By citing *Bowen* in *California*, the Supreme Court demonstrated that *Bowen* is distinguishable here.

APA claim by asking the court to declare that the failure to fund his proposal was an arbitrary or capricious act”); *Am. Sci. & Eng’g, Inc. v. Califano*, 571 F.2d 58, 63 (1st Cir. 1978) (“We have concluded that the essence of the action is in contract, and plaintiff cannot by the mystique of a different form of complaint make it otherwise” (internal quotation marks and citation omitted)). Plaintiffs’ requested injunction makes clear that the essence of their action is to “set aside” the termination of (i.e. continue to perform on) the terminated NIH grants. *See* PI Proposed Order, ECF No. 37-1 at ¶ 1 (“cease implementation of the following directives”), ¶ 2 (“inform all agency personnel they are not to implement the Directives,” ¶ 3 (“cease termination of any NIH . . . grant or grant program”), ¶ 6 (“refrain from freezing or otherwise withholding NIH grant funding”); ¶ 7 (“restore grants, retroactive to the respective termination date); ¶ 9 (“unfreeze and release any reimbursements or other funding awards issued by or on behalf of NIH”); ¶ 11 (“refrain from terminating NIH grants and grant programs”); ¶ 12 (“restore grants that NIH has terminated”). Like their arguments, the injunctive relief Plaintiffs requests closely match the district court’s order stayed by the Supreme Court in *California*. *See California v. U.S. Dept. of Ed.*, No. 25-cv-10548, ECF No. 41 at 9-10 (D. Mass. Mar. 10, 2025) (“Defendants are temporarily enjoined from . . . maintaining... the termination of any previously awarded . . . grants for recipients in Plaintiff States, . . . such as suspension or withholding of any funds approved and obligated for the grants”).

As Judge Stearns noted in another case challenging grant terminations brought under the cloak of the APA, although plaintiffs based their claims on federal statutes instead of using contract-based language, the claims in essence “sought to enforce a contractual obligation to pay money.” *Mass. Fair Hous. Ctr. v. Dep’t of Hous. & Urban Dev.*, No. 3:25-cv-30041, ECF No. 42 (Apr. 14, 2025) (citing *California*). Thus, the district court was obligated to “defer . . . to the Supreme Court’s unmistakable directive that, for jurisdictional purposes, the proper forum for this case is the Court of Federal Claims.” *Id.* Plaintiffs attempt to distinguish their claims from those



in *California* by noting they “assert both statutory and constitutional claims,” ECF No. 41 at 17, but this is simply the same contract-based claim repackaged in a different box.<sup>9</sup> *See Ingersoll*, 780 F.2d at 78 (citing *J.C. Prods., Inc. v. United States*, 608 F. Supp. 92, 94 (W.D. Mich. 1984) (where government terminated plaintiffs contract, cause of action is on the contract despite plaintiffs’ claims of statutory and constitutional violations)).

Finally, Plaintiffs argue that NIH grants are not contracts. ECF No. 41 at 15. Courts have routinely held that “grant agreements [are] contracts when the standard conditions for a contract are satisfied.” *Columbus Reg’l Hosp. v. United States*, 990 F.3d 1330, 1338 (Fed. Cir. 2021); *see also San Juan City Coll. v. United States*, 391 F.3d 1357, 1360-62 (Fed. Cir. 2004) (treating a “Program Participation Agreement” and related grants under Higher Education Act as a contract). The standard contract conditions—offer, acceptance, consideration, and authority to contract—are all satisfied with respect to the NIH grants. Each grant consists of an offer (Notice of Funding Opportunity and application); acceptance (approved grant application and Notice of Award); consideration (funding to grantees; publication, licensing rights to NIH, *see* NIHGPS § 8.2.1; and benefits to third-parties); and the authority to contract, *see* 42 U.S.C. §§ 241(a)(7), 284(b)(2). Even where grants are intended to “carry out a public purpose authorized by law of the United States,” and not to “acquire property or services for the Federal awarding agency,” 45 C.F.R. § 75.2, they are considered contracts under the Tucker Act. *See Thermalon Indus., Ltd. v. U.S.*, 34 Fed. Cl. 411, 416-19 (1995) (National Science Foundation grant designed to “carry out a public purpose” instead of for direct benefit of United States constituted contract enforceable under Tucker Act).

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<sup>9</sup> Moreover, the statutes at issue here do not create entitlements for the Plaintiffs; they simply require NIH to “encourage” certain things. 42 U.S.C. § 282(b)(8)(D)(ii). At most, they require NIH to enter into grants to encourage those objectives, and any APA claim would have to allege that the government failed to enter into any such agreement in the first place.

**2. The Court lacks jurisdiction to order the relief that plaintiffs request because the United States has not waived sovereign immunity for specific performance of contracts.**

The Court also lacks jurisdiction to grant specific performance of the grant agreements the Plaintiffs seek. The United States cannot be sued unless it waives sovereign immunity, and Congress has not waived sovereign immunity for that relief. *Block v. North Dakota*, 461 U.S. 273, 287 (1983) (“[W]hen Congress attaches conditions to legislation waiving sovereign immunity of the United States, those conditions must be strictly observed, and exceptions thereto are not to be lightly implied.”); *Coggeshall Dev. Corp. v. Diamond*, 884 F.2d 1, 3-4 (1st Cir. 1989) (stating “[w]e are unaware of any waiver of sovereign immunity by the United States as to specific performance for breach of contract” and dismissing for lack of subject matter jurisdiction).

Plaintiffs ask the Court to order NIH to “restore grants” and “refrain from freezing or otherwise withholding NIH grant funding.” *See, e.g.*, PI Prop. Order, Doc No. 37-1 at ¶¶ 6, 7, 11, 12. This would require the Court to order specific performance of those grant agreements by paying the grants. *See Ingersoll*, 780 F.2d at 79-80 (finding request to order reinstatement of an original contract award to be a request for specific performance). That Plaintiffs seek specific performance is made evident by the Supreme Court’s description of the district court’s Order in *California* — which provided the same relief that Plaintiffs now seek—as “require[ing] the Government to pay out past-due grant obligations and to continue paying obligations as they accrue.” 145 S. Ct. at 968. But, requiring specific performance by a government agency “is well beyond the Court’s power.” *Imaginarium LLC v. U.S. Small Bus. Admin.*, 618 F. Supp. 3d 1225, 1232 (D. Utah 2022) (emphasis added) (citing *Coggeshall*, 884 F.2d at 3).

**3. In cloaking their contract suit under the guise of an APA claim, plaintiffs would assert an impermissible programmatic challenge.**

By challenging the “still evolving” “Directives,” ECF No. 41 at 8, Plaintiffs broadly challenge how NIH administers its program. They include, amongst those Directives, actions that are moot or are not final agency actions. *See* Argument § V(A)(4). This broad programmatic challenge to a series of individual agency decisions “cannot be laid before the court for wholesale correction under the APA, simply because one of them that is ripe for review adversely affects one of respondent’s members.” *Lujan v. National Wildlife Federation*. 497 U.S. 871, 890–93 (1990). Requests for “wholesale improvement of this program” must be brought “in the offices of the Department or the halls of Congress, where programmatic improvements are normally made.” *Id.* at 891. Plaintiffs complain that programmatic changes here are the result of the President’s election, *see* ECF No. 41 at 1 (claiming that “Defendants began an unprecedented and ideologically driven purge” “in January 2025”); but, as *Lujan* teaches, the APA does not allow plaintiffs to challenge programmatic changes wrought by the outcome of an election. *See* 497 U.S. at 893.

The decision in *Alabama-Coushatta Tribe of Tex. v. United States*, 757 F.3d 484 (5th Cir. 2014), is instructive. There, a Tribe sought to challenge the approval of all “drilling leases and permits to third parties” on land to which the Tribe asserted title. *Id.* at 486. The Fifth Circuit held that it lacked jurisdiction to hear such a “blanket challenge to all of the Government’s actions with respect to all permits and leases” that was directed at “the way the Government administers these programs and not to a particular and identifiable action taken by the Government.” *Id.* at 491–92.

The programmatic nature of Plaintiffs’ § 706(1) “delay” challenge is made plain by their comparison of the Agency’s overall grant processing progress under the current administration with prior administrations. *See* ECF No. 41 at 11 (citing declaration of former director (Ex. 26) comparing present administration’s management with past administration’s management). Indeed,

plaintiffs do not even purport to identify all grant applications for which they allege unreasonable delay, instead citing in a footnote the declaration of only two individuals claiming delays for grant processing in a single grant program. *See* ECF No. 41 at 11 n.14.

Plaintiffs’ § 706(2) claims also have the hallmarks of an impermissible programmatic challenge: (1) Plaintiffs style their claims as being against “NIH Directives,” *e.g.*, Compl., Doc No. 1 at 30 & ¶ 103; ECF No. 37-1 at 2 ¶ 1; (2) they request that Court order NIH to “restore grants . . . that NIH has terminated based on or as a result of the Directives,” PI Prop. Order, Doc No. 37-1 ¶ 7; (3) and they seek to control future conduct of the agency in “actions yet to be taken.” *Lujan*, 497 U.S. at 893. For example, they request that the Court order that NIH shall “refrain from”: (1) withdrawing Notices of Funding Opportunities issued by or on behalf of NIH”; (2) “withdrawing [or] denying . . . NIH grant applications or grant renewal applications”; (3) “freezing or otherwise withholding NIH grant funding”; and (4) “terminating NIH grants and grant programs.” PI Prop. Order, Doc No. 37-1 ¶¶ 4-6, 11. But claims that “cover actions that have yet to occur . . . do not challenge specific ‘agency action.’” *Alabama-Coushatta*, 757 F.3d at 490.

Plaintiffs’ claims are not saved by their identification of seven documents as among the Directives, as well as “any nonpublic or undisclosed directives.”<sup>10</sup> ECF No. 37-1 ¶ 1. Identifying an array of challenged actions is typical of a programmatic challenge, and, as explained below, the identified actions are not subject to judicial review under the APA. Nor does *New York v. Trump*, 33 F.4th 51, 57 (1st Cir. 2025), help Plaintiffs. There, plaintiffs challenged a temporary pause in grant funding to *all* heads of executive departments and agencies in response to an OMB Directive.

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<sup>10</sup> Plaintiffs cannot state a claim based on any other nonpublic or undisclosed directives. The United States cannot defend, and the court cannot review, unidentified agency action.

*Id.* Unlike in *New York*, NIH has not categorically terminated *all* NIH grants, but rather only select grants—disbursed by a single agency—that do not align with agency priorities.

#### **4. Plaintiffs’ challenge to NIH’s actions is not justiciable**

Even viewed individually, each of the Directives is either moot, unconnected to Plaintiffs’ alleged harms, or is not a final agency action. For these additional reasons, Plaintiffs’ have not established jurisdiction to review any challenged action.

- a. By its own terms, the February 13 memorandum, and any pause in review of grant applications expired before plaintiffs sued.

As the First Circuit explained, challenges “to government regulatory schemes which have expired or been effectively repealed” are moot. *Am. Civ. Liberties Union of Mass. v. U.S. Conf. of Cath. Bishops*, 705 F.3d 44, 53 (1st Cir. 2013). The February 13 memorandum entitled “Supplemental Guidance to Memo Entitled – NIH Review of Agency Priorities Based on the New Administration’s Goals,” ECF No. 38-12 (Exhibit 12), was expressly rescinded (twice). *See* “Priorities Directive,” ECF No. 37-13 at 2 (“This staff guidance rescinds the guidance provided in the February 13, 2025, memo”); *see also* “Revised Priorities Directive,” ECF No. 37-14 at 2 (same). Plaintiffs admit as much in their Complaint. *See* ECF No. 1 ¶ 92. Plaintiffs’ challenge of the February 13 memorandum is thus moot.

Moreover, Plaintiffs’ claims that NIH is failing to review or decide grant applications is similarly moot. *See* ECF No. 41 at 31. As explained above, *see supra* n.4, n.5, any pause in publication of any meeting notices in the Federal Register expired before plaintiffs sued. NIH is working diligently to reschedule all cancelled meetings. *See* Lorsch Decl. ¶¶ 22, 24-27. Since March 4, NIH has published over 150 notices of scheduled meetings in the Federal Register. *Id.* ¶ 24; *see supra nn. 4, 5*. And it has scheduled 245 more meetings from March 24 to May 31 than it did in the previous year. *See id.* As of the end of May 2025, NIH will have held 100% of the

meetings that were impacted by any temporary pauses and reviewed 100% of all applications submitted for the impacted Cycle III Advisory Council cycle meetings. Lorsch Decl. ¶ 25.

- b. Two other Directives did not harm Plaintiffs and instead facilitated actions that plaintiffs seek.

Two other Directives that Plaintiffs challenge did not cause Plaintiffs' alleged injuries. To establish standing, plaintiffs must demonstrate that their alleged injury is "fairly traceable to the challenged action." *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013). First, the February 12, 2025 memorandum entitled "NIH Review of Agency Priorities Based on the New Administration's Goals" (Exhibit 11) authorized grant managers "to proceed with issuing awards" in response to recent court orders. ECF No. 37-11. Plaintiffs' alleged harms are unquestionably not traceable to this memorandum. Second, plaintiffs do not assert in any of their pleadings that grants have been cut pursuant to the alleged "directive issued by NIH that NIH funding shall not be made available to research related to the health effects of climate change." Prop. PI Order, ECF No. 37-1 ¶ 1(g). *See generally* ECF Nos. 1, 41.<sup>11</sup> Thus, Plaintiffs do not have standing.

- c. The remaining Directives are not final agency actions subject to judicial review under the APA.

The remaining Directives are not final agency actions subject to judicial review and are instead interlocutory processes to review grants. The APA only permits review of "final agency action." 5 U.S.C. § 704. To be final, the action must satisfy two conditions. First, it "must mark the consummation of the agency's decision-making process." *Harper v. Werfel*, 118 F.4th 100, 116 (1st Cir. 2024) (quoting *Bennett v. Spear*, 520 U.S. 154, 178 (1997)). "Second, the action must

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<sup>11</sup> Plaintiffs allege that "UAW Pre-Member 6" studies "the replication of mechanisms of viral diseases spread by mosquitoes to identify targets for drug therapeutics" which has been "increased" by a "warming climate." However, Plaintiffs further allege that UAW Pre-Member 6 grant application had been terminated because they applied for a "F31 Diversity Fellowship." ECF No. 1 ¶¶ 192-94.

be one by which ‘rights or obligations have been determined,’ or from which ‘legal consequences will flow.’” *Id.* (quoting *Bennett*, 520 U.S. at 178). The Directives fail both conditions.

For the first condition, the First Circuit recently explained in *Harper* that “investigatory measures are not final agency action,” because such measures are “tentative or interlocutory in nature.” *Id.* (collecting cases). The opening of a review or investigation is a preliminary step, “leading toward the possibility of a final action in the form of an enforcement or other action.” *Id.* (quoting *Univ. of Med. & Dentistry of N.J. v. Corrigan*, 347 F.3d 57, 69 (3d Cir. 2003)). The final agency action would occur when the agency decides to act on an existing grant.

Here, the Directives merely ordered a *review* of the grants to determine whether they were consistent with the agency’s priorities. *See* “Secretarial Directive on DEI-Related Funding,” ECF No. 38-10 (Exhibit 10) at 2 (directing “a review of the overall contracts and grants to determine whether those contracts or grants are . . . consistent with current policy priorities” and noting that, “after review,” “such contracts may be terminated”); “Priority Directives,” ECF No. 38-13 (Exhibit 13) at 2 (directing NIH institutes and centers to “review the specific aims [and] assess whether the proposed project contains any DEI research activities” before issuing any awards or approving requests for carryover); “NIH Grants Management Staff Guidance – Award Assessments for Alignment with Agency Priorities—March 2025,” ECF No. 38-14 (Exhibit 14) at 2 (directing NIH institutes and centers to “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”). Initiating a review is not the consummation of the agency’s decision-making process. *Cf. Sackett v. EPA*, 566 U.S. 120, 127 (2012) (finding final agency action where a compliance order was “not subject to further Agency review”).

Initiating an agency review also does not determine the grantees’ rights and obligations. *See FTC v. Standard Oil Co. of California*, 449 U.S. 232, 241 (1980) (issuing a complaint and



initiating enforcement proceedings did not have “definitive” legal consequences and was still subject to challenge and review). Here, too, the Directives did not definitively affect any of Plaintiffs’ or their members’ rights and obligations and remained subject to review.

Additionally, the Directives’ procedural guidance does not qualify as agency action. The Directives outline the process for staff to follow when renegotiating or terminating awards based on the review results. *See* “Staff Guidance – Award Assessments for Alignment with Agency Priorities—March 2025,” ECF No. 38-13 at 6–7 (detailing the steps to follow when issuing a revised NOA for terminated grants and language to use in renegotiated awards); “Award Revision Guidance and List of Terminated Grants via letter on 03/12,” ECF No. 38-18; “NIH Grants Management Staff Guidance – Award Assessments for Alignment with Agency Priorities—March 2025,” ECF No. 38-14. Directing staff on the process to follow and language to use when implementing a decision is not agency action. *See Vill. of Bald Head Island v. U.S. Army Corp. of Eng’rs*, 714 F.3d 186, 193 (4th Cir. 2013) (“[o]perating a program” does not qualify as agency action). This guidance remained subject to the decision to be made for each grant after review. “Article III’s case-or-controversy requirement does not cover a challenge to the kind of intra-governmental directives and policy planning implicated by the [Directives].” *Nat’l Urban League v. Trump*, \_\_ F. Supp. 3d \_\_, 2025 WL 1275613, at \*8 (D.D.C. May 2, 2025).

The Directives’ procedural guidance was also interlocutory, not final. The procedural guidance in the initial “Staff Guidance” Directive (ECF Nos. 38-13 (Exhibit 13)) was revised in the Award Revision Guidance (ECF No. 38-18 (Exhibit 18)), which was again updated in the revised Staff Guidance (ECF No. 38-14). Reinforcing that the staff guidance was tentative, the Award Revision Guidance directed staff to “save this guidance until we can clear the updated staff guidance.” ECF No. 38-18 at 2. This is not the stuff of final agency action.

This case is nothing like *Biden v. Texas*, where the agency directed personnel to take all necessary actions to shut down an entire program. 597 U.S. 785, 808–09 (2022). At most, the guidance here resembles the manual in *Whitewater Draw Natural Resources Conservation District v. Mayorkas*, 5 F.4th 997, 1008 (9th Cir. 2021). There, the Ninth Circuit held a Department of Homeland Security manual was not challengeable final agency action because it did “not prescribe any particular option in any particular way” and “[a]ny guidance that could be attributed to the Manual would be subsumed” in the subsequent action. So too with the Directives here.

Because the Directives are either moot, unconnected to any alleged injuries, or not final agency action, plaintiffs’ asserted claims based on the “Directives” are non-justiciable.<sup>12</sup>

### **5. Congress committed grant administration to agency discretion.**

Plaintiffs’ claims are also unreviewable because they challenge funding decisions “committed to agency discretion by law.” 5 U.S.C. § 701(a)(2). The “allocation of funds” is an “administrative decision traditionally regarded as committed to agency discretion.” *Lincoln v. Vigil*, 508 U.S. 182, 192 (1993). “[A]s long as the agency allocates funds from a lump-sum appropriation to meet permissible statutory objectives, § 701(a)(2) gives the courts no leave to intrude.” *Id.* at 193. These principles are not limited to lump-sum appropriations; § 701(a)(2) bars review when an appropriation confers discretion on the agency. *Milk Train, Inc. v. Veneman*, 310 F.3d 747, 751-52 (D.C. Cir. 2002). NIH actions to terminate existing grants or award future grants are unreviewable.

That is precisely what has happened here. Congress has made lump sum appropriations to the agency to meet broad statutory objectives and has conferred considerable agency discretion about how to accomplish that task. Plaintiffs’ assertion that “meaningful standards in statute and

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<sup>12</sup> For the same reasons, Plaintiffs are not likely to succeed on the merits of their APA Claims.

regulation cabin agency discretion here,” ECF No. 41 at 22 (cleaned up), cannot overcome the discretion conferred by Congress. Congress granted NIH broad discretion when awarding grants and provided no “circumscribing [the] agency’s power to discriminate among issues or cases it will pursue.” *Holbrook v. Tennessee Valley Auth.*, 48 F.4th 282, 293 (4th Cir. 2022) (quoting *Heckler v. Chaney*, 470 U.S. 821, 833 (1985)). Unlike the constraints placed on the Secretary of Commerce in the Census Act at issue in *Dep’t of Commerce v. New York*, 588 U.S. 752 (2019), Congress has not dictated the “form and content” by which NIH must accomplish its statutory objectives. *See, e.g.*, 42 U.S.C. §§ 241(a)(3) (“[T]he [HHS] Secretary is **authorized** to make grants-in-aid”) (emphasis added); 282(b)(11)(B) (“[T]he [HHS] Secretary, acting through the Director of NIH . . . **may** conduct and support research training”) (emphasis added); 284(b)(1)(D) (Director each research institute “**may** conduct and support research training”) (emphasis added); 284(b)(2) (“Support for an activity or program under this subsection **may** be provided through grants, contracts, and cooperative agreements.”) (emphasis added); 284(b)(2)(A)–(B) (providing that the agency “**may** enter into a contract for research” and “**may** make grants and cooperative agreements . . . for research [and] training”) (emphasis added).

NIH is not statutorily required to enter into *any* grant agreements. The Secretary of HHS, acting through the Director of NIH, is authorized to “conduct[] priority-setting reviews to ensure that the research portfolio of the National Institutes of Health is balanced and free of unnecessary duplication.” 42 U.S.C. § 282(b)(3). As in *Lincoln*, Congress gave NIH “the capacity to adapt to changing circumstances and meet its statutory responsibilities in what it sees as the most effective or desirable way,” 508 U.S. at 192. NIH’s discretionary spending decisions are thus unreviewable by this Court.

## 6. The organizational Plaintiffs Do Not Have Standing

To establish Article III standing, a plaintiff must demonstrate that it (1) suffered an injury in fact; (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision. *See Lujan*, 504 U.S. at 560-61. Each element of standing “must be supported in the same way as any other matter on which the plaintiff bears the burden of proof, i.e., with the manner and degree of evidence required at the successive stages of litigation.” *Dubois v. U.S. Dep’t of Agriculture*, 102 F.3d 1273, 1281-82 (1st Cir. 1996). Each plaintiff must demonstrate its own Article III standing, as “Article III does not give federal courts the power to order relief to any uninjured plaintiff, class action or not.” *Tyson Foods, Inc. v. Bouaphakeo*, 577 U.S. 442, 466 (2016). And each plaintiff must also maintain its personal interest in the dispute at all stages of litigation. *See Davis v. Federal Election Comm’n*, 554 U.S. 724, 733 (2008). Finally, each plaintiff must demonstrate standing for each claim that it presses against each defendant, and for each form of relief that it seeks. *Murthy v. Missouri*, 603 U.S. 43, 61 (2024) (quoting *TransUnion v. Ramirez*, 594 U.S. 413, 431 (2021)).

The organizational Plaintiffs in this case—APHA and UAW—rely on “associational standing.” Under that theory, an association has standing to bring suit on behalf of its members when “(a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization’s purpose; and (c) neither the claims asserted nor the relief requested requires the participation of individual members in the lawsuit.” *Hunt v. Wash. State Apple Advert. Comm’n*, 432 U.S. 333, 343 (1977). As shown by the sheer number of declarations submitted by the organizational Plaintiffs’ members in an attempt to show irreparable harm, Plaintiffs fail the third requirement: Individual members must participate to show entitlement to injunctive relief—particularly if this Court follows the proper practice of limiting any injunction to those that have shown that the Directives will cause them irreparable harm. *See*

*infra* at Argument § 5(D). Moreover, nothing in Plaintiffs’ Complaint (ECF No. 1) or in their PI motion establish that the interests that organizational Plaintiffs seeks to protect are germane to their purpose. *See id.*<sup>13</sup>

More fundamentally, the theory of associational standing improperly “relaxes both the injury and redressability requirements for Article III standing” by allowing the association to assert and obtain relief for someone else’s injury (even in the absence of an injury of its own); “subverts the class action mechanism”; and creates the “possibility of asymmetrical preclusion,” where the members might not be bound by the association’s loss in litigation. *See FDA v. Alliance for Hippocratic Medicine*, 602 U.S. 367, 399-403 (2024) (Thomas, J., concurring). Thus, while Defendants acknowledge that the Supreme Court has recognized the theory of associational standing, they preserve their challenge to the theory of associational standing for further review.

**B. Plaintiffs are unlikely to succeed on the merits.**

**1. Plaintiffs’ 706(2) claims fail because NIH followed the law and provided sufficient reasons when it terminated the grants.**

a. The terminations complied with the terms of the agreements and the regulations.

Although framing it as a challenge to Defendants’ “statutory jurisdiction, authority, or limitations,” the crux of Plaintiffs’ argument is that the agency’s reasons for grant termination violates the grant agreement’s terms and HHS regulations. *See* ECF No. 41 at 26-29. Not so. Plaintiffs ignore that the contract terms that they and their members agreed to allow Defendants to terminate grants if the “award no longer effectuates the program goals or agency priorities.” 2

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<sup>13</sup> This is particularly so with respect to the UAW, a labor union aimed at improving working conditions for its members. *See* Article 2, Objects, “Constitution of the International Union, United Automobile, Aerospace and Agricultural Implement Workers of America, UAW,” available at <https://uaw.org/wp-content/uploads/2024/06/Updated-2022-Constitution-6-7-24-1.pdf> (last accessed, May 8, 2025)

C.F.R. § 200.340. The Notice of Award for each grant explains that it “is subject to the terms and conditions incorporated either directly or by reference in the . . . NIH Grants Policy Statement.” *See, e.g.*, ECF No. 38-19 at 20 § III(d). Section 8.5.2 of the NIHGPS explicitly states that “NIH may also terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.” NIHGPS at IIA-155 (2024). That regulation allows the agency to terminate an award in whole or in part “if an award no longer effectuates the program goals or agency priorities.” 2 C.F.R. § 200.340(a)(4).

Plaintiffs’ argument that section 200.340 is only “guidance” instead of an HHS regulation ignores that the provision was expressly *incorporated into the grant agreement*. This is entirely consistent with the regulations. Section 75.372(a) lists four grounds upon which an award “may” be terminated. It does not say that an award may be terminated “only” or “exclusively” on those grounds. *See* 45 C.F.R. § 75.372(a); *see Carlson v. United States*, 837 F.3d 753, 765 (7th Cir. 2016) (holding that an enumerated list of exceptions in the rules was not exclusive because the rule “uses the word ‘may,’ which ‘usually implies some degree of discretion.’”) (quoting *United States v. Rodgers*, 461 U.S. 677, 706 (1983)). The fact that 2 C.F.R. § 200.340 is not yet adopted by HHS does not prevent the parties to a grant agreement from contracting to additional terms.<sup>14</sup>

Plaintiffs also misread section 8.5.2 of the NIHGPS when they contend that it authorizes terminating a grant only if a recipient has failed to comply with the award’s terms and conditions.

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<sup>14</sup> In fact, it was two professional university associations that encouraged NIH to adopt OMB’s 2020 revisions to 2 C.F.R. § 200 to align with other research agencies in an effort to reduce administrative burden on entities. OMB added § 200.340(a)(4) in 2020 to strengthen the ability of the Federal awarding agency to terminate Federal awards without breaching them, to the greatest extent authorized by law, when the Federal award no longer effectuates the program goals or Federal awarding agency priorities. 85 Fed. Reg. 49506-01, 49507 (Aug 13, 2020). After OMB issued revisions to 2 C.F.R. § 200 in 2020, the two professional university associations asked NIH to adopt the 2020 revisions to align with other research agencies. NIH did just that by incorporating part 200, including § 200.340 specifically, into the NIHGPS, which is itself incorporated into every NIH grant. *Id.*

ECF No. 41 at 28. The plain language of the policy says otherwise. The first sentence of section 8.5.2 states that “NIH may take one or more enforcement actions . . . [i]f a recipient has failed to comply with the terms and conditions of award.” NIHGPS at IIA-155 (2024). The next sentence states that “NIH may *also* terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.” *Id.* (emphasis added). The Plaintiffs’ argument that the citation to 2 C.F.R. § 200.340 is only triggered by, or somehow modifies, the first sentence of section 8.5.2 is inconsistent with a plain meaning of the word “also.”

Here, consistent with the terms and conditions of the grants, NIH terminated a small subset of grants that no longer effectuates agency priorities. NIH issued termination notices that provided its causes for termination, including the change in agency priorities and grant-specific causes for termination. *See, e.g.*, ECF No. 38-33 at 56 (identifying why this specific grant “no longer effectuates agency priorities,” does “not enhance health, lengthen life, or reduce illness,” and may “support unlawful discrimination.”) Thus, these terminations were terminated pursuant to the grants’ own terms.

b. The grant terminations were adequately reasoned.

Even if the grant terminations were reviewable under the APA, which they should not be, they would be sustained under the APA standard. The scope of review under the “arbitrary and capricious” standard, 5 U.S.C. § 706(2)(A), is “narrow and a court is not to substitute its judgment for that of the agency.” *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). Rather, the standard “deems the agency action presumptively valid provided the action meets a minimum rationality standard.” *Sierra Club v. EPA*, 353 F.3d 976, 978 (D.C. Cir. 2004) (citation omitted). As a result, a court must “uphold a decision of less than ideal clarity if the agency’s path may reasonably be discerned.” *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 513-14 (2009) (quotation marks and citation omitted). The terminations clear these hurdles.



In terminating individual grants, NIH did more than simply state that the grants “no longer effectuate [] agency priorities.” Rather, NIH provided the reasons for its terminations, the authority under which it was terminating those grants, and the grantee’s appeal rights. The fact that the reason for those terminations applied to multiple grants does not make that reason any less salient. Where that reason was a change in agency priorities, a change in administration “is a perfectly reasonable basis for an executive agency’s reappraisal of the costs and benefits of its programs,” *Motor Vehicle Mfrs. Ass’n*, 463 U.S. at 59 (Rehnquist, J., concurring in part, dissenting in part). “As long as the agency remains within the bounds established by Congress, it is entitled to assess administrative records and evaluate priorities in light of the philosophy of the administration.” *Id.* Plaintiffs’ critique of and disagreement with the stated rationale misses the point. The notices properly stated the reasons for termination and the only available remedy is remand back to NIH for follow up, not an injunction requiring specific performance.

Plaintiffs’ contention that the terminations “cite no project-specific information or data to explain why each project no longer ‘effectuates agency priorities,’” ECF No. 41 at 23, ignores the specific reasoning spelled out in each and every termination letter. *See, e.g.*, ECF Nos. 38-20 at 50, 38-24 at 37, 38-28 at 146, 38-32 at 34; 38-33 at 56. Although Plaintiffs’ may disagree with the agency’s new priorities, the agency “need not demonstrate . . . that the reasons for the new policy are *better* than the reasons for the old one; it suffices that the new policy is permissible . . . , that there is good reasons for it, and that the agency *believes* it to be better.” *Fox Television*, 566 U.S. at 515. The reasoning provided in each grant termination adequately displayed awareness that the agency was changing position by noting that the terminated grant award “*no longer* effectuates agency priorities,” provided a grant-specific basis for why that termination did not advance the

agency's priorities and explained why it was no longer NIH's policy to prioritize that research program.<sup>15</sup> This is all that is required under the APA. *See id.*

Plaintiffs' reliance-interest argument fails for two different reasons. First, Plaintiffs and their members have no legally protectible reliance interests in grants that they have not yet been awarded. *See Nat'l Org. of Veterans' Advocs., Inc. v. Sec'y of Veterans Affs.*, 927 F.3d 1263, 1269 n.4 (Fed. Cir. 2019) (holding amendment to Veterans Affairs' regulations "[did] not defeat veterans' reliance interests" because the amendment "applied only prospectively"). And even as to now-terminated grants, Plaintiffs' invocation of reliance interests is unavailing because NIH necessarily understood and considered that it was terminating funding on which the grantee relied to conduct research when it terminated the grant for that research. Plaintiffs may not like the agency's conclusion that Plaintiffs' and their members' interests were outweighed by the agency's responsibilities and priorities, but Plaintiffs cannot substitute their judgment for the agency's. *See Am. Petro. Inst. v. U.S. Dep't of Interior*, 81 F.4th 1048, 1066 (10th Cir. 2023) ("Though an agency must adequately consider any 'legitimate reliance' on an existing policy, such reliance is not 'necessarily dispositive' to the agency's decision"; "an agency may conclude, for instance, that reliance interests were 'entitled to no or diminished weight' or outweighed by 'other interests and policy concerns'" (quoting *U.S. Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 591 U.S. 1, 32 (2020))); *Calixto v. Walsh*, No. 19-1853, 2022 WL 4446383, at \*16 (D.D.C. Sep. 23, 2022) ("Even if the agency considers the reliance interests to be serious, it my nonetheless determine that

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<sup>15</sup> Plaintiffs rely on totem-pole hearsay to suggest that an employee of the Department of Government Efficiency ("DOGE") directed the agency's changed priorities and authored the termination letters. *See* ECF No. 41 (citing ECF No. 38-17 at 2). Each letter, however, is signed by an NIH official, and Plaintiffs' own exhibits demonstrate that the agency's priorities are designed to align with a democratically elected administration. *See* ECF No. 38-10 through ECF No. 38-14.

other interests and policy concerns outweigh any reliance interests.”) (cleaned up). Where NIH decided to terminate a grant that was funding research, Plaintiffs’ or their members’ reliance on that research funding cannot compel NIH to maintain the grant.

c. The grant terminations were consistent with the relevant statutes.

Statutes do not prevent HHS from exercising its discretion to identify agency priorities and terminate grants that do not effectuate those priorities. Plaintiffs argue that the termination of grants is contrary to various statutes that direct HHS or NIH to support research into certain minority-related topics. ECF No. 41 at 18-21, 25-26. Plaintiffs also argue that deciding DEI projects are not an agency priority is contrary to a statute providing for the establishment of a strategic plan every six years. *Id.* at 25-26. Both arguments fail.<sup>16</sup>

First, Plaintiffs wrongly presume that their terminated grants are the *only* research grants on these topics. On the contrary, entirely consistent with the statutes directing HHS and NIH to support research into certain minority-related topics, *see* 42 U.S.C. §§ 282(h), 283p, 285a-6, 285b-7a(c)(1), 285t(a), NIH is continuing at least 25 research grants on these topics. Lorsch Decl. ¶ 15 & Ex. A (listing minority-related grants that were preserved).<sup>17</sup> NIH exercised its discretion to terminate DEI grants that it determined did not promote health, while preserving grants into health disparities. Similarly, NIH maintained over 5,170 Kirschstein-NRSA grants, consistent with their obligations under 42 U.S.C. § 288(a)(4), *see* Lorsch Decl. ¶ 34 & Ex. B (active NRSA grants), which “support the training and development of a diverse corp of health science researchers.” *See*

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<sup>16</sup> Plaintiffs make a third statutory argument related to appropriations, which is addressed in section II.C., *supra*. In short, NIH has continued to issue awards and intends to reallocate the appropriated funds to grants that align with the agency’s priorities.

<sup>17</sup> Those grants are publicly available <https://reporter.nih.gov/search/s2chZVOP-0Wi9TkGeyYICA/project-details/11124106>

ECF No. 38-27 at ¶ 18. Amongst these active NSRA grants are “Developing a Diverse Next Generation of Leaders in Respiratory Science,” “Research on Eating and Activity for Community Health (REACH): An Applied Epidemiology Training Program to Improve Weight-Related Health in Youth and Families from Diverse Communities,” “Diverse Predoctoral Training in Genetics,” and “Diverse & Equitable Student Inclusion in Research for future VETerinarians (DESIRE-Vet).” *See* Lorsch. Decl. Ex. B. And, as Plaintiffs also acknowledge, NIH continues to issue Notice of Funding Opportunities for some of the NRSA programs that Plaintiffs contend were terminated (T32, T35, F32),<sup>18</sup> and is in the process of reissuing Notice of Funding Opportunities for additional NRSA programs. Lorsch Decl. ¶ 33.

Defendants’ action is not only consistent with the statutes that Plaintiffs cite, which do not require NIH to approve and preserve every grant or proposal that in any way relates to minorities, but furthers the statutes’ aims. NIH is supporting research on minority-related projects and the recruitment of researchers from disadvantaged backgrounds. The statutes permit NIH discretion to decide which grants among these categories are worthy of approving and renewing to effectuate those goals.

Second, NIH has fully complied with the statutory directive to develop a Strategic Plan. Section 282(m)(1) directs NIH to develop a “National Institutes of Health Strategic Plan” every six years. 42 U.S.C. § 282(m)(1). NIH has done precisely that, and most recently published a Strategic Plan in compliance with the statute in 2021. NAT’L INSTS. OF HEALTH, NIH-WIDE STRATEGIC PLAN (2021). But such plans are aspirational. Nothing in the statute suggests that Congress intended the Strategic Plan to be a six-year straight jacket that prevents NIH from shifting priorities in the interim.

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<sup>18</sup> <https://grants.nih.gov/funding/nih-guide-for-grants-and-contracts/parent-announcements>

## 2. Plaintiffs' due process challenge (Count IV) fails at the threshold and on the merits

To begin with, the void-for-vagueness doctrine “guarantees that ordinary people have ‘fair notice’ of the conduct a *statute* proscribes.” *Sessions v. Dimaya*, 584 U.S. 148, 155-56 (2018) (plurality) (emphasis added). Although courts have applied this doctrine outside of the statutory context, they have done so only with respect to regulations of primary conduct. *See, e.g., FCC v. Fox Television Stations, Inc.*, 567 U.S. 239, 253 (2012) (“A fundamental principal in our legal system is that laws *which regulate persons or entities* must give fair notice of conduct that is forbidden or required.”) (emphasis added) (citations omitted). There is good reason for the doctrine’s limited reach. The Due Process Clause prohibits uneven enforcement, and ensures notice, of requirements with which the public must comply. *Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972). But here, the Directives do not regulate conduct but instead direct the agency to conduct a review, after which the agency will make decisions about what agreements it chooses to fund or terminate. The directions neither require nor prohibit any actions from grantees.

Plaintiffs’ challenge suffers from yet another threshold flaw: it is facial in nature. The appropriate posture for Due Process vagueness challenges is as-applied. That is because “[o]bjections to vagueness under the Due Process Clause rest on the lack of notice, and hence may be overcome in any specific case where reasonable persons would know that their conduct is at risk.” *Maynard v. Cartwright*, 486 U.S. 356, 361 (1988); *see also Carman*, 112 F.4th at 402 (noting that plaintiffs were unable to identify “a case when a preenforcement-facial-vagueness challenge was ripe, presumably because such cases benefit from factual development and applications of statutory provisions to particular scenarios”). Plaintiffs’ facial challenge to an agency’s Directives to its employees demands a stunning expansion of the doctrine. *See Nat’l Urban League v. Trump*, \_\_ F. Supp. 3d \_\_, 2025 WL 1275613, at \*15 & n.8 (D.D.C. May 2,

2025) (noting inappropriate nature of facial challenges to agency directives). Plaintiffs’ theory also raises serious separation-of-powers concerns by allowing courts to engage in searching judicial review of all agency policy directives, which by their nature, often necessarily outline policy initiatives and priorities in broad terms.

Plaintiffs’ claim also fails on the merits. *First*, Plaintiffs fail to establish that they have either a liberty or property purported contracts/grants that is protected by the Due Process Clause. While the Supreme Court has identified a narrow set of government benefits protected under the Due Process Clause, it has not extended this protection to “‘ordinary’ or ‘routine’ government contracts.” *Gizzo v. Ben-Habib*, 44 F. Supp. 3d 374, 385 (S.D.N.Y. 2014); *see also Redondo-Borges v. U.S. Dep’t of Hous. & Urb. Dev.*, 421 F.3d 1, 10 (1st Cir. 2005) (“We have held with a regularity bordering on the echolalic that a simple breach of contract does not amount to an unconstitutional deprivation of property.”); *see also Nat’l Urban League*, 2025 WL 1275613, at \*18 (“Plaintiffs offer no reason to think their contracts and grants . . . are different from the millions of government contracts in effect at any point in time to which courts seldom apply due-process principles.”) (cleaned up).

*Second*, Plaintiffs improperly invoke the vagueness standard that pertains to government enforcement actions. But, in *Nat’l Endowment for the Arts v. Finley*, the Supreme Court rejected the application of that demanding vagueness standard in the context of government funding decisions. *See* 524 U.S. 569, 588-89 (1998) (“The terms of the provision are undeniably opaque, and if they appeared in a criminal statute or regulatory scheme, they could raise substantial vagueness concerns. . . . But when the Government is acting as patron rather than as sovereign, the consequences of imprecision are not constitutionally severe.”). 524 U.S. 569 *Id.* at 589; *see also id.* (cautioning that “[t]o accept [plaintiffs’] vagueness argument would be to call into question the constitutionality of . . . valuable Government programs and countless others like them” that

“award[] scholarships and grants on the basis of subjective criteria such as ‘excellence’”); *Nat’l Urban League*, 2025 WL 1275613, at \*18-\*19 (refusing to apply more demanding vagueness standards to government funding directives).

**3. Plaintiffs’ “delay” claims under § 706(1) are unlikely to succeed because plaintiffs have not identified a discrete and mandatory agency action that the agency failed to take.**

Plaintiffs’ claim to compel action on pending applications cannot succeed because APA section 706(1) does not permit broad challenges to program management, plaintiffs identify no discrete and mandatory agency action that the agency failed to take, and in any event the agency is taking the very actions that plaintiffs seek to compel. “[I]n an APA challenge to federal agency inaction it must be shown that [the agency] ‘failed to take a discrete agency action that it is required to take.’” *Scarborough Citizens Protecting Res. v. U.S. Fish & Wildlife Serv.*, 674 F.3d 97, 99 (1st Cir. 2012) (quoting *Norton v. S. Utah Wilderness All.*, 542 U.S. 55, 64 (2004)). Plaintiffs’ effort to compel the agency to comply with prior “norms” fails because—as explained above—the Supreme Court prohibits programmatic delay claims like the ones asserted here. *See Norton*, 542 U.S. at 64; *Lujan v. Nat’l Wildlife Fed’n*, 497 U.S. 871, 893 (1990).

Plaintiffs cite four statutory or regulatory provisions, but their reliance is both insufficient and factually wrong. Each provision they cite is not discrete, not mandatory, and not an action that the agency has failed to take. Indeed, plaintiffs’ flawed contention on delay relies on a brief pause that NIH took on processes following the change in administrations. But that pause is over: NIH has resumed reviewing and deciding applications and holding the meetings that plaintiffs presently seek to compel.



- a. Plaintiffs have not identified a discrete and mandatory agency action that the agency failed to take.

Plaintiffs’ “delay” claim is not justiciable under the APA because they have not shown the agency failed to take a discrete and mandatory agency action that it was required to take. Plaintiffs assert that NIH was required to (1) hold study section meetings, (2) hold advisory council meetings, and (3) issue final decision on grant applications. Plaintiffs’ first two targets—holding meetings—are not discrete “agency actions” that can be compelled under the APA. The third is neither discrete nor mandatory under the regulations.

Holding meetings is part of the NIH’s “common business of managing government programs,” and is not itself a discrete agency action that can be compelled. *See Funds for Animals, Inc. v. U.S. Bureau of Land Mgmt.*, 460 F.3d 13, 19-20 (D.C. Cir. 2006) (“Much of what an agency does is in anticipation of agency action.”). As the Supreme Court explained in *Norton*, a failure to act under § 706(1) is “properly understood as a failure to take an agency action—that is, a failure to take one of the agency actions (including their equivalents) earlier defined in § 551(13).” 542 U.S. at 62. That earlier APA section, 5 U.S.C. § 551(13), defines “agency action” as “the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act.” Holding meetings—even meetings established by statute—fall well outside this definition. “The prospect of pervasive oversight by federal courts over the manner and pace of agency compliance with such congressional directives is not contemplated by the APA.” *Norton*, 542 U.S. at 67. Thus, the APA does not allow the Court to compel the pace of NIH’s meetings.

Notwithstanding use of the word “shall,” the agency retains the discretion to “defer” deciding on any grant application. *See* 42 C.F.R. § 52.5(b). No statute or regulation mandates a decision, and thus plaintiffs cannot compel such a decision on their desired timeline. And NIH’s discretion to make such a decision is not reviewable by the Court. Similarly, because the regulation

maintains the agency’s option to defer a decision, it does not require an action that is “discrete.” In any event, NIH resumed both peer review and advisory council meetings before plaintiffs sued, has been evaluating grant applications at a rapid pace, and has caught up with their application review after the pause when compared to prior years. Lorsch Decl. ¶¶ 22, 24-27.

b. NIH is already holding the meetings that Plaintiffs seek to compel.

Because NIH has been conducting all necessary steps in the review and disposition of grant applications, Plaintiffs cannot obtain an order requiring NIH to resume those steps (or any of the variations of the same in their Proposed Order, *see* ECF No. 37-1). Defendants resumed holding meetings and taking all procedural steps needed to issue awards even before plaintiffs sued. Lorsch Decl. ¶ 22. NIH canceled previously scheduled meetings and did not schedule new meetings based on the January 21, 2025, temporary freeze, but resumed holding all meetings by March 18, 2025. *See supra* nn.4, 5; *see also* Lorsch Decl. ¶¶ 22, 24. By the time plaintiffs filed suit, there was not, and is not currently, any active policy preventing NIH from scheduling peer reviews. Lorsch Decl. ¶ 22. Since the pause expired, NIH has or will manage over 300 peer reviews, more than either of the last two years, *see supra* n.4, and is on track to hold at least the three advisory council meetings this fiscal year required by 42 U.S.C. § 284a(e), *see supra* n.5; Lorsch Decl. ¶¶ 24-26.

Moreover, short pauses as part of changes in administration are reasonable and do not warrant an injunction. *See, e.g., Alaska Indus. Dev. & Exp. Auth. v. Biden*, 685 F. Supp. 3d 813, 858 (D. Alaska 2023). A short pause of a few weeks during an administration transition hardly constitutes an “unreasonable delay,” particularly in the absence of any regulation mandating an immediate decision on any particular grant application. Certainly, there is no basis to enjoin a short pause after it has ended. *Am. Ass’n of Retired Persons v. E.E.O.C.*, 823 F.2d 600, 604-05 (D.C. Cir. 1987) (finding 706(1) claim moot once the agency took the ostensibly unreasonably delayed

action). Plaintiffs’ failure to file suit *during* this pause, and to instead wait until any pause has terminated, provides further proof that this short pause was reasonable.

Enjoining differences in program management as “unreasonable” based on a short snapshot is precisely what the Supreme Court prohibits: “The prospect of pervasive oversight by federal courts over the manner and pace of agency compliance with [broad statutory mandates] is not contemplated by the APA.” *Norton*, 542 U.S. at 55.

#### **4. The Amended Complaint asserts no viable separation of powers claim.**

Plaintiffs’ separation-of-powers argument fails for additional independent reasons. *First*, the Executive has both express and implied authority to terminate individual grants. *Second*, plaintiffs’ separation-of-powers argument fundamentally misrepresents the impact of the grant terminations and delayed and cancelled meetings.

Congress explicitly authorized NIH to take the challenged actions. “[W]hen the President acts pursuant to an express or implied authorization of Congress, his authority is at its maximum, for it includes all that he possesses in his own right plus all that Congress can delegate.” *Zivotofsky ex rel. Zivotofsky v. Kerry*, 576 U.S. 1, 10 (2015). Congress specifically charges the Secretary of HHS, through the Director of NIH, with responsibility “for the overall direction of the National Institutes of Health and for the establishment and implementation of general policies respecting the management and operation of programs and activities within the National Institutes of Health.” 42 U.S.C. § 282(b)(1). The Director of NIH also “shall, in consultation with the heads of the national research institutes and national centers, be responsible for program coordination across the national research institutes and national centers, including conducting priority-setting reviews, to ensure that the research portfolio of the National Institutes of Health is balanced.” 42 U.S.C. § 282(b)(3). Taken together these two provisions explicitly authorize the Director of NIH to wield significant discretion in setting NIH’s priorities, scheduling meetings, and terminating grants.

The Executive also has implicit authority to terminate grants because Congress authorized NIH to make grant awards and left the design, implementation, and administration of those grants to NIH's discretion, *see* 42 U.S. Code § 241(a)(3). Indeed, the appropriation for each institute of NIH is breathtakingly capacious. *See, e.g.*, H.R. 2882, 118th Cong. (2024) (appropriating funds to the National Cancer Institute “[f]or carrying out section 301 and title IV of the PHS Act.”). Congress knows how to write laws that constrain Executive Branch discretion, including laws that mandate inclusion of terms in agency contracts. *Am. Tel. and Tel. Co. v. United States*, 124 F.3d 1471, 1478 (Fed. Cir. 1997), *aff’d*, 307 F.3d 1374 (Fed. Cir. 2002). Congress did not do so here. *See Brendsel v. Off. of Fed. Hous. Enter. Oversight*, 339 F. Supp. 2d 52, 65 (D.D.C. 2004) (Congress’ “silence is controlling”). Because Congress empowered the NIH to administer grants and did not cabin its discretion to terminate grants, no separation of powers concern exists.

Furthermore, as previously noted NIH is working diligently to reschedule all cancelled meetings after a brief pause to allow the new administration to get its bearings. *See supra* nn. 4, 5; Lorsch Decl. ¶¶ 24-27. Since March 4, NIH has published over 150 notices of scheduled meetings in the Federal Register and will have completed 100% of its Cycle III peer review meetings by the end of May 2025. *See supra* nn. 4, 5; Lorsch Decl. ¶¶ 24, 25. And it has scheduled 245 more meetings from March 24 to May 31 than it did in the previous year. *See* Lorsch Decl. ¶ 24. Far from subverting Congress’ intent by holding back appropriated funding, NIH is working overtime to boost the grant approval process. By the end of May 2025, NIH will have reviewed 100% of all applications impacted by the pause. *Id.* ¶ 25.

Finally, Plaintiffs would like the Court to believe that all Congressionally mandated Kirschstein-NRSA grants were terminated. This is factually incorrect. NIH continues to fund more than 5,170 of these grants, which satisfies any requirements of 42 U.S.C. § 288(a)(4). Lorsch Dec. ¶¶ 34 & Ex. B. NIH continues to publish Notice of Funding Opportunities for, and award, NRSA

grants, and is in the process of reissuing Notice of Funding Opportunities for additional NRSA programs. *Id.* ¶¶ 31-34 & Ex. B. Similarly, NIH continues to fund research that fulfills its obligation to address health disparities, consistent with its agency discretion to discern how best to do so. *See id.* ¶ 15 & Ex. A.

**C. Plaintiffs’ Alleged Harms are Not Certain, Imminent, and Irreparable.**

**1. Plaintiffs’ alleged harm is not irreparable**

Plaintiffs have shown that they or their members will suffer irreparable harm in the absence of a preliminary injunction. *See EEOC v. Astra USA, Inc.*, 94 F.3d 738, 743 (1st Cir. 1996). In considering whether plaintiffs have met their “exceedingly high burden,” the Court should not consider plaintiffs in the collective. Instead, each Plaintiff, as well as each grantee—must on its own, make a clear showing of irreparable harm. *See, e.g., Adams v. Freedom Forge Corp.*, 204 F.3d 475, 485-86 (3d Cir. 2000) (partially vacating a preliminary injunction because “[i]nstead of making a case-by-case determination that each plaintiff demonstrated irreparable harm . . . , the court dealt with the plaintiffs as a unit and concluded that because several of them probably risked irreparable harm, that was sufficient to satisfy the prong of the preliminary injunction test.”). Plaintiffs’ (and their members) circumstances vary significantly, and no relief may be ordered unless each Plaintiff meets this burden. *See Tamko Roofing Prods., Inc. v. Ideal Roofing Co.*, 282 F.3d 23, 40 (1st Cir. 2002).

Variation exists not just on a Plaintiff-by-Plaintiff and grant-by-grant basis. Plaintiffs have not identified all specific grant terminations they ask this Court to reverse. Despite identifying some allegedly impacted grants in their declarations, Plaintiffs do not identify the universe of grant terminations they are challenging. This ambiguity alone disfavors any preliminary injunctive relief when many of the terminations fall far short of meeting the standard for irreparable harm.

Plaintiffs also fail to establish irreparable harm as to the grant terminations and delays for three additional reasons. *First*, plaintiffs’ primary claimed injury is the delayed payment of money—a standard part of litigation and quintessential example of what never counts as irreparable injury. *Sampson v. Murray*, 415 U.S. 61, 90 (1974) (“temporary loss of income, ultimately to be recovered, does not usually constitute irreparable injury.”). In terminating plaintiffs’ grants, NIH has not prohibited or made it unlawful for plaintiffs to carry out their work; NIH has just used its lawful discretion not to fund that work. *See e.g., Faculty Senate of Fla. Int’l Univ. v. Winn*, 477 F. Supp. 2d 1198, 1208 (S.D. Fla. 2007) (“There is no irreparable harm here because the plaintiffs can fund the desired travel themselves and then, if they prevail in this suit, obtain reimbursement. In other words, the harm is financial.”). As Plaintiffs note, Plaintiffs may secure alternative sources of funding to continue their research.

*Second*, a plaintiff seeking preliminary relief must demonstrate that irreparable injury is *likely* absent an injunction. *See Charlesbank Equity Fund II v. Blinds To Go, Inc.*, 370 F.3d 151, 162 (1st Cir. 2004); *see also Winter*, 555 U.S. at 22 (issuing a preliminary injunction “based only on a possibility of irreparable harm” would be “inconsistent” with treating a preliminary injunction as an “extraordinary remedy”). Here, Plaintiffs’ declarations are rife with speculative language that is patently insufficient to support a finding of irreparable harm. *See, e.g.*, ECF Nos. 38-19 ¶ 53 (describing breach of trust with research participants); ECF No. 38-20 ¶ 42 (describing stress level); ECF No. 38-21 ¶ 22 (“I have potentially lost out on the ability to pursue a career path”); ECF No. 38-30 ¶ 27 (noting that grant termination “may” cause study participants’ future avoidance of healthcare”); ECF No. 38-31 ¶¶ 28 (describing inability to serve as a mentor to future scientists); 30 (noting that two advisory board members may need to turn to other work); ECF No. 41 at 36 (broadly contending that “the public will miss out on an opportunity to benefit from the research). Mere possibility, not likelihood, cannot support injunctive relief. *See Narragansett*

*Indian Tribe v. Guilbert*, 934 F.2d 4, 6–7 (1st Cir. 1991) (“[I]rreparable harm is not assumed; it must be demonstrated”) (citation omitted).

Unsurprisingly, Plaintiffs make no argument concerning any irreparable harm from the alleged delay claims. *See* ECF No. 33-37. at 37-38. A party that cannot show irreparable harm arising from the delayed payment of funds with respect to current grants cannot show irreparable harm based on grants that do not yet exist.

Plaintiffs’ Motion should be denied in full because they have not shown irreparable harm.

**D. An Injunction Would be Contrary to the Public Interest.**

The balance of equities and public interest weigh against granting a preliminary injunction. The government has a strong interest in safeguarding the public fisc. *See Mathews v. Eldridge*, 424 U.S. 319, 348 (1976). NIH is unlikely to recover funds after the grantees spend them. *See California*, 145 S. Ct. at 969. The loss of likely unrecoverable funds is a classic injury to the government that should preclude preliminary relief. *See Heckler v. Turner*, 468 U.S. 1305, 1307-1308 (1984) (Rehnquist, J.).

**E. Any Injunction should be Narrowly Tailored.**

Should the Court conclude that an injunction is required, which it should not do, the “[i]njunctive relief should be no more burdensome to the defendant[s] than necessary to provide complete relief to plaintiffs[.]” *Tamko Roofing Prods*, 282 F.3d at 40 (quoting *Califano v. Yamasaki*, 442 U.S. 682, 702 (1979)). Court must “closely tailor injunctions to the harm that they address.” *Id.*

Here, at most, any remedy should address only sufficiently and specifically proven irreparable harms by the Plaintiffs. Anything beyond that, including the nationwide injunction that Plaintiffs seek, violates Article III, stretch traditional principles of equity past the breaking point, and “take a toll on the federal court system—preventing legal questions from percolating through

the federal courts, encouraging forum shopping, and making every case a national emergency for the courts and for the Executive Branch.” *Trump v. Hawaii*, 585 U.S. 667, 713 (2018) (Thomas, J., concurring); *see also Free Speech Coal., Inc. v. Att’y Gen. United States*, 974 F.3d 408, 431 (3d Cir. 2020) (vacating nationwide injunction and remanding for entry of relief limited to successful as-applied plaintiffs). That two of the plaintiffs are membership associations does not warrant extending injunctive relief to every member of that association or beyond. Nor does irreparable harm resulting from one grant termination warrant a preliminary injunction for all other terminations. Moreover, given that many of the declarations only discuss harms insufficient to justify a preliminary injunction,<sup>19</sup> this Court should tailor any injunction to the irreparable harms proven (and the grantees that proved it).

**F. The Court Should Stay Any Order for Preliminary Relief and Order That Plaintiffs Post Bond.**

Based on the arguments in this Opposition, and due to the extraordinary breadth of the relief sought in Plaintiffs’ motion, the United States respectfully requests that the Court stay any preliminary injunction pending the disposition of any authorized appeal. At a minimum, the Court should administratively stay any order, should the court decide to issue an injunction, for seven days should the court decide to allow an opportunity to seek an emergency, expedited stay.

Moreover, if the Court decides to grant preliminary injunctive relief, the Court should order plaintiffs to post a bond equal to the amounts of any disbursements on previously terminated grants during the pendency of this litigation. Under Federal Rule of Civil Procedure 65(c), the Court may issue a preliminary injunction “only if the movant gives security” for “costs and damages

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<sup>19</sup> *See* Doc Nos. 77-13 ¶ 5; 77-14 ¶ 64; 77-15 ¶¶ 40-45; 77-16 ¶¶ 35-37; 77-17 ¶¶ 36-39; 77-18 ¶ 45, 51; 77-20 ¶ 51-54; 77- 22 ¶¶ 34-35; 77-24 ¶¶ 51-54; 77-25 ¶ 22; 77-26 ¶ 21; 77-27 ¶¶ 50, 51; 77-28 ¶¶ 1-5; 77-29 ¶¶ 32, 37; 77-30 ¶¶ 7, 11, 32-35.



sustained” by defendants if they are later found to “have been wrongfully enjoined.” Fed. R. Civ. P. 65(c); *see also iQuartic, Inc. v. Simms*, 15-cv-13015, 2015 WL 5156558, at \*6 (D. Mass. 2015) (“A movant for injunctive relief must give security in an amount that the Court considers proper to pay costs and damages sustained by any party found to have been improvidently enjoined.”).

“Since a preliminary injunction may be granted on a mere probability of success on the merits, generally the moving party must demonstrate confidence in his legal position by posting bond in an amount sufficient to protect his adversary from loss in the event that future proceedings prove that the injunction issued wrongfully. The bond, in effect, is the moving party’s warranty that the law will uphold the issuance of the injunction.” *Glob. Naps, Inc. v. Verizon New England, Inc.*, 489 F.3d 13, 21–22 (1st Cir. 2007) (quoting *Edgar v. MITE Corp.*, 457 U.S. 624 (1982)).

As the party seeking security, Defendants need only establish a “rational basis” for the amount of the bond. *Int’l Equity Inv., Inc. v. Opportunity Equity Partners, Ltd.*, 441 F. Supp. 2d 552, 566 (S.D.N.Y. 2006). Although the amount of an injunction bond is within the Court’s discretion, courts “should err on the high side” because setting a bond amount too low might produce injury since “the damages for an erroneous preliminary injunction cannot exceed the amount of the bond.” *Mead Johnson & Co. v. Abbott Labs.*, 201 F.3d 883, 888 (7th Cir. 2000). “An error in setting the bond too high . . . is not serious” because, if the preliminary injunction is subsequently found wrongful, the defendant does not automatically recover the entirety of the bond amount, but instead must “prove its loss, converting the ‘soft’ numbers to hard ones.” *Mead*, 201 F. 3d at 888. On the other hand, “an error in the other direction produces irreparable injury, because the damages for an erroneous preliminary injunction cannot exceed the amount of the bond.” *Id.*

## VI. CONCLUSION

Wherefore, Defendants respectfully request that the Court deny plaintiffs’ Motion for preliminary injunctive relief.

Respectfully submitted,

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Dated: May 12, 2025

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**CERTIFICATE OF SERVICE**

I, Anuj Khetarpal, Assistant United States Attorney, hereby certify that this document, filed through the ECF system, will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF). Paper copies will be sent to those indicated as non-registered participants.

Dated: May 12, 2025

By: /s/ Anuj K. Khetarpal  
Anuj Khetarpal  
Assistant United States Attorney