

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

AMERICAN PUBLIC HEALTH
ASSOCIATION, *et al.*,

Plaintiffs,

v.

NATIONAL INSTITUTES OF HEALTH, *et al.*,

Defendants.

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

**MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF DEFENDANTS’
MOTION TO DISMISS PLAINTIFFS’ UNREASONABLE DELAY CLAIMS**

Table of Contents

Introduction	1
Background	2
Procedural History.....	5
Legal Standard	6
Argument	7
I. Plaintiffs lack standing to challenge alleged agency delay related to grant applications. ..	7
A. Plaintiffs cannot enforce the rights of nonparties.....	9
B. Plaintiffs also lack Article III standing.....	11
II. Plaintiffs’ claims under 5 U.S.C. § 706(1) should be dismissed for three independent reasons.....	12
A. Plaintiffs’ claims that NIH should be compelled to resume holding meetings and deciding awards are moot because NIH resumed before Plaintiffs sued.....	12
B. Any claims that NIH should not apply the Challenged Directives when considering and deciding Plaintiffs’ applications about de-prioritized research topics are properly § 706(2) claims, not § 706(1) claims.....	133
C. The Court cannot compel NIH to decide applications because doing so is not a discrete and mandatory duty.....	15
III. Any unreasonable delay claim under 5 U.S.C. § 706(2) should be dismissed.	177
A. Plaintiffs did not allege sufficient facts to state a plausible claim for relief from delay in considering specific applications.	177
B. In any event, an application remaining under review is not a final agency action...	177
IV. All phase 2 claims should be dismissed because the consideration of applications is committed to agency discretion by law.....	188
Conclusion	19

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>AAUP, et al. v. U.S. Dep’t of Justice, et,</i> No. 25-cv-2429 (MKV), 2025 WL 1684817 (S.D.N.Y. June 16, 2025).....	10, 11
<i>ABC, Inc. v. Stewart,</i> 360 F.3d 90 (2d Cir. 2004).....	13
<i>Ahadian & Fathollahzadeh v. Rubio,</i> No. 24-cv-12168, 2025 WL 1617224 (D. Mass. June 6, 2025).....	14
<i>Ashcroft v. Iqbal,</i> 556 U.S. 662 (2009).....	7
<i>Associated Builders & Contractors, Inc. v. Herman,</i> 976 F. Supp. 1 (D.D.C. 1997).....	13
<i>Barrett v. United States,</i> 105 F.3d 793 (2d Cir. 1996).....	13
<i>Bell Atl. Corp. v. Twombly,</i> 550 U.S. 544 (2007).....	7
<i>Bennett v. Spear,</i> 520 U.S. 154 (1997).....	18
<i>Clapper v. Amnesty Int’l USA,</i> 568 U.S. 398 (2013).....	11, 12
<i>Delta Data Sys. Corp. v. Webster,</i> 744 F.2d 197 (D.C. Cir. 1984)	19
<i>Dep’t of Educ. v. California,</i> 604 U.S. ---, 145 S. Ct. 966 (2025).....	11
<i>Dosmetova v. USCIS,</i> No. 3:24-cv-7409, 2025 WL 1663661 (D.S.C. Feb. 7, 2025)	19
<i>Edwards v. Aurora Loan Servs.,</i> 791 F. Supp. 2d 144 (D.D.C. 2011).....	9
<i>FDIC v. Meyer,</i> 510 U.S. 471 (1994).....	7

Friends of the Wild Swan, Inc. v. EPA,
130 F. Supp. 2d 1184 (D. Mont. 1999)..... 13

Funds for Animals, Inc. v. U.S. Bureau of Land Mgmt.,
460 F.3d 13 (D.C. Cir. 2006)..... 16

Gonzalez v. Cuccinelli,
985 F.3d 357 (4th Cir. 2021)..... 20

Haaland v. Brackeen,
599 U.S. 255 (2023)..... 11

Hells Canyon Pres. Council v. U.S. Forest Serv.,
593 F.3d 923 (9th Cir. 2010)..... 14

Hillside Metro Assocs., LLC v. JPMorgan Chase Bank, Nat. Ass’n,
747 F.3d 44 (2d Cir. 2014)..... 9

Karst Env’t Educ. and Prot., Inc. v. U.S. Env’t Prot. Agency,
403 F. Supp. 2d 74 (D.D.C. 2005)..... 19

Klamath Water Users Protective Ass’n v. Patterson,
204 F.3d 1206 (9th Cir. 1999)..... 9, 10

Kowalski v. Tesmer,
543 U.S. 125 (2004)..... 10

Lujan v. Def. of Wildlife,
504 U.S. 555 (1992)..... 8, 12

Maldonado-Coronel v. McElroy,
943 F. Supp. 376 (S.D.N.Y. 1996)..... 19

Merlonghi v. United States,
620 F.3d 50 (1st Cir. 2010)..... 7

Murphy v. United States,
45 F.3d 520 (1st Cir. 1995)..... 7

Murthy v. Missouri,
603 U.S. 43 (2024)..... 11

Nat’l Parks Conservation Ass’n v. U.S. Dep’t of the Interior,
No. 1:20-cv-3706, 2024 WL 1344450 (D.D.C. Mar. 29, 2024)..... 14

Norton v. S. Utah Wilderness All.,
542 U.S. 67 (2004)..... 13, 15, 16

Planned Parenthood of Wisc., Inc. v. Azar,
316 F. Supp. 3d 291 (D.D.C. 2018)..... 18

Powers v. Ohio,
499 U.S. 410 (1991)..... 8

Rattlesnake Coal. v. EPA,
509 F.3d 1095 (9th Cir. 2007)..... 18

Rezaii v. Kennedy,
No. 1:24-cv-10838, 2025 WL 750215 (D. Mass. Feb. 24, 2025) 13

Sardarian v. Fed. Emergency Mgmt. Agency,
No. 3:19-cv-00910, 2022 WL 4080325 (D. Conn. Apr. 1, 2022) 10

Scarborough Citizens Protecting Res. v. U.S. Fish & Wildlife Serv.,
674 F.3d 97 (1st Cir. 2012)..... 15

Taber Partners, I v. Merit Builders, Inc.,
987 F.2d 57 (1st Cir. 1993)..... 7

Touarsi v. Mueller,
538 F. Supp. 2d 447 (D. Mass. 2008)..... 19

Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council, Inc.,
435 U.S. 519, (1978)..... 19

Warth v. Seldin,
422 U.S. 490 (1975)..... 8

West v. Lynch,
845 F.3d 1228 (D.C. Cir. 2017) 12

Statutes

5 U.S.C. § 551(13)..... 16

5 U.S.C. § 701..... 19

5 U.S.C. § 706(1) 1, 12, 14, 16

5 U.S.C. § 706(2)..... 1, 18

5 U.S.C. § 1009..... 4

42 U.S.C. § 241..... 2
42 U.S.C. § 282..... 2
42 U.S.C. § 284a..... 3, 13
42 U.S.C. § 284..... 19

Rules

Fed. R. Civ. P. 12(b)(6)..... 7

Regulations

42 C.F.R. § 52h.2..... 3
42 C.F.R. § 52h.8..... 3
42 C.F.R. § 52.5..... 4, 17
42 C.F.R. § 52.6..... 2, 4

Other Authorities

90 Fed. Reg. 11175-01 (Mar. 4, 2025)..... 5, 12
90 Fed. Reg. 11323-02 (Mar. 5, 2025)..... 5, 12
90 Fed. Reg. 11324-01 (Mar. 5, 2025)..... 5
90 Fed. Reg. 11422-01 (Mar. 6, 2025)..... 5, 12
90 Fed. Reg. 12325 (Mar. 17, 2025)..... 5, 12
90 Fed. Reg. 12333 (Mar. 17, 2025)..... 5, 12
90 Fed. Reg. 13175..... 13
90 Fed. Reg. 13182 (Mar. 20, 2025)..... 5, 12
90 Fed. Reg. 13187 (Mar. 20, 2025)..... 5, 12
90 Fed. Reg. 13376..... 13
90 Fed. Reg. 13379..... 13

90 Fed. Reg. 13604.....	13
90 Fed. Reg. 13755.....	13
90 Fed. Reg. 14143.....	13
90 Fed. Reg. 14267.....	13
90 Fed. Reg. 14454.....	13
90 Fed. Reg. 15009.....	13

INTRODUCTION

Defendants respectfully move under Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6) to dismiss Plaintiffs' Phase 2 claims.

First, Plaintiffs lack both Article III and prudential standing to raise these claims. Plaintiffs attempt to assert the legal rights of nonparties, and their allegations of harm are too attenuated to support jurisdiction.

Plaintiffs' 5 U.S.C. § 706(1) claim should also be dismissed for three independent reasons. First, Plaintiffs acknowledge that NIH's delay in holding meetings and approving applications ended before Plaintiffs sued, thus rendering Plaintiffs' § 706(1) claim moot. Second, Plaintiffs' § 706(1) claim is an improper attempt to circumvent the final agency action requirement. Alternatively, if the Court rules that its phase 1 order under § 706(2) about the challenged Directives encompasses NIH's consideration of Plaintiffs' grant applications, applying the phase 1 ruling would remedy the alleged harms that Plaintiffs seek to redress in phase 2. This would mean—if phase 2 can proceed at all—the Court would need to consider Plaintiffs' remaining claims under 5 U.S.C. § 706(2), which courts recognize is the appropriate and preferred approach. Finally, even if the foregoing were not true, and the Court applies § 706(1), Plaintiffs cannot compel the actions that they seek to compel because those actions are not discrete and mandatory.

Any unreasonable delay claim pursued under 5 U.S.C. § 706(2) should also be dismissed. First, continued consideration of an application is not a final agency action. Second, to the extent Plaintiffs intend to argue that NIH has delayed or ended consideration of certain grants because of the challenged Directives, that claim should be dismissed under Rule 12(b)(6) because Plaintiffs failed to plead facts sufficient to state a claim for relief. They failed to put NIH on notice of which applications they allege are unreasonably delayed because Plaintiffs did not identify the allegedly delayed applications, and the few examples provided are insufficient.

Finally, all claims should be dismissed for phase 2 because considering applications and entering grant agreements is committed to agency discretion by law.

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.¹ 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).

Congress gave NIH broad discretion in awarding grants. 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) (emphasis added). NIH also maintains broad discretion when administering grants. *See, e.g.*, 42 C.F.R. § 52.6(f).

Before approving any grant, NIH subjects grant applications to two levels of review; the first, by "peer review groups" and the second, by the funding institute's "Advisory Council." Peer review groups are composed of "primarily nongovernment experts qualified by training and experience in particular scientific or technical fields, or as authorities knowledgeable in the various disciplines and fields related to the scientific areas under review, to give expert advice on the scientific and technical merit of grant applications or contract proposals, or the concept of contract

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

projects[.]” 42 C.F.R. § 52h.2(k). Annually, NIH engages roughly 25,000 peer reviewers. Advisory Councils are also composed of primarily non-government experts, and they “advise, assist, consult with, and make recommendations to the Secretary and the Director of such institute on matters related to the activities carried out by and through the institute and the policies respecting such activities.” 42 U.S.C. § 284a. Among other responsibilities, Advisory Councils “review applications for grants and cooperative agreements for research or training and for which Advisory Council approval is required . . . and recommend for approval applications for projects which show promise of making valuable contributions to human knowledge[.]” *Id.*

The regulations governing the first level of NIH peer review process provide, in part, that each “scientific peer review group shall assess the overall impact that the project could have on the research field involved, taking into account a variety of factors.” 42 C.F.R. § 52h.8. If the peer review group advises approval, the recommendation of the proposal then goes to the Advisory Councils. These bodies are *not* subject to specific review criteria identified in regulation; their role focuses on the prioritization of funding in light of NIH’s budget and other competing grant applications. The Advisory Councils broadly consider whether applications “show promise of making valuable contributions to human knowledge,” 42 U.S.C. § 284a, consistent with the priorities, missions, and purposes of the institute they advise.

Following review, if a project is approved by the relevant peer review group and Advisory Council, NIH may award that grant. 42 C.F.R. § 52.5(b). For any grant, NIH may also deny the application or take additional time to review. *Id.*

When NIH awards a grant, it enters an agreement with the grantee through the issuance of a Notice of Award (NOA), and the terms of that NOA govern the relationship between the grantee and NIH. Although 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).

Following the 2024 Presidential election, NIH’s priorities shifted. Consistent with past practice when NIH comes under new management, on January 21, 2025, the Administration issued a temporary freeze on the publication of any documents in the Federal Register until they had been reviewed by a presidential appointee. NIH_GRANTS_000001. Because NIH must post a notice to the Federal Register when it schedules a peer review meeting for grant applications, it scheduled no meetings for the duration of the temporary pause. 5 U.S.C. § 1009(a)(2). NIH also cancelled all peer review meetings for that brief period.

NIH also began exercising its broad discretion to make and administer grants in alignment with its priorities. On February 10, 2025, the Acting Secretary of Health and Human Services directed agency personnel to “briefly pause all payments made to contractors, vendors, and grantees related to DEI and similar programs” to allow time for an internal review, including “to determine whether those contracts or grants are in the best interest of the government and consistent with current policy priorities.” Feb. 10, 2025 Secretarial Directive, NIH_GRANTS_000004.² On February 21, 2025, then-Acting Director Dr. Matthew Memoli announced a shift in NIH’s priorities. NIH_GRANTS_002930-1. Consistent with these priorities, the head of NIH, exercising the delegated authority of the Secretary, reviewed lists of grants and directed the termination of grants that did not effectuate agency priorities. *See, e.g.,*

² NIH stopped and re-started its processes to comply with court orders. *See* Feb. 12, 2025 NIH Review of Agency Priorities Based on the New Administration’s Goals, NIH_GRANTS_000009 (directing agencies to resume issuing grants without restriction); Feb. 13, 2025 Supplemental Guidance, NIH_GRANTS_00016 (providing guidance about NIH priorities review).

NIH_GRANTS_003752–3. Additionally, various Institutes and Centers did not award renewals of certain grants following their investigation and review of individual grants. *See, e.g.*, NIH_GRANTS_001444-50.

While NIH continued to review and terminate grants, by March 23, 2025, NIH’s pause on holding peer review meetings and awarding new grants ended.³ Working to make up for lost time, NIH increased the rate at which it scheduled and held peer review meetings. From March 23, 2025, to June 30, 2025, NIH scheduled 837 peer review group meetings, according to publicly available NIH data.⁴ That is a faster pace than NIH maintained in 2023 or 2024. For comparison, during the same period in 2024, NIH held 651 peer review group meetings. In 2023, it held 665. *Id.* Publicly available public documents thus show that, at present, NIH is not delaying consideration and award of grants, in general.

Plaintiffs nonetheless allege that NIH has delayed consideration of Plaintiffs’ grants due to the challenged Directives. Compl. Doc No. 1 ¶¶ 237-40.

PROCEDURAL HISTORY

Plaintiffs sued on April 2, 2025, over a month after grant terminations started and after NIH resumed holding meetings and deciding grants. *See* Compl., Doc No. 1. More than three weeks later, Plaintiffs moved for a Preliminary Injunction. *See* Doc No. 37. Defendants opposed the Preliminary Injunction Motion on May 12, 2025. Doc. No. 66. On May 22, 2025, the Court collapsed the request for a Preliminary Injunction with a trial on the merits and treated the

³ *See, e.g.*, 90 Fed. Reg. 11175-01 (Mar. 4, 2025); 90 Fed. Reg. 11324-01 (Mar. 5, 2025); 90 Fed. Reg. 11323-02 (Mar. 5, 2025); 90 Fed. Reg. 11422-01 (Mar. 6, 2025); 90 Fed. Reg. 12333 (Mar. 17, 2025); 90 Fed. Reg. 12325 (Mar. 17, 2025); 90 Fed. Reg. 13187 (Mar. 20, 2025); 90 Fed. Reg. 13182 (Mar. 20, 2025).

⁴ <https://www.csr.nih.gov/RevPanelsAndDates/RevDates.aspx>

Defendants' Opposition as a Motion to Dismiss. Doc No. 77. On May 30, the Court entered a Order dismissing Counts IV, VI, and VII, but allowing the remaining Counts to proceed.

On June 3, 2025, the Court held a status conference in which it consolidated the proceedings in *Massachusetts, et al. v. Kennedy, et al.*, 1:25-cv-10814 (D. Mass.), with this case. See Doc No. 87. The Court decided that it would consider Plaintiffs' allegations in two phases, with the first phase considering the "challenged Directives" and terminations and the second phase considering Plaintiffs' unreasonable delay claims. Defendants timely filed administrative records by June 13, 2025. Doc No. 117. On the phase 2 proceedings, the Court ordered Defendants to produce an administrative record by July 9 and allowed Defendants to file this Motion to Dismiss by June 20. Doc. No. 87.⁵

On June 16, 2025, after briefing and a hearing on phase 1, the Court ruled from the bench that the challenged Directives, taken as a whole, and related grant terminations were arbitrary, capricious, and unlawful under the APA. It ruled that it would vacate the grant terminations listed on Plaintiffs' spreadsheets.

LEGAL STANDARD

A district court must dismiss claims under Rule 12(b)(1) when it lacks subject-matter jurisdiction to decide them. That includes claims for which the United States has not waived its sovereign immunity. See *FDIC v. Meyer*, 510 U.S. 471, 475 (1994) ("Sovereign immunity is jurisdictional in nature"). "When a district court considers a Rule 12(b)(1) motion, it credits the plaintiff's well-pled factual allegations and draws all reasonable inferences in the plaintiff's favor"

⁵ Defendants understand the Court's scheduling order provided Defendants the opportunity to file a proper motion to dismiss in this case, not just the States case. Although APHA disagrees, Defendants file this motion because—regardless—12(b)(1) arguments can be raised at any time and many remaining arguments apply to APHA as well as the States, thus APHA should have opportunity to respond.

Merlonghi v. United States, 620 F.3d 50, 54 (1st Cir. 2010). “A plaintiff, however, may not rest merely on unsupported conclusions or interpretations of law.” *Murphy v. United States*, 45 F.3d 520, 522 (1st Cir. 1995) (citation omitted). Moreover, “the party invoking the jurisdiction of a federal court carries the burden of proving its existence.” *Taber Partners, I v. Merit Builders, Inc.*, 987 F.2d 57, 60 (1st Cir. 1993).

A suit also must be dismissed if the complaint fails to “state a claim upon which relief can be granted.” Fed. R. Civ. P. 12(b)(6). To defeat a Rule 12(b)(6) motion to dismiss, a plaintiff must plead sufficient facts “to ‘state a claim to relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim is facially plausible when the pleaded facts allow a court “to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.* at 678. When evaluating a Rule 12(b)(6) motion, the Court must accept all material factual allegations in the complaint as true and draw any reasonable inferences in the non-moving party’s favor. *Id.* However, the Court is “not bound to accept as true a legal conclusion couched as a factual allegation,” or to credit “mere conclusory statements” or “[t]hreadbare recitals of the elements of a cause of action.” *Id.* (quoting *Twombly*, 550 U.S. at 555).

ARGUMENT

I. Plaintiffs lack standing to challenge alleged agency delay related to grant applications.

As an initial matter, the Court should dismiss all of Plaintiffs’ claims because Plaintiffs lack both prudential and Article III standing. At its “irreducible constitutional minimum,” Article III standing requires a plaintiff, as the party invoking the Court’s jurisdiction, to establish three elements: (1) a concrete and particularized injury-in-fact, either actual or imminent, and not conjectural or hypothetical, (2) a causal connection between the injury and defendants’ challenged

conduct, and (3) a likelihood that the injury suffered will be redressed by a favorable decision. *Lujan v. Def. of Wildlife*, 504 U.S. 555, 560-61 (1992). Moreover, courts adhere to the rule that a party “generally must assert his own legal rights and interests, and cannot rest his claim to relief on the legal rights or interests of third parties.” *Warth v. Seldin*, 422 U.S. 490, 499 (1975). Court disfavor granting third-party standing in the absence of a “hindrance to the third party’s ability to protect his or her own interests.” *Powers v. Ohio*, 499 U.S. 410, 411 (1991).⁶

A. Plaintiffs cannot enforce the rights of nonparties.⁷

Plaintiffs allege that the Defendants are delaying or suspending review of grant applications in which neither Plaintiffs nor their members have a legally cognizable interest. Indeed, all of Plaintiffs’ § 706(1) claims are aimed at challenging NIH’s handling of grant applications for *other nonparty entities*. Therefore, Plaintiffs lack prudential standing to assert these claims.

“In order to establish standing to” enforce rights related to a government contract, a plaintiff must show that they are party to the putative contract or an intended third-party beneficiary. *Edwards v. Aurora Loan Servs.*, 791 F. Supp. 2d 144, 150 (D.D.C. 2011); *see also Hillside Metro Assocs., LLC v. JPMorgan Chase Bank, Nat. Ass’n*, 747 F.3d 44, 49 (2d Cir. 2014) (holding that plaintiff lacked prudential standing because it could not “enforce the terms of” an agreement “as to which it is neither a party nor a third-party beneficiary”); *Klamath Water Users Protective Ass’n v. Patterson*, 204 F.3d 1206, 1210 (9th Cir. 1999), *opinion amended on denial of reh’g*, 203 F.3d 1175 (9th Cir. 2000) (“Before a third party can recover under a contract, it must

⁶ As the Court has already ruled that associational Plaintiffs have associational standing, Defendants do not reassert those arguments here but preserve the issue for any potential appeal.

⁷ Although not raised in “phase 1” of this case, the same reasoning for Plaintiffs’ lack of standing here applies to all grant terminations at issue in phase 1 for all Plaintiffs other than Ibis. And, importantly, as it is a jurisdictional matter, standing cannot be waived.

show that the contract was made for its direct benefit—that it is an intended beneficiary of the contract.”). Plaintiffs can show neither.

Other than Ibis, each Plaintiff in this case is either a researcher that works for a nonparty entity or membership organization whose members are individual researchers. None of the individual or associational Plaintiffs or their members have directly applied for a grant themselves; rather, they work for institutions who may have applied for NIH grants. They therefore have no legally cognizable interest in the grant applications. Ibis has not itself submitted a grant application consideration of which was delayed. Doc No. 1 ¶¶ 20, 160-61.⁸

As the Administrative Record in Phase 1 of this case makes clear, each of the grant applications that Plaintiffs claim to have an interest in are for grants that would be awarded to *their employer* institutions, none of which are parties to this suit. *See, e.g.*, NIH_Grants_004271; 5570.; *see also* Doc No. 38-21 (Maphis Decl.) ¶ 20 (“*My institution* (UNM) has lost out on the opportunity to train me for the next two years”); Doc No. 38-26 (Berg Decl) at ¶ 13 (noting that Congress authorized grants to “universities, hospitals, laboratories, and other public or private institutions” – but not to researchers); ¶ 28 (noting that a scientist submits a grant “*through their organization*” (emphasis added)). Plaintiffs and their members were not party to any of the grant applications whose consideration they allege were delayed.

Nor have Plaintiffs alleged in their complaint or elsewhere that they are intended beneficiaries. *See Klamath*, 204 F.3d at 1211 (“[T]he third party must show that the contract reflects the express or implied intention of the parties to the contract to benefit the third party.”).

⁸ The only named individual Plaintiff who alleges that they submitted a grant application that NIH refuses to consider is Plaintiff Nicole Maphis. *See* Doc No. 1 ¶ 18. However, any such grant is awarded to the institution for which she works, University of New Mexico School of Medicine, and not Plaintiff Maphis. *Id.*; *see also* Doc No. 38-21 at ¶ 20. And, as explained below, as a “Principal Investigator,” she is not an intended beneficiary of the grant.

While the nonparty institutions may list an individual researcher as a “Principal Investigator or Project Director” on their grants, *see, e.g.*, NIH_Grants_004278, the researchers are not themselves intended beneficiaries of any awarded contract. *See AAUP v. U.S. Dep’t of Justice*, No. 25-cv-2429, 2025 WL 1684817, at *5, 6, 12 n.7 (S.D.N.Y. June 16, 2025) (finding “principal investigators” lacked legal interest in terminated NIH grants). The researchers therefore lack standing to sue for NIH’s alleged delay in considering their employers’ grant applications. *See Kowalski v. Tesmer*, 543 U.S. 125, 129 (2004) (noting that only parties, or select nonparties (intended beneficiaries), may seek to enforce their rights); *see also Sardarian v. Fed. Emergency Mgmt. Agency*, No. 3:19-CV-00910 (OAW), 2022 WL 4080325, at *1–2 (D. Conn. Apr. 1, 2022) (dismissing suit for lack of standing because FEMA awarded “the grant in question” to the State of Connecticut and to the Town of Westport, and plaintiff was not the recipient of the Federal grant).

Recently, the Southern District of New York dismissed a similar jurisdictional overreach by Plaintiff UAW and another organizational plaintiff claiming their members had an interest in Columbia University’s terminated NIH research grants. *See AAUP v. U.S. Dept’ of Justice*, No. 25-cv-02429-MKV, 2025 WL 1684817 (S.D.N.Y. June 16, 2025). The district court recognized that these associational plaintiffs lack prudential standing to challenge NIH grant terminations:

Neither the Executive Branch nor the Legislature ever awarded the grants and contracts at issue to Plaintiffs or any of their members. The funding that Plaintiffs ask this Court to commandeer was awarded to Columbia, which is conspicuously absent from this case. If any funds have been wrongfully withheld, such funds may be recovered at the end of a successful lawsuit by the appropriate plaintiff in an appropriate forum. *See Dep’t of Educ. v. California*, 604 U.S. ---, 145 S. Ct. 966, 969 (2025).

Id. at *1. Here too, the institutions that employ Plaintiffs may themselves file suit (and in some instances have in the related matter), but Plaintiffs and their members lack prudential standing.

B. Plaintiffs also lack Article III standing

Plaintiffs alleged harms are also too attenuated to support jurisdiction because any asserted harms must flow from independent choices made by their employers, or their injury is otherwise too speculative. A “federal court cannot redress ‘injury that results from the independent action of some third party not before the court.’” *See Murthy v. Missouri*, 603 U.S. 43, 57 (2024). Courts are “reluctant to endorse standing theories that require guesswork as to how independent decisionmakers will exercise their judgment,” *id.* (quoting *Clapper v. Amnesty Int’l USA*, 568 U.S. 398, 413 (2013)), and have rejected theories of redressability that depend on such guesswork, *id.*, 603 U.S. at 73; *Haaland v. Brackeen*, 599 U.S. 255, 293-94 (2023).

Plaintiffs claim that NIH delays in considering may cause “large numbers of current and future biomedical researchers risk unexpected job loss that will harm them personally.” Doc No. 1 ¶ 240. It is, however, the choice of *their employers*, nonparties to this case who are taking such actions. *See, e.g.*, Doc No. 38-21 (“My institution . . . may not have the money to support my salary.”). If, for example, their employer chooses to continue funding their project despite any delays on the part of NIH, then no harm flows to Plaintiffs’ members. Thus, the choices of nonparties who have “broad and legitimate discretion,” interrupt any link between any alleged harms. *See Lujan*, 504 U.S. at 562. When this kind of “conjecture is necessary, redressability is lacking.” *West v. Lynch*, 845 F.3d 1228, 1237 (D.C. Cir. 2017) (internal citation omitted).

Plaintiffs also contend that “they may not be able to continue their projects,” have had to “take on additional responsibilities,” are in “administrative limbo,” and other vague and undefined alleged harms. *See* Doc No. 41 at 33-34. But such claims are far too speculative to satisfy Article III standing. *See Clapper*, 568 U.S. at 409 (explaining that any allegation of “threatened injury must be *certainly impending*” (citation omitted)); *see also* Doc No. 41 at 34 (noting that Plaintiffs’ members are trying to secure replacement fund but “do not anticipate” being able to raise enough).

II. Plaintiffs' claims under 5 U.S.C. § 706(1) should be dismissed for three independent reasons.

A. Plaintiffs' claims that NIH should be compelled to resume holding meetings and deciding awards are moot because NIH resumed before Plaintiffs sued.

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 the relevant directives ended before Plaintiffs even sued. Defendants have resumed holding meetings and taking the procedural steps needed to review new applications and issue awards. NIH did cancel previously scheduled meetings and refrained from setting new meetings based on the January 21, 2025 Notice Pause Directive. APHA Doc No. 66-1 ¶ 20. But that Directive—by its own terms—expired on February 1, 2025. NIH_GRANTS_000001. Since then, from March 24 through June 30, NIH has scheduled or held 837 peer review meetings. This is 186 more peer review meetings than NIH held for this same time period last year.⁹ NIH is also on track to complete at least three advisory council meetings this fiscal year, as contemplated by 42 U.S.C. § 284a(e).¹⁰ APHA Doc No. 66-1 ¶ 24. Peer reviews are also ongoing. APHA Doc No. 66-1 ¶ 22. So, although NIH briefly paused certain processes upon the change in administrations, NIH has been conducting all necessary steps in the review and disposition of grant applications.

Once an agency resolves a challenged delay, the issue becomes moot. *See Norton v. S. Utah Wilderness All.*, 542 U.S. 67, 68 (2004) (holding two claims moot because they sought creation of Bureau of Land Management plans, which were later created); *Friends of the Wild Swan, Inc. v.*

⁹ 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.

¹⁰ *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.

EPA, 130 F.Supp.2d 1184, 1192 (D. Mont. 1999) (APA claim moot when the EPA, thirteen years after its alleged duty arose, cured its failure to act by finally acting); *Associated Builders & Contractors, Inc. v. Herman*, 976 F. Supp. 1, 8 (D.D.C. 1997) (holding an APA claim challenging an agency's delay moot because the agency had finally acted). The Second Circuit has explained that “if an event occurs while a case is pending on appeal that makes it impossible for the court to grant any effectual relief whatever to a prevailing party, [the court] must dismiss the case” as moot “rather than issue an advisory opinion.” *ABC, Inc. v. Stewart*, 360 F.3d 90, 97 (2d Cir. 2004); *see also Barrett v. United States*, 105 F.3d 793, 794 (2d Cir. 1996); *Rezaii v. Kennedy*, No. 1:24-cv-10838, 2025 WL 750215 at *3 (D. Mass. Feb. 24, 2025) (holding unreasonable delay claim moot where agency took the allegedly delayed action). The Challenged Directives relating to the pause about which Plaintiffs complain have expired, and so too have the temporary pauses themselves. This claim is moot and should be dismissed.

B. Any claims that NIH should not apply the Challenged Directives when considering and deciding Plaintiffs’ applications about de-prioritized research topics are properly § 706(2) claims, not § 706(1) claims.

Plaintiffs cannot evade the § 706(2)’s final-agency-action requirement by disguising § 706(2) claims as § 706(1) claims. Courts routinely reject such efforts, especially when plaintiffs bring both § 706(2) claims and § 706(1) claims that are based on the same legal theory. *Hells Canyon Pres. Council v. U.S. Forest Serv.*, 593 F.3d 923, 934 (9th Cir. 2010) (rejecting effort to bring a § 706(1) claim where the “argument is better phrased as” a § 706(2) claim.); *see Ahadian & Fathollahzadeh v. Rubio.*, No. 24-cv-12168, 2025 WL 1617224 at *4 (D. Mass. June 6, 2025) (refusing to “separately consider” claims brought pursuant to § 706(1) and § 706(2) where the two claims rely “on the same theory.”); *Nat’l Parks Conservation Ass’n v. United States Dep’t of the Interior*, No. 20-cv-3706, 2024 WL 1344450 at *9 (D.D.C. Mar. 29, 2024) (emphasizing that “because [plaintiff’s] Section 706(2)(A) claims assert that what [defendant] has already done is

impermissible, it is better to resolve that question before deciding whether [defendant] must be compelled to do anything else under Section 706(1).”). *Hells Canyon Preservation Council v. U.S. Forest Service*, is instructive. 593 F.3d 923 (9th Cir. 2010). There, the Ninth Circuit rejected an effort to cast a § 706(2) claim as a § 706(1) claim. *Id.* at 933. In doing so, it emphasized that the defendant *had* engaged in final agency action, and that plaintiffs’ contentions under § 706(1) were actually a challenge to a final agency action. *Id.* at 930. As such, § 706(2), not § 706(1), was the only proper avenue for relief. *Id.* at 933.

Ultimately, Plaintiffs’ § 706(1) claims are simply another assault on the Challenged Directives. They styled their admitted § 706(2) claims as attacks on these directives in phase 1. APHA Compl. Doc No. 1 ¶ 215; Sates Am. Compl. Doc No. 75 ¶ 215. And their purported § 706(1) claims are just another volley on that front in phase 2. State Plaintiffs’ § 706(1) claim in their amended complaint emphasizes “in implementing the *Challenged Directives*, defendants have cancelled and/or substantially delayed ... NIH’s advisory councils and study sections—a significant and unprecedented departure from the NIH’s published review process and the agency’s past practice.” States’ Am. Compl. Doc No. 75 ¶ 264 (emphasis added). Indeed, the *entirety* of Count 7, State Plaintiffs’ § 706(1) claim, emphasizes that the delays flow from the Challenged Directives. *Id.* ¶ 264-66. APHA plaintiffs take the same approach. APHA Compl. Doc No. 1 ¶ 239. Just as in *Hells Canyon Preservation Council*, Plaintiffs here are still attacking the Challenged Directives, which the Court has already determined to be final agency action.¹¹ If so, law of the case holds that the Court’s recent conclusion in phase 1 extends to the alleged delays to be examined in phase 2. Thus, at this stage, no § 706(1) claim exists.

¹¹ Defendants respectfully disagree with this conclusion and include a no-final-agency-action argument below to preserve their arguments.

C. The Court cannot compel NIH to decide applications because doing so is not a discrete and mandatory duty.

To establish a claim under § 706(1), Plaintiffs must show 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)). As the Supreme Court recognized, “[t]his is a high standard,” and the “central question in evaluating such a claim is whether the agency’s delay is so egregious that mandamus is warranted.” APHA Doc. 84 at 29 (quotations omitted). Plaintiffs have failed to identify a discrete and mandatory agency action that the Court can compel under § 706(1).

Plaintiffs assert that NIH was required to (1) hold study section and advisory council meetings to consider and make final recommendations on grant applications, and (2) make a final decision on grant applications and requests for renewals. States Doc No. 75 at 85-87; APHA Doc No. 1 at 74. In previous briefing, Plaintiffs maintained that they also assert that the withholding of consideration of grant applications for withdrawn Notices of Funding Opportunities was unlawful.¹² APHA Doc No. 66 at 18-19. Putting aside that NIH is holding meetings and deciding applications, none of these is a discrete and mandatory agency action.

First, holding meetings is not “agency action” at all. 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

¹² In fact, Plaintiffs omit this theory in the portions of their complaints that asserted a § 706(1) claim. *See* States Doc No. 75 at 84-87; APHA Doc No. 1 at 74.

equivalent or denial thereof, or failure to act.” Holding meetings—even meetings established by statute—fall well outside this definition.

Moreover, holding meetings is not a *discrete* action. It is part of NIH’s “common business of managing government programs,” rather than a discrete action that can be compelled. *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.”). Plaintiffs acknowledge that NIH resumed holding the study section and advisory council meetings, but Plaintiffs still take issue and ask this Court to monitor how many meetings are being scheduled and how quickly. This is precisely the sort of invasive supervision that the Supreme Court has said to avoid. *Norton*, 542 U.S. at 67 (“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.”). The APA does not permit the Court to compel the pace of NIH’s meetings.

Second, making a final decision on grant applications and requests for renewal is not a mandatory agency action. To the contrary, HHS regulations expressly authorize the agency to “defer” making a final decision “because of either lack of funds or a need for further evaluation.” 42 C.F.R. § 52.5(b). That is exactly what NIH briefly did here (before resuming issuing notices of award): NIH deferred decisions on grant applications due to a need to evaluate whether such applications were consistent with revised agency priorities following a change in administration. Making a final decision cannot be mandatory when the regulations permit deferring that decision.

Finally, Plaintiffs argued in previous briefing that, even though NIH had resumed holding meetings and resumed issuing notices of award, NIH continued to withhold consideration of certain applications. *See* APHA Doc No. 71 at 18. Specifically, Plaintiffs alleged that NIH had “begun to ‘administratively withdraw’ applications for some programs purged as a result of the

Directives.” *Id.* This allegation refers to applications that were mooted when NIH withdrew the Notice of Funding Opportunity (“NOFO”). But maintaining a NOFO is neither discrete nor mandatory. A NOFO is merely a notice that invites applications for a *potential* grant, not an agency action. And Plaintiffs do not cite any authority that requires NIH to maintain—and that denies NIH any discretion to withdraw—a NOFO. Thus, no basis exists for the Court to compel NIH to restore a NOFO and revive a mooted application.¹³

III. Any unreasonable delay claim under 5 U.S.C. § 706(2) should be dismissed.

A. Plaintiffs did not allege sufficient facts to state a plausible claim for relief from delay in considering specific applications.

Plaintiffs fail to state a claim for relief related to unreasonable delay because they do not allege that Ibis Reproductive Health—the only plaintiff that applies for and receives grants—submitted an application that has been delayed. *See* APHA Compl., Doc No. 1 ¶¶ 20, 160, 161. The Complaint alleges delayed applications related only to Plaintiff Maphis, APHA Members 1 and 6, UAW Members 1-8, and UAW Pre-Members 1-6. *See* APHA Compl., Doc No. 1 ¶¶ 162-194. As explained above, none of these people have standing to challenge alleged agency inaction related to the grants. *See supra* Part I. Accordingly, Plaintiffs have failed to state any claim for which relief could be granted, and their complaint should be dismissed for purposes of phase 2.

B. In any event, an application remaining under review is not a final agency action.

Even if Plaintiffs had sufficiently alleged that NIH has not scheduled reviews for certain applications, doing so is not a final agency action subject to judicial review because it neither (1) “marks the consummation of the agency’s decision-making process,” nor (2) is “one by which rights or obligations have been determined, or from which legal consequences will flow.” *Bennett*

¹³ Following the Court’s entry of partial judgment on phase 1, absent a stay, NIH will restore NOFOs related to terminated programs listed on Plaintiffs’ spreadsheet.

v. Spear, 520 U.S. 154, 177-78 (1997). In the context of agency grant-making in particular, no final agency action exists “until the [agency] has reviewed a grant application and decided to disburse the funds.” *Rattlesnake Coal. v. EPA*, 509 F.3d 1095, 1103-04 (9th Cir. 2007); *Planned Parenthood of Wisc., Inc. v. Azar*, 316 F. Supp. 3d 291, 300-01 (D.D.C. 2018), *vacated as moot on other grounds*, 942 F.3d 512, 519 (D.C. Cir. 2019) (emphasizing that, in the grant application context, “courts usually recognize final agency action only after grant awards issue.”). Before the agency makes an award, “the federal money is but an expectancy that has not yet materialized.” *Karst Env’t Educ. and Prot., Inc. v. U.S. Env’t Prot. Agency*, 403 F. Supp. 2d 74, 81 (D.D.C. 2005); *see Delta Data Sys. Corp. v. Webster*, 744 F.2d 197, 206 (D.C. Cir. 1984) (“award procedures are not designed to establish private entitlements to public contracts but to produce the best possible contracts for the government.”). Indeed, State Plaintiffs admit that while a review is not scheduled “the grant remains under review.” States Doc No. 75 at 44, ¶ 183. Not scheduling review of an application neither denies nor establishes any rights, obligations, or legal consequences since NIH can schedule review at any time.

IV. All phase 2 claims should be dismissed because the consideration of applications is committed to agency discretion by law.

For many of the same reasons that holding meetings does not constitute a discrete agency action, NIH’s management of its grant review process is also “committed to agency discretion by law.” 5 U.S.C. § 701(a)(2). “Internal agency procedures are committed to the agency’s discretion.” *Maldonado-Coronel v. McElroy*, 943 F. Supp. 376, 381 (S.D.N.Y. 1996) (citing *Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council, Inc.*, 435 U.S. 519, 524, (1978)). In the context of application processes, Plaintiffs must show that NIH “has a nondiscretionary duty to adjudicate” grant applications “within a certain timeframe. *Dosmetova v. USCIS*, No. 3:24-cv-7409, 2025 WL 1663661 *2 (D.S.C. Feb. 7, 2025) (collecting cases).

Otherwise, the APA provides no opportunity to review. *Id.*; see *Touarsi v. Mueller*, 538 F. Supp. 2d 447,452 (D. Mass. 2008) (holding claim to compel agency action under 706(1) precluded where statute imposed no timing requirements on agency).

NIH has no nondiscretionary duty to process applications, or hold peer review meetings, within a certain timeframe. Indeed, it need not process grant applications *at all*. 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). This statutorily discretionary approach to grant review is fatal to Plaintiffs’ 706(1) claims, because “where an agency is not required to do something, [the Court] cannot compel the agency to act—let alone to act faster.” *Gonzalez v. Cuccinelli*, 985 F.3d 357, 466 (4th Cir. 2021). And even if the Court determines NIH must process grant applications, Plaintiffs can point to nothing that requires it to do so on any particular timeline.

CONCLUSION

For the foregoing reasons, the Court should dismiss all Plaintiffs’ phase 2 claims.

Defendants respectfully request that the Court enter an expedited deadline for Plaintiffs’ response of June 26, 2025, which is the same amount of time the Court provided for Defendants to move to dismiss after the phase 1 hearing concluded. Defendants had four business days (and four calendar days) to move. Defendants propose that Plaintiffs be provided four business days (six calendar days) to respond. This promotes the interests of justice and efficiency, since the Court’s ruling on the motion to dismiss could impact the administrative record that is being prepared for phase 2. Plaintiffs informed Defendants’ counsel that they oppose the request for expedited briefing.

Defendants respectfully submit ten days as proposed by Defendants' in the related case is inappropriate based on the expedited nature of this case and because Defendants in that case proposed more reciprocal deadlines (Defendants had 7 days to move while Plaintiffs had 10 days to respond) which Plaintiffs opposed. Most important, in Defendants' proposal, the decision on the motion to dismiss triggered the deadline for the administrative record. Without an expedited response deadline, Defendants will need to produce the administrative record shortly after Plaintiffs' respond to their motion to dismiss, and potentially before the Court has opportunity to rule.

Respectfully submitted,

BRETT A. SHUMATE
Assistant Attorney General

LEAH B. FOLEY
United States Attorney

KIRK T. MANHARDT
Director

MICHAEL J. QUINN
Senior Litigation Counsel

Dated: June 20, 2025

/s/ Anuj Khetarpal

ANUJ KHETARPAL
Assistant U.S. Attorney
1 Courthouse Way, Suite 9200
Boston, MA 02210
(617) 748-3658
anuj.khetarpal@usdoj.gov

THOMAS W. PORTS, Jr. (Va. Bar No.
84321)
Trial Attorney
U.S. Department of Justice
Civil Division, Corporate/Financial Section
P.O. Box 875
Ben Franklin Stations
Washington D.C. 20044-0875
(202) 307-1105
thomas.ports@usdoj.gov

Attorneys for Defendants

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).

Dated: June 20, 2025

/s/ Anuj Khetarpal
Anuj Khetarpal