UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS, et al.,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., in his official capacity as Secretary of Health and Human Services, *et al.*,

Defendants.

No. 1:25-cv-10814-BEM

Leave to file excess pages granted April 9, 2025 (Doc No. 59)

DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

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INTRODUCTION

Fifteen of sixteen plaintiff states have moved for preliminary injunctive relief, on a subset of NIH grant terminations, after withdrawing a motion for a temporary restraining order and retooling their complaint in the wake of a Supreme Court order that gored their case. *United States Department of Education v. California*, 604 U.S. ----, 145 S. Ct. 966 (2025). Now they pursue a preliminary injunction based on an Amended Complaint that tries harder to conceal its contract-based nature by adding a thicker veneer of Administrative Procedure Act jargon, like "Challenged Directives." But as the Supreme Court recently stated, "[t]he APA's waiver of sovereign immunity does not apply 'if any other statute that grants consent to suit expressly or impliedly forbids the relief which is sought." *Id.* at *1. "Instead, the Tucker Act grants the Court of Federal Claims jurisdiction over suits based on any express or implied contract with the United States." *Id.*

The moving plaintiffs also seek preliminary relief for another set of claims, contending that the National Institutes of Health (NIH) and most of its constituent Institutes and Centers have unduly delayed the review and processing of pending grant applications. These claims are likewise not justiciable by the Court. The APA does not authorize a district court to review day-to-day program operations of federal agencies. And equally important, these "delay" claims are moot because the "pause" of which plaintiffs complain has ended.

Plaintiffs' new "Challenged Directives" mantra is a vain effort to make their claims resemble APA claims. They are not. Plaintiffs seek to undo grant terminations and to require the United States to specifically perform the agreements, thus plaintiffs' claims are rooted in the Grant Agreements at issue, not in any regulation or statute. The APA thus

confers no jurisdiction upon this Court to review plaintiffs' claims to vacate the termination of previously existing grants (or, as rephrased after plaintiffs' amendment, to enjoin the "eliminat[ion]" of award funding).

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. Their goal is to hamper the NIH's ability to take stock of its current programs and to make adjustments when priorities change. The attack is on the Executive's authority to alter the government's course following a change in administration, as made plain where plaintiffs decry changed priorities as a "blacklist." The claims would impermissibly call upon this Court to supervise agency operations.

Second, even considering the array of identified actions individually, the Court lacks jurisdiction to review them. Indeed, the challenge to each "Challenged Directive" suffers from at least one of three fatal flaws: it has already expired, it did not harm plaintiffs, or it is not a final 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 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.

Beyond lack of jurisdiction, plaintiffs' claims are unlikely to succeed on their merits. Plaintiffs' agreements provided that a change in priorities is a basis for the agency to terminate the grants at issue and the terminations complied with the grants and the regulations. Defendants' new priorities and grant terminations were reasoned. And the agency's terminations complied with applicable statutes.

Beyond their unlikely success on the merits, plaintiffs cannot otherwise justify a preliminary injunction. Plaintiffs cannot show they will suffer irreparable harm from the grant terminations and delays without judicial intervention because the harms they claim are monetary, speculative, or described with such high generality 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, and as explained further below, plaintiffs' motion for a preliminary injunction should be denied.

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. 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) ("Supplemental Guidance").

¹ NIH, Mission and Goals, available at https://www.nih.gov/about-nih/what-we-do/mission-goals (last visited Feb. 14, 2025).

In awarding grants, NIH exercises broad discretion. 42 U.S.C. § 241(a)(3); 42 U.S.C. § 282(b)(3). The 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 CFR § 52.6(a). NIH also maintains broad discretion when administering grants. When NIH chooses to award a grant, it enters a grant agreement with the grantee through the issuance of a Notice of Award, and those are the terms that govern the relationship between the grantee and NIH. Under the grant agreements, upon incurring approved expenses, the grantees may draw down granted funds from the HHS Payment Management System to support costs allowed under the grant agreement.

These grant agreements are subject to certain conditions and NIH rights. One of NIH's rights under the grant agreements is NIH's right to terminate grants because of a change in NIH priorities. Specifically, the grants at issue incorporate NIH's Standard Award Terms and Conditions, which in turn incorporates 2 C.F.R. § 200.340. As incorporated, that regulation 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). Importantly, while a grant agreement permits the grantee to draw funds, it does not "commit[] or obligate[] the United States 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 CFR § 52.6(c)(3).

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² As but one example, the regulations authorize a grant award to be transferred to another entity or person. 42 CFR § 52.6(f).

Following the 2024 Presidential election and change in Administrations, NIH's priorities shifted. Under NIH's independent authorities, it 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 NIH's priorities. Beginning in late February, once NIH identified grants for termination, it sent termination letters explaining NIH's decision. Doc No. 77-12 at 38. These letters also notified grantees of their appeal rights. *Id.* at 39.

From January 21 to February 1, the Administration issued a temporary freeze on publication of any documents in the Federal Register until they had been reviewed by a presidential appointee. *See* Doc No. 77-39 at 2. This Notice Pause Directive also instructed federal employees to "[r]efrain from participating in any public speaking engagement until the event and material have been reviewed and approved by a Presidential appointee." NIH *Id.* 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. Code § 1009(a)(2). NIH also cancelled all peer reviews for that time period. That pause has ended, and NIH is now in the process of holding 305 peer reviews between

March 24 and May 31.3 NIH has also resumed advisory council meetings, with sufficient time for each council to meet requirements contemplated by 42 U.S.C. section 284a(e).⁴

PROCEDURAL HISTORY

Plaintiffs filed this suit on April 4, 2025, over a month after grant terminations started. See Compl., Doc No. 1. That same day, a subset of the plaintiffs—states whose instrumentalities had grant agreements terminated—moved for a Temporary Restraining Order (TRO). See Temporary Restraining Order Motion, ("TRO Mot."), Doc No. 4. After the Court promptly set a briefing schedule and a hearing for April 15, 2025, Doc Nos. 15, 19, plaintiffs withdrew their TRO motion in favor of an agreed briefing schedule on a motion for Preliminary Injunction (PI). The Court approved the schedule, and plaintiffs filed an Amended Complaint on April 14, 2025, along with a PI Motion filed by all plaintiffs except Colorado. Am. Compl., Doc. No. 75; PI Motion ("Mot.), Doc. No. 78.

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). To establish entitlement, plaintiffs bear the

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³ This is shown by searching the relevant date range through NIH's public calendar of peer review meetings: https://www.csr.nih.gov/RevPanelsAndDates/RevDates.aspx; see also. 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.

⁴ 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.

burden of establishing (1) a likelihood of success on the merits, (2) irreparable harm in the absence of preliminary relief, (3) a balance of the equities favoring the movant, and (4) that an injunction is in the public interest. *Allscripts Healthcare, LLC v. DR/Decision Resources, LLC*, 592 F. Supp. 3d 1, 3 (D. Mass. 2022). 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). Of course, as a threshold matter, the court must have jurisdiction to order any preliminary relief. *Lowenthal v. Massachusetts*, No. 14–13631, 2014 WL 5285615, at *2 (D. Mass. Oct. 14, 2014).

ARGUMENT

I. This Court Lacks Jurisdiction over Plaintiffs' Claims.

Before addressing the merits of a preliminary injunction application, the Court must 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"); *see also Arbaugh v. Y & H Corp.*, 546 U.S. 500, 514 (2006) (recognizing that complaint must be dismissed in its entirety if subject matter jurisdiction is lacking). Plaintiffs bear the burden of demonstrating subject-matter jurisdiction. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992). Here, Plaintiffs have not proven this Court has subject matter jurisdiction.

A. As underscored by *California*, the Court of Federal Claims has exclusive jurisdiction over plaintiffs' claims.

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); see Tortorella v. United States, 486 F. Supp. 2d 159, 161 (D. Mass. 2007); Burgos v. Milton, 709 F.2d 1, 3 (1st Cir. 1987). 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 jurisdictional divide 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).

In Department of Education v. California (California), the Supreme Court addressed this issue in the same context in which plaintiffs' claims arise, grant awards. 145 S. Ct. 966. The Supreme Court explained 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. Instead, according to the Supreme Court, suits seeking relief like that sought by the California plaintiffs belong in the Court of Federal Claims:

The APA's waiver of sovereign immunity does not apply "if any other statute that grants consent to suit expressly or impliedly forbids the relief which is sought." 5 U.S.C. §702. Nor does the waiver apply to claims seeking "money damages." Ibid. True, a district court's jurisdiction "is not barred by the possibility" that an order setting aside an agency's action may result in the disbursement of funds. Bowen v. Massachusetts, 487 U. S. 879, 910 (1988).[5] But, as we have recognized, the APA's limited waiver of

⁵ Plaintiffs rely on *Bowen*, but the Supreme Court held in *California* that *Bowen* does not take lawsuits—like this one—to compel the payment of money under grants out of the Tucker Act's grant of exclusive jurisdiction to the Court of Federal Claims. Bowen did not 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 the cause of action generally and the intricate features of the Medicaid Act specifically underscoring that the case (unlike this case) did not implicate the Tucker Act's application

immunity does not extend to orders "to enforce a contractual obligation to pay money" along the lines of what the District Court ordered here. Great-West Life & Annuity Ins. Co. v. Knudson, 534 U. S. 204, 212 (2002). Instead, the Tucker Act grants the Court of Federal Claims jurisdiction over suits based on "any express or implied contract with the United States." 28 U. S. C. §1491(a)(1).

Id. at 969.

Plaintiffs attempt to disguise their claims as APA claims by styling their complaint as one for injunctive relief against "Challenged Directives" and then arguing that there is no statute that expressly or impliedly forbids the relief that is sought. Mot., Doc No. 78 at 18-23. But this is precisely what the plaintiffs argued in *California*, and this reasoning was rejected by the Supreme Court. 145 S. Ct. at 968-696. The assertion that plaintiffs "ask the Court to set aside the Challenged Directives, including actions taken to implement them" meaning "set aside" the grant terminations—does not change the result. Mot., Doc No. 78 at 19. Recently, another session of this Court rejected that argument in a similar case involving grant terminations. See Mass. Fair Hous. Ctr. v. Dep't of Hous. & Urban Dev., 3:25-cv-30041 (Text Order entered Apr. 14, 2025). Citing California, the Court found that, even though plaintiffs based their claims on federal statutes instead of contracts, their claims still "sought to enforce a contractual obligation to pay money." Id. It went on to dissolve its own temporary restraining order based on the Supreme Court's "unmistakable directive that, for jurisdictional purposes, the proper forum for this case is the Court of Federal Claims." Id.

to contract claims. Bowen, 487 U.S. at 900 n.31. By citing Bowen in Calfornia, the Supreme Court showed that *Bowen* is distinguishable here.

Even before the Supreme Court's decision in *California*, the First Circuit held that where "the essence of the [plaintiffs'] action is in contract," a plaintiff may not evade the Tucker Act's exclusive grant of jurisdiction "by the mystique of a different form of complaint," such as a suit under the APA. Am. Sci. & Eng'g, Inc. v. Califano, 571 F.2d 58, 63 (1st Cir. 1978); see also Diaz v. Johnson, No. 19-1501, 2020 WL 9437887, at *2 (1st Cir. Nov. 12, 2020) (holding that plaintiff "cannot manufacture an APA claim by asking the court to declare that the failure to fund his proposal was an arbitrary or capricious act"). And, here, plaintiffs seek to compel continued payment of money under the terms of grants and to "set aside" the termination of grants—all of which is to say plaintiffs seek continued payment under contracts. See PI Prop. Order, Doc No. 76-1 at 5(NIH "shall refrain from eliminating any funding for awards issued by or on behalf of NIH "). "[D]espite [plaintiffs'] valiant effort to frame the suit as one for declaratory or injunctive relief'—or as a suit under the APA—"this kind of litigation should be understood for what it is," a "suit for money for which the Court of Federal Claims can provide an adequate remedy," and which "therefore belongs in that court." Suburban Mortg. Assocs. v. U.S. Dep't of Housing & Urban Dev., 480 F.3d 1116, 1118 (Fed. Cir. 2007); see also U.S. Conf. of Catholic Bishops v. U.S. Dep't of State, No. 1:25-cv-465, 2025 WL 763738, at *7 (D.D.C. Mar. 11, 2025) ("Sure, the Conference seeks to set aside agency action. But the agency action that it asks the Court to reverse is the Government's decision to cease a financial relationship with the Conference."). Just as the Supreme Court held in California, so too should this Court hold in this case.

Plaintiffs resist this conclusion, seeking to downplay *California*'s significance. Ironically, in assailing the precedential value of the decision, plaintiffs first cite three cases

that themselves have limited precedential value: two unpublished decisions, neither from the District of Massachusetts, and a concurrence. Mot., Doc No. 78 at 21-22. In any event, as discussed above, one court in *this* district has already acknowledged, in a grant termination case similar to this one, that *California* is an "unmistakable directive that, for jurisdictional purposes, the proper forum for this case is the Court of Federal Claims." *Mass. Fair Housing Center v. Department of Housing and Urban Dev.*, 3:25cv30041, ECF No. 42; *see also Pippenger, v. U.S. DOGE Service*, No. 25-cv-1090, 2025 WL 1148345 at *5 (D.D.C. Apr. 17, 2025) (recognizing that *California* "may deprive this Court of the authority to consider claims sounding in contract or to enjoin further termination of contracts, *even if they are styled as APA claims*") (emphasis added).

The relief requested by plaintiffs closely mirrors the relief provided by the district court in *California*. *Compare California* v. *U.S. Dept. of Ed.*, --- F.Supp.3d ----, 2025 WL 760825 at *5 (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") *with* PI Proposed Order, Doc No. 76-1 at 3 ("Defendants shall unfreeze and release to the Plaintiffs..., any reimbursements or other funding for awards issued by or on behalf of NIH"). The Supreme Court correctly identified these functionally identical remedies as orders "to enforce a contractual obligation to pay money." *California*, 145 S. Ct. at 968. The fact that plaintiffs avoid saying "termination" (preferring "eliminat[ion]" instead) and have tacked the phrase "Challenged Directives" onto various sections of their request for relief does not transform them into claims cognizable under the APA.

B. 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 lacks jurisdiction to grant the relief that plaintiffs request because that relief would reinstate terminated grant agreements and bar NIH from terminating other grant agreements—compelling the United States to specifically perform those agreements—and Congress has not waived the United States' sovereign immunity for that relief. The United States cannot be sued unless it waives sovereign immunity, which waiver must be strictly observed and is not lightly implied. *Block v. North Dakota*, 461 U.S. 273, 287 (1983). First Circuit precedent recognizes that the United States has not waived sovereign immunity for specific performance and requires courts to dismiss actions that would compel the United States to perform a contract. *See 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).

Here, plaintiffs ask the Court to compel specific performance of the grants by, for example, ordering that NIH "shall refrain from eliminating any funding for awards issued by or on behalf of NIH" PI Prop. Order, Doc No. 76-1 at 5; see also TRO Prop. Order, Doc No. 8-1 at 2 (phrasing same relief as "refrain from terminating any individual NIH grant to Plaintiffs . . . "). Of course, if the Court bars NIH from terminating grant agreements, then the Court is ordering NIH to perform those agreements by paying the grants. Because courts cannot order agencies to specifically perform agreements, a district court in Utah—citing the First Circuit's holding in *Coggeshall*—recently dismissed a purported APA claim brought by a grantee against the Small Business Administration

("SBA") following SBA's termination of a grant. *Imaginarium LLC v. U.S. Small Bus. Admin.*, 618 F. Supp. 3d 1225, 1232 (D. Utah 2022). There, SBA approved a grant then denied the grant, and the grantee sued including for declaratory relief under the APA that would order the SBA to follow the grantee's view of the law. *Id.* at 1228, 1231. The court explained "some of Plaintiff's requests for declaratory judgment require the Court to order specific performance by the SBA of its alleged contractual obligations to Plaintiff—this is well beyond the Court's power." *Id.* at 1232. Other claims for damages, the court transferred to the Court of Federal Claims. *Id.* at 1231-32. Just so here.

C. In cloaking their contract suit as an APA claim, plaintiffs assert an impermissible programmatic challenge.

Plaintiffs broadly challenge how the agency is administering its program in the same way that the Supreme Court prohibited in *Lujan v. National Wildlife Federation*. 497 U.S. 871, 890–93 (1990). In *Lujan*, the plaintiff sought judicial review of a "so-called 'land withdrawal review program'" that it described as consisting of numerous individual land use decisions. *Id.* But the Supreme Court held that "the flaws in the entire 'program'—consisting principally of the many individual actions referenced in the complaint and presumably actions yet to be taken as well—cannot be laid before the courts for wholesale correction under the APA." *Id.* at 893. Instead, 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.* Plaintiffs even assert that the programmatic changes here are the result of an election. *See* Mot., Doc No. 78 at 7 ("The present state of disruption traces its origin, at least in part, to a series of executive orders issued on or shortly after Inauguration Day."); *see also* TRO Mot., Doc No. 8 at 1 ("norms

have been upended in a matter of weeks"). But, as *Lujan* teaches, elections appropriately effect programmatic changes, the APA does not allow plaintiffs to challenge programmatic changes wrought by the outcome of an election.

The Fifth Circuit's decision in *Alabama-Coushatta Tribe of Tex. v. United States*, 757 F.3d 484 (2014), is also 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 citation to *statistics* about the agency's overall grant processing progress rather than on individual grant applications. Mot., Doc No. 78 at 11-12, 36 (citing declaration of former director 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 resorting to "examples" of some grants and applications *See* Mot., Doc No. 78 at 13.

Plaintiffs' § 706(2) claims also have all the hallmarks of an impermissible programmatic challenge. In their transparent attempt to avoid the Tucker Act's bar of contract-based claims against the United States seeking injunctive relief, plaintiffs have styled their claims as being against "Challenged Directives." *See, e.g.*, Am. Compl., Doc No. 75 at 40 ¶ 117. They request that all of plaintiffs' grants be restored to "the pre-existing status quo prior to" President Trump's inauguration, "January 20, 2025." TRO Prop. Order,

Doc No. 8-1 at 2; PI Prop. Order, Doc No. 76-1 at 3 (seeking same relief, rephrased). They also 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 eliminating any funding for awards issued by or on behalf of NIH " PI Prop. Order, Doc No. 76-1 at 5. 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 eight documents as among the Challenged Directives, as well as "any nonpublic or undisclosed directives." Am. Compl., Doc No. 75 at 34–40 ¶ 103–117; Mot., Doc No. 78 at 18–21. Identifying an array of challenged actions is typical of a programmatic challenge, and the identified actions are not subject to judicial review under the APA in any event.

D. Even if considered individually, plaintiffs have not established jurisdiction to review any action that they challenge.

Even viewed individually, each of the Challenged Directives is either moot, unconnected to plaintiffs' alleged harms, or is not a final agency action. For these additional reasons, plaintiffs' claims against the Challenged Directives are not justiciable.

> 1. By their own terms, two Challenged Directives expired before plaintiffs sued.

Two of the Challenged Directives are moot. As the First Circuit has 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

⁶ 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.

F.3d 44, 53 (1st Cir. 2013). First, the Notice Pause Directive⁷ ordered a brief, ten-day pause on issuing documents and public communications "through February 1, 2025." Doc No. 75-1 at 2. By its own terms, the Notice Pause Directive expired on February 1, 2025, and although a pause continued in practice after that time the meeting pause ended before plaintiffs sued. See supra n.3, n.4. Plaintiffs' challenge of that directive is moot. Second, the Supplemental Lauer Memorandum, Doc No. 75-4, was expressly rescinded (twice). See Priorities Directive, Doc No. 75-5 at 2 ("This staff guidance rescinds the guidance provided in the [Supplemental Lauer Memorandum]."); see also Revised Priorities Directive, Doc No. 75-7 at 2 (same). Plaintiffs' challenge of the memorandum is thus moot.

2. Two other Challenged Directives did not harm plaintiffs and instead facilitated actions that plaintiffs want.

Two other Challenged Directives 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 Lauer Memorandum authorized grant managers "to proceed with issuing awards" in response to recent court orders. Doc No. 75-3 at 2. Plaintiffs' alleged harms are not traceable to restoring the issuance of awards; to the contrary, restoring grants is a goal of plaintiffs' amended complaint. Second, plaintiffs do not assert any injuries traceable to the alleged Climate Change Directive. Citing only a news article, plaintiffs allege that one or all of the defendants issued a Climate Change Directive concerning research related to the

⁷ Although a misleading characterization, for ease of reference, the United States uses Plaintiffs' shorthand for referring to the Challenged Directives.

health effects of climate change. Am. Compl., Doc No. 75 at 39 ¶ 115; Mot., Doc No. 78 at 21. But plaintiffs do not allege that any grants related to climate change research have been terminated. *See generally* Doc Nos. 75, 77, 78. Plaintiffs thus do not have standing to challenge the Lauer Memorandum or the Climate Change Directive.

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

The remaining Challenged 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 agency action must satisfy two conditions. First, the action "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 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 Challenged 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 consummation of the decisionmaking process would occur when the agency decides to act on an existing grant.

Here, the Challenged Directives merely ordered a review of the grants to determine whether they were consistent with the agency's priorities. *See* Secretarial Directive, Doc

No. 75-2 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"); Priorities Directive, Doc No. 75-5 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); Revised Priorities Directive, Doc No. 75-7 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" before issuing awards or approving requests for carryover). Initiating a review is not the consummation of the agency's decisionmaking 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").

For the second condition, initiating a review does not determine the grantees' rights and obligations. In FTC v. Standard Oil Co. of California, the Supreme Court held that issuing a complaint and initiating enforcement proceedings did not have "definitive" legal consequences for the respondent such that it was a final agency action. 449 U.S. 232, 241 (1980). The court emphasized that the complaint was still subject to challenge and review. Id. Here, too, the Challenged Directives did not definitively affect plaintiffs' rights and obligations, because the status of their grants remained subject to review.

Additionally, the Challenged Directives' procedural guidance does not qualify as agency action. The Challenged Directives outline the process for staff to follow when renegotiating or terminating awards based on the results of the review. *See* Priorities Directive, Doc No. 75-5 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, Doc No. 75-6; Revised Priorities Directive, Doc No. 75-7. Directing staff on the process to follow and the 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) (noting that "operating a program" does not qualify as agency action). This ministerial guidance remained subject to the decision to be made for each grant following the review.

The Challenged Directives' procedural guidance was also interlocutory, not final. The procedural guidance in the Priorities Directive was revised in the Award Revision Guidance, which was again updated in the Revised Priorities Directive. *See* Doc Nos. 75-5, 75-6, and 75-7. Reinforcing that the guidance was tentative, the Award Revision Guidance directed staff to "save this guidance until we can clear the updated staff guidance." Award Revision Guidance, Doc No. 75-6 at 2. This is not the stuff of final agency action.

Because the Challenged Directives are either moot, unconnected to the alleged injuries, or not final agency action, plaintiffs' attempt to assert claims based on the "Challenged Directives" is non-justiciable.

E. Congress committed grant administration to agency discretion.

Plaintiffs' claims are also unreviewable because they challenge funding decisions that are "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 lumpsum appropriations and § 701(a)(2) bars review where an appropriation confers discretion on the agency. *Milk Train, Inc. v. Veneman*, 310 F.3d 747, 751-52 (D.C. Cir. 2002). Any NIH actions to terminate existing grants or to award future grants are unreviewable.

Plaintiffs cannot overcome the discretion conferred by Congress. Where a decision is presumptively non-reviewable, as with funding allocation, "Congress may overcome the presumption against review by providing 'guidelines for the agency to follow in exercising its enforcement powers,' by 'setting substantive priorities, or by otherwise circumscribing an agency's power." *Holbrook v. Tennessee Valley Auth.*, 48 F.4th 282, 293 (4th Cir. 2022) (quoting *Heckler v. Chaney*, 470 U.S. 821, 833 (1985)). This is a question of statutory interpretation. *Id.* (citing *Webster v. Doe*, 486 U.S. 592, 600 (1988) ("[Section] 701(a)(2) requires careful examination of the statute on which the claim of agency illegality is based")). So too with express conferrals of discretion. *See Milk Train, Inc.*, 310 F.3d at 751-52 (holding plain language of statute conferred discretion on Secretary where statute directed distribution of funds "as soon as practicable").

Congress granted NIH broad discretion when awarding grants. 42 U.S.C. §§ 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") (emphasis added). Indeed, NIH is not statutorily required to enter into *any* grant agreements. Furthermore, 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." As in *Lincoln*, Congress gave the agency "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 unreviewable.

II. Plaintiffs are unlikely to succeed on the merits.

- A. Plaintiffs' 706(2) claims fail because NIH followed the law and provided sufficient reason when it terminated the grants.
- 1. The terminations complied with the terms of the agreements and the regulations.

Plaintiffs do not dispute that the agency followed its procedures when it terminated the grant agreements by providing notice to grantees that their grants had been terminated and by providing for appeal rights. *See* Mot. at 23-31. They claim, however, that the agency's cause for termination violates the agreement and regulations. Mot., Doc No. 78 at 25-28. Not so.

The Notice of Award explains that the grant "is subject to the terms and conditions incorporated either directly or by reference in the" agreement. Doc. No. 77-12 at 33. As one of the terms and conditions of the grant, the Notice of Award expressly incorporates the NIH Grants Policy Statement. *Id.* The NIH Grants Policy Statement covers the grounds for terminating grants in Section 8.5.2, which explicitly states that "NIH may also terminate the grant in whole or in part as outlined in 2 CFR Part 200.340." NAT'L INSTS. OF HEALTH, NIH GRANTS POLICY STATEMENT at IIA-155 (2024). In turn, part 200.340(a)(4) provides that the agency may terminate an award in whole or in part "if an award no longer effectuates the program goals or agency priorities." Thus, the terms of the award permit NIH to terminate a grant for no longer effectuating agency priorities.

Plaintiffs make several arguments to void the incorporation in the grants of part 200.340(a)(4), none of which withstand scrutiny. First, plaintiffs' argument that part 200.340 is mere "guidance" sidesteps the fact that the provision was expressly *incorporated into the 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)). Here, the agency and the grantee agreed in the contract terms to an additional ground on which the agency may terminate awards: "if an award no longer effectuates the program goals or agency priorities." NAT'L INSTS. OF HEALTH, NIH GRANTS POLICY STATEMENT at IIA-155 (2024). Nothing in the regulations prevents the parties from contracting to additional terms.

In fact, two professional university associations representing many of the colleges and universities on whose behalf plaintiffs bring this suit 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, 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 its Grant Policy Statement. *Id*.

Second, plaintiffs argue that part § 200.340(a)(4) only permits terminating based on changes "stemming from the grant recipient." Mot., Doc No. 78 at 27. This argument finds no support in the text. The provision authorizes the agency to terminate "if an award no longer effectuates the program goals or agency priorities." 2 C.F.R. § 200.340(a)(4). The text says nothing about what may cause the award to no longer effectuate agency priorities. The cause could be a change with the recipient or a change in agency priorities. Plaintiffs respond that it would be unduly broad if an agency could terminate a grant merely by incanting the words 'agency priorities," Mot., Doc No. 78 at 27, but the agency did more than that here and agencies, like any party to a contract, can always terminate.

Finally, plaintiffs argue that the NIH Grant Policy Statement authorizes terminating a grant only if a recipient has failed to comply with the award's terms and conditions. Mot., Doc No. 78 at 26. 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." NAT'L INSTS. OF HEALTH, NIH GRANTS POLICY STATEMENT 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.* The policy plainly states NIH may *also* terminate grants consistent with § 200.340. Plaintiffs' suggestion to the contrary is baseless.

Here, consistent with § 200.340(a)(4) and the terms and conditions of the grants, NIH terminated a small subset of grants that no longer effectuate agency priorities. NIH issued termination notices that provided its causes for termination. For example, in the

letter terminating Project No. R01MH134176-02S1, NIH identified a change in agency priorities and other stated causes including that "[r]esearch programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities." Doc No. 78-12 at 38.

2. The grant terminations were reasoned.

Even if the grant terminations were reviewed 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 readily clear these hurdles.

In terminating individual grants, NIH provided the reasons for its terminations and the fact that 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' fault-finding over the stated rationale misses the point. The notices properly stated the reasons for termination and the only cure for such an imagined problem is remand back to NIH for follow up, not an injunction designed to effect specific performance.

Plaintiffs' reliance-interest argument fails for two different reasons. First, plaintiffs can 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 (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 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' 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 other interests and policy concerns outweigh any reliance interests.") (cleaned up). Where NIH

decided to terminate a grant that was funding research, plaintiffs' reliance on that research funding cannot compel NIH to maintain the grant.

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3. 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. Mot., Doc No. 78 at 33. 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 34. Both arguments are misplaced.⁸

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), HHS is continuing at least 26 research grants on these topics. Those grants are publicly available and a table is attached hereto as Exhibit A. (listing minority-related grants that were preserved). For example, HHS has an ongoing research grant to "reduce cervical cancer disparities in African American Women," to understand the "risk of gestational diabetes among Asian Americans," to prevent "anxiety and depression" in "older Latinos," and to understand "cancer and comorbidities among

⁸ 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.

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⁹ https://reporter.nih.gov/search/s2chZVOP-0Wi9TkGeyYICA/project-details/11124106

American Indian and Alaska Native people." Ex. A. HHS exercised its discretion to terminate DEI grants that it determined did not enhance health, while preserving grants into health disparities. This action is not only consistent with the statutes that Plaintiffs cite, which do not require HHS to approve and preserve every grant or proposal that in any way relates to minorities, but furthers the statutes' aims. HHS is supporting research on minority-related projects and did not adopt a policy to no longer support any such projects. The statutes permit HHS discretion to decide which grants among this category are worthy of approving and renewing.

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. Even Plaintiffs acknowledge that "new administrations are certainly permitted to shift priorities in NIH research." Mot., Doc No. 78 at 34.

B. 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 presently 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 three 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 shortly following the change in administrations. But that pause is over: Plaintiffs do not and cannot dispute that NIH has resumed reviewing and deciding applications and holding the meetings that plaintiffs presently seek to compel.

1. <u>Plaintiffs have not identified a discrete and mandatory agency action that the agency failed to take.</u>

Plaintiffs' "delay" claim is not justiciable under the APA because they have not shown the agency failed to a 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 agency's ongoing administration, not a discrete agency action that can be compelled. 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, § 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." 5 U.S.C. § 551(13). Meetings—even meetings established by statute—fall well outside this definition. They are instead comparable to the Federal-State consultations that a court ruled it could not compel in *Texas Health and Human Services Commission v. United States.* 193 F. Supp. 3d 733, 742 (N.D. Tex. 2016). There, a statute directed agencies to "consult regularly (not less often than quarterly)" with States and to "take into account" the consultation when taking a subsequent action. *Id.* The court held that it could not compel a consultation because it was "not a discrete agency action, but rather an ongoing process." *Id.* So too with holding meetings at NIH.

Notwithstanding use of the word "shall," the agency clearly retains discretion to continue evaluating any application and to not decide on that application. *See* 42 C.F.R. § 52.5(b). As plaintiffs recognize, the agency retains the discretion to "defer" making a decision on any application. *Id.* Because no statute or regulation mandates a decision, plaintiffs cannot compel one, and that discretion is not reviewable by the Court. Similarly, because the statute maintains the agency's option to defer a decision, the regulation does not require an action that is "discrete." In any event, the agency resumed holding meetings and deciding applications before plaintiffs sued.

2. <u>Plaintiffs also cannot compel NIH to hold meetings because NIH is already holding meetings.</u>

Plaintiffs cannot obtain an order requiring NIH to "refrain from delaying" meetings and procedural steps needed to issue awards "based on the Challenged Directives" because Defendants resumed holding meetings and taking all procedural steps needed to issue awards even before plaintiffs sued. NIH canceled previously scheduled meetings and did not schedule new meetings based on the January 21, 2025 Notice Pause Directive. But by its own terms, the Notice Pause Directive expired on February 1, 2025 and the pause on peer review and advisory committee meetings ended when NIH resumed holding meetings by March 18, 2025. Notice Pause Directive, Doc No. 77-39 at 2; see supra n.3, n.4. By the time plaintiffs filed suit, there was no longer any active policy preventing NIH from scheduling peer reviews. And since the pause expired, NIH has scheduled or held over 300 peer reviews. See supra n.3. NIH is also on track to hold advisory council meetings this fiscal year, as contemplated by 42 U.S.C. section 284a(e). See supra n.4. In conclusion, although NIH briefly paused certain processes as part of the change in administrations, NIH has been conducting all necessary steps in the review and disposition of grant applications.

Courts find that short pauses as part of changes in administration are reasonable and decline to enjoin such pauses while they are ongoing. *See, e.g., Alaska Indus. Dev. & Exp. Auth. v. Biden*, 685 F. Supp. 3d 813, 858 (D. Alaska 2023). 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' appeal to the timelines followed by prior administrations distorts the authority on which plaintiffs rely and demonstrates the improper programmatic nature of plaintiffs' challenge and requested relief. Mot., Doc No. 78 at 35-36. In each case plaintiffs cite, the court addressed an alleged delay on a specific application and compared the agency's time to process that application with the timelines then-prevailing at the agency. See Ashtari v. Pompeo, 496 F. Supp. 3d 462, 470 (D.D.C. 2020) (comparing time to process plaintiff's application for waiver of Iranian-citizen ban with then-current guidelines); Rezaii v. Kennedy, No. 1:24-cv-10838, 2025 WL 750215, at *5 (D. Mass. Feb. 24, 2025) (comparing time to process plaintiff's visa residency waiver application with agency's then-prevailing timeline to process other applications). Plaintiffs' argument is different in kind. It compares the agency's time to process all applications under a new administration against the time that the agency took to process all applications under previous administrations. Mot, Doc No. 78 at 11-12, 36 (citing declaration of former director comparing present administration's management with past administration's management). Enjoining differences in program management as "unreasonable" based on such comparisons 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.

C. 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, and by extension the Director of NIH, with responsibility "for the overall direction of the National Institutes of Health and for the establishment and implementation of general polices 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, the plain meaning of these two provisions explicitly authorizes 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."). Plainly, 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, plaintiffs are only able to manufacture a separation of powers claim by asserting that the grant terminations and meeting disruptions will result in NIH "unilaterally refus[ing] to spend ... duly appropriated funding." Mot., Doc No. 78 at 33. Not so. NIH is working diligently to reschedule all cancelled meetings. *See supra* n.3, n.4. Since March 4, NIH has published over 150 notices of scheduled meetings in the Federal Register. *See id.* And it has scheduled 201 more meetings from March 24 to May 31 than it did in the previous year. *See id.* Far from subverting Congress' intent by holding back appropriated funding, NIH is working overtime to boost the grant approval process.

III. Plaintiffs' Alleged Harms are Not Certain, Imminent, and Irreparable.

A. Plaintiffs' alleged harm is not irreparable

The Court should deny plaintiffs' motion for the additional, independently sufficient reason that plaintiffs have not shown irreparable harm. *See EEOC v. Astra USA*, *Inc.*, 94 F.3d 738, 743 (1st Cir. 1996); *In re TelexFree Sec. Litig.*, No. CV 4:14-MD-02566-TSH, 2021 WL 11604879, at *7 (D. Mass. Apr. 21, 2021) (finding likelihood of success on the merits but denying emergency relief for failure to show irreparable harm); *Doble Seis Sport TV, Inc. v. Puerto Rico*, 18-cv-1432, 2019 WL 1153432, at *5 (D.P.R. Mar. 12, 2019) ("Plaintiffs face a high burden of showing that irreparable harm will result. . . .").

In considering whether plaintiffs have met the "exceedingly high burden" of demonstrating that, absent the injunctive relief they seek, they are likely to suffer Plaintiff—and each institution represented by a Plaintiff, as well as each grant—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 member institutions) circumstances vary significantly, and no relief may be ordered unless each Plaintiff (and member institution) meets this burden. *See Tamko Roofing Prods., Inc. v. Ideal Roofing Co.*, 282 F.3d 23, 40 (1st Cir. 2002) ("Injunctive relief should be no more burdensome to the defendant than necessary to provide complete relief to plaintiffs[.]").

Variation exists not just on a Plaintiff-by-Plaintiff basis, but also on a grant-by-grant basis. Plaintiffs have not even identified the specific grant terminations they ask this Court to reverse. They are ostensibly challenging at least 253 terminations. *See* Doc Nos. 77-12 through 77-36, 77-45 through 77-65. But their declarations and attached exhibits identify only around 114 grants specifically. *See* Doc Nos. 77-12 through 77-36, 77-45 through 77-65. It is unclear which other grant terminations they are challenging. This ambiguity alone disfavors any preliminary injunctive relief when so many of the challenged terminations fall far short of meeting the standard for irreparable harm, as detailed below.

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 a quintessential example of what never counts as irreparable injury. *Sampson v. Murray*, 415 U.S. 61, 90 (1974) (stating that "the 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, nor has any other government action done so. The government is not preventing plaintiffs from conducting their research; NIH has just terminated the agreements under which the government would provide reimbursement for those activities. *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.").

This distinction is particularly crucial where, as here, plaintiffs are states with significant financial means. Indeed, it is hard to conceive of a party for whom mere financial harm could be *less* irreparable than a state. If plaintiffs are truly concerned about the supposedly irreparable harm that will occur if preliminary relief is not granted, they may step in themselves to support any project. *See Rosario-Urdaz v. Rivera-Hernandez*, 350 F.3d 219, 222 (1st Cir. 2003) (identifying the availability of alternative sources of funding as relevant to the irreparable harm inquiry). Many of them are doing just that. *See* Doc Nos. 77-12 ¶ 62(c); 77-14 ¶ 68; 77-15 ¶ 41; 77-16 ¶ 7, 36; 77-17 ¶ 37.

Second, plaintiffs couch their discussion of many imagined harms absent a preliminary injunction in speculative terms. 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. Doc No. 77-13 ¶ 6 (noting that delays in grant approval "may" cause the university to lose employees and "may affect the progress of students") Doc No. 77-46 ¶ 14 (noting grant delays and terminations "may result in the loss of research materials") (emphasis added). This language of mere possibility, not likelihood, cannot support injunctive relief. See Narragansett Indian Tribe v. Guilbert, 934 F.2d 4, 6–7 (1st Cir. 1991) (holding that "irreparable harm is not assumed; it must be demonstrated") (quoting Pub. Serv. Co. of New Hampshire v. Town of W. Newbury, 835 F.2d 380, 383 (1st Cir. 1987)).

Third, "bare conclusory assertions" are insufficient to support a preliminary injunction. Augusta News Co. v. News Am. Pub. Inc., 750 F. Supp. 28, 32 (D. Me. 1990). But Plaintiff's supporting declarations offer little more than conclusory assertions about "irreparable harm." See, e.g., Doc No. 77-16 ¶ 46-48 (discussing irreparable harm in broad terms), Doc No. 77-20 ¶ 61-65 (the same).

Plaintiffs are even more circumspect when it comes to supposed "irreparable" harm due to allegedly delayed action on pending grant applications. Tellingly, plaintiffs minimally discuss the applications issue in alleging that NIH has caused them irreparable harm. Mot., Doc No. 78 at 37-38. Obviously, 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. Moreover, there is no stopping point to this argument: If a plaintiff's desire for a future government grant or contract, or a future

government grant or contract with more advantageous terms, qualifies as irreparable harm, the irreparable harm element would be automatically met in every case involving a potential future government grant or contract. That is not the law: Irreparable harm must be proved. *See Voice of the Arab World, Inc. v. MDTV Med. News Now, Inc.*, 645 F.3d 26, 26. And, in any event, a showing of irreparable harm limited to future grants would support injunctive relief only with respect to future grants—and not existing grants. *See Tamko Roofing Prods., Inc.*, 282 F.3d at 40. But plaintiffs' Motion should be denied in full because they have not shown irreparable harm with respect to any grants.

IV. 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., in chambers) (prospect of the government being forced to make \$1.3 million in improper payments per month supported a stay of injunction). For this reason, a preliminary injunction should be denied.

V. Any Injunction should be Narrowly Tailored.

For the reasons explained above, plaintiffs are not entitled to a preliminary injunction. But should the Court conclude otherwise, 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)); see also NACM-New England, Inc. v. Nat'l Ass'n of Credit Mgmt., Inc., 927 F.3d 1, 7 (1st Cir. 2019).

Here, at most, any remedy should address only sufficiently proven irreparable harms of the plaintiffs in these cases, or of those they represent: the members of the plaintiff organizations and the public institutions of the Plaintiff States. Many of the declarations only discuss harms insufficient to justify a preliminary injunction. That plaintiffs are States claiming harm to their public institutions does not warrant extending injunctive relief to every institution within those States. "[E]ven when the plaintiff has alleged injury sufficient to meet the 'case or controversy' requirement," "the plaintiff generally must assert his own legal rights and interests." *Warth v. Seldin*, 422 U.S. 490, 499 (1975). A plaintiff "cannot rest his claim to relief on the legal rights or interests of third parties." *Id.* The plaintiff states can only seek relief on their own behalf, not on behalf of unaffiliated institutions in their states. Nor does irreparable harm resulting from one grant termination warrant a preliminary injunction hindering all other terminations.

VI. 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 appeal that is authorized. At a minimum, the Court should administratively stay any order granting plaintiffs' motion

 $^{10} \textit{See} \; \mathsf{Doc} \; \mathsf{Nos.} \; 77\text{-}13 \; \P \; 5; \; 77\text{-}14 \; \P \; 64; \; 77\text{-}15 \; \P \P \; 40\text{-}45; \; 77\text{-}16 \; \P \P \; 35\text{-}37; \; 77\text{-}17 \; \P \P \; 36\text{-}39; \\ 77\text{-}18 \; \P \; 45, \; 51; \; 77\text{-}20 \; \P \; 51\text{-}54; \; 77\text{-}22 \; \P \P \; 34\text{-}35; \; 77\text{-}24 \; \P \P \; 51\text{-}54; \; 77\text{-}25 \; \P \; 22; \; 77\text{-}26 \; \P \; 21; \\ 77\text{-}27\text{-}77\text{-}27\text{-}77\text{-}27\text{-}77\text{-}27\text{-}77\text{-}27\text{-}77\text{-}27\text{-}27\text{-}77\text{-}27\text{-$

77-27 ¶¶ 50, 51; 77-28 ¶¶ 1-5; 77-29 ¶¶ 32, 37; 77-30 ¶¶ 7, 11, 32-35.

for seven days to allow an opportunity to seek an emergency, expedited stay from the Court of Appeals, if an appeal is authorized.

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 ligation. Defendants are currently analyzing the data supporting the amount of any required bond, and they will set out their position in a court filing if the Court orders a preliminary injunction.

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 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); cf. Amazon Web Servs., Inc. v. United States, 147 Fed. Cl. 146, 159–60 (2020) (requiring security in the amount of \$42 million and explaining that "some degree of uncertainty or speculation is inherent in defendant's attempt to quantify the harm it may suffer as a result of the preliminary injunction"). Although the amount of an injunction bond is within the Court's discretion, when setting security, 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.

CONCLUSION

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

Respectfully submitted,

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Dated: April 30, 2025

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CERTIFICATE OF SERVICE

I 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).

I further certify that I served a copy of the foregoing document, by email, on counsel for plaintiffs shortly after midnight because, following multiple attempts on multiple devices and without issues accessing other websites, I was unable to access the Court's CM/ECF system to file before midnight on April 30, 2025.

/s/ Thomas Ports Dated: May 1, 2025

Thomas Ports

Exhibit A

NIH Minority-Related Health Projects That Were Not Terminated					
Туре	Actv	Project	Title	Institution	
5	R44	MD015221-04	Enhancing the Effectiveness of Community Health Workers to Reduce Cervical Cancer Disparities in African American Women	ISA ASSOCIATES, INC.	
1	R01	MD019748-01	Actívatexto: Advancing smoking cessation and physical activity among Latinos	UNIVERSITY OF ROCHESTER	
5	R01	MD018459-02	Elucidating the high and heterogeneous risk of gestational diabetes among Asian Americans: an integrative approach of metabolomics, lifestyles, and social determinants	UNIVERSITY OF CALIFORNIA LOS ANGELES	
5	R01	MD013352-04	Impact of Navajo Nation Tax on Junk Food	NORTHERN ARIZONA UNIVERSITY	
5	R01	MD018583-03	Family mHealth Intervention to Improve Health Outcomes in Black Youth with Type 1 Diabetes: A Multi-Center Randomized Controlled Trial	WAYNE STATE UNIVERSITY	
5	R01	MD014859-05	Elucidating Lung Cancer Etiology Among Asian American Female Never Smokers	UNIVERSITY OF CALIFORNIA, SAN FRANCISCO	
7	R01	MD018193-04	Church Wellness Coordinator-led Intervention to Improve Hypertension Control in the Black Community	UT SOUTHWESTERN MEDICAL CENTER	
5	R01	MD014127-05	Achieving American Indian Youth Energy and Mental Health Balance	UNIVERSITY OF ARIZONA	
5	R01	MD015724-04	A Randomized Control Trial to improve metabolic outcomes in African American pregnant women	UNIVERSITY OF ILLINOIS AT CHICAGO	
5	R01	MD012610-05	Health Promotion in the Prevention of Anxiety and Depression: The Happy Older Latinos are Active (HOLA Study)	UNIVERSITY OF MIAMI SCHOOL OF MEDICINE	
5	R01	MD016068-03	Effects of DASH Groceries on Blood Pressure in Black Residents of Urban Food Deserts	BETH ISRAEL DEACONESS MEDICAL CENTER	
5	R44	MD017106-03	Reducing Hypertension among African American Men: A Mobile Stress Management Intervention to Address Health Disparities	ISA ASSOCIATES, INC.	
5	R01	MD015186-05	Sleep and health disparities among Asian Americans: roles of stressors and protective factors	UNIVERSITY OF CALIFORNIA- IRVINE	
1	R21	MD020158-01	Equity Implications of Lung Cancer Screening Strategies for Population Health: a Distributional Cost-Effectiveness Analysis	WAKE FOREST UNIVERSITY HEALTH SCIENCES	
5	R01	MD014035-05	AMERICAN INDIAN CHronic disEase RIsk and Sleep Health (AI-CHERISH)	WASHINGTON STATE UNIVERSITY	

į	R01	MD013752-05	Access to Kidney Transplantation in Minority Populations (AKT-MP)	UNIVERSITY OF NEW MEXICO HEALTH SCIS CTR
į	R21	MD018641-02	Understanding cancer and comorbidities among American Indian and Alaska Native people	UNIVERSITY OF IOWA
į	R01	MD014146-06	Understanding the Multiple-levels of Influence on Access to Care for Latino Youth	UNIVERSITY OF HAWAII AT MANOA
į	R01	MD013858-05	Designing a Plan of Action for Better Access and Quality of Surgery for African- Americans with Gastrointestinal Cancers in the Deep South	UNIVERSITY OF ALABAMA AT BIRMINGHAM
į	R01	MD016961-03	Long-Term Effects of Hurricane Maria on Healthcare Delivery, Migration and Mortality Among People with Kidney Failure in Puerto Rico	BROWN UNIVERSITY
į	R01	MD014145-05	A Coping Skills Intervention for Low-SES Latino Families of Children with Asthma	UNIVERSITY OF TEXAS AT AUSTIN
Ļ	R01	MD016738-04	The ADELANTE Trial: Testing a multi-level approach for improving household food insecurity and glycemic control among Latinos with diabetes	STANFORD UNIVERSITY
Į	U01	MD019397-03	Engaging Partners in Caring Communities (EPICC): Building capacity to implement health promotion programs in African American churches	TENNESSEE STATE UNIVERSITY
Ę	R01	MD015080-04	Latinos Understanding the Need for Adherence in Diabetes using Care Coordination, Integrated Medical and Behavioral Care and E-Health (LUNA-E)	SAN DIEGO STATE UNIVERSITY
į	R21	MD019333-02	Adapting and testing a physical activity dyad intervention for Black girls with asthma and their mothers	UNIVERSITY OF CHICAGO
Ļ	R21	MD019227-02	A Mixed-Methods Study of the Social Ecological and Integration Factors Associated with HIV Prevention Measures Among Latino/x Sexual Minority Migrant Men in the US	RUTGERS, THE STATE UNIVERSITY OF N.J.