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.	Civil Action No. 1:25-cv-10814-WGY

Defendants' Motion to Dismiss

Pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6), Local Rule 7.1, and the Court's scheduling order, Doc No. 121, Defendants move to dismiss Plaintiffs' complaint with respect to all unreasonable delay/phase 2 claims for the reasons set forth in the accompanying memorandum of points and authorities.

Defendants respectfully request that the Court enter an expedited deadline for Plaintiffs' response of June 26, 2025, which is reciprocal to the 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.

Defendants asked Plaintiffs for their position on this proposal. State Plaintiffs did not agree and insisted on the 10-day response deadline proposed by Defendants in the parties' joint

statement, and previously unaltered by the Court. Defendants respectfully submit that ten days is inappropriate because Defendants proposed more reciprocal deadlines (Defendants had 7 days to move while Plaintiffs had 10 days to respond) and—most important—in Defendants' proposal, the decision on the motion to dismiss triggered the deadline for the administrative record. Plaintiffs requested and the Court entered significantly more expedited deadlines for Defendants, including a fixed date to produce 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.

Respectfully submitted,

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Dated: June 20, 2025

/s/ Thomas W. Ports, Jr.

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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).

Dated: June 20, 2025

/s/ Thomas W. Ports, Jr.
Thomas W. Ports, Jr.

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

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INTRODUCTION

Defendants respectfully move under Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6) to dismiss Plaintiffs' phase 2 claims. Defendants are filing a separate motion to dismiss in the related matter, *American Public Health Association v. National Institutes of Health*, 1:25-cv-10787 (D. Mass.).

Plaintiffs' 5 U.S.C. § 706(1) claim should 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.

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

Finally, to the extent Plaintiffs intend to assert Constitutional claims related to alleged unreasonable delay, those claims fail for the reasons that Defendants articulated in prior briefing.

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

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

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 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

[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).

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.*, 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 pauses 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. States Am. Compl. Doc No. 75 ¶ 265.

PROCEDURAL HISTORY

Plaintiffs sued on April 4, 2025, over a month after grant terminations started and a week after NIH resumed holding meetings and deciding grants. *See* Compl., Doc No. 1. That same day, a subset of Plaintiffs—states whose instrumentalities had grant agreements terminated—moved

[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

for a Temporary Restraining Order (TRO). *See* State TRO Motion, Doc No. 4. After the Court promptly set a briefing schedule and a hearing, 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. Am. Compl., States Doc. No. 75; PI Motion, Doc. No. 78. Defendants opposed on numerous grounds, including a contention that the Court of Federal Claims has exclusive jurisdiction over Plaintiffs' claims seeking to vacate the "Challenged Directives" and to reinstate their terminated grants. States Doc No. 95.

On May 12, 2025, following a hearing, the Court entered a Memorandum and Order ruling that the District Court had jurisdiction to hear Plaintiffs' grant termination claims, not the Court of Federal Claims. States Doc No. 105. It discussed but did not decide Defendants' other arguments. *See id.*

The next day, on May 13, 2025, the Court held a case management conference. *See* States Doc. No. 109. The Court decided that it would consider Plaintiffs' allegations in two phases, with the first phase considering the grant terminations and the second phase considering Plaintiffs' unreasonable delay claims. Defendants timely filed administrative records by June 2, 2025. States Doc No. 118.

On June 3, 2025, the Court held a status conference in which it consolidated the proceedings in *American Public Health Association v. National Institutes of Health*, 1:25-cv-10787 (D. Mass.), with this case. *See* States Doc No. 119. On the phase 2 proceedings, the Court ordered Defendants to produce an administrative record by July 9. *Id.* Also as to the phase 2 proceedings, State Plaintiffs requested that Defendants file their Motion to Dismiss on the day of the phase 1 hearing, but the Court denied that request because, it said, the Court's ruling on phase

1 could be relevant and the Motion should account for it. The Court thus ordered Defendants to file their Motion to Dismiss by June 20. *Id.*

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. A written memorandum will follow. At the Court's direction, Plaintiffs filed and revised proposed partial final judgments.

Pursuant to the Court's scheduling order, Defendants move to dismiss all remaining claims.

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" *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' 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.[5] NIH is also on track to

[5] 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.

complete at least three advisory council meetings this fiscal year, as contemplated by 42 U.S.C. § 284a(e).[6] 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. 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.

[6] *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.

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. 20-3706, 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.[7] 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.

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

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

withholding of consideration of grant applications for withdrawn Notices of Funding Opportunities was unlawful.[8] 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 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.

[8] 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.

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.[9]

[9] 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.

II. 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.

State Plaintiffs allege that they are "awaiting a decision on hundreds of applications currently pending before the agency. . . .," States Doc No. 75 at 44, ¶ 133, but fail to state a claim for § 706(2) relief. Indeed, their allegations are bereft of facts in asserting that "upon information and belief" Defendants are causing delays because they are "implement[ing] the Challenged Directives." *Id.* Without identifying all the specific applications that have allegedly been delayed, Defendants cannot defend against Plaintiffs' claim and the Court cannot properly consider it.

State Plaintiffs' examples do not state a claim for § 706(2) relief. For example, they provide non-renewals for the University of Washington as an "example," States Doc No. 75 at 44, ¶ 136-37, but non-competitive renewals delayed by the Challenged Directives were listed on Plaintiffs spreadsheet and thus this allegation should have been resolved by phase 1 of this proceeding. Another example shows that the review date for an Alzheimer's application was rescheduled, but there is no allegation that the delay was due to a relationship with de-prioritized topics. *Id.* ¶ 162. Indeed, by admitting that NIH rescheduled the review, Plaintiffs' bolster Defendants' argument that the earlier pause has ended and Plaintiffs' claims are moot. In another example, Plaintiffs allege an application "has been delayed multiple times in its review and currently has no advisory-council review date," but they do not say when those delays occurred or otherwise connect the delays to the Challenged Directives. States Doc No. 75 at 44, ¶ 183.

At bottom, if State Plaintiffs intended to assert that the Challenged Directives created an unreasonable delay of certain grants, Plaintiffs had to identify those applications *and* connect the delay to the Challenged Directives. Vague and conclusory allegations about "hundreds" of

delayed applications fails to give Defendants sufficient notice to defend against Plaintiffs' claims and leaves the Court with no basis to adjudicate it.

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 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.

III. 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.

IV. Plaintiffs' non-APA claims all fail.

Defendants are not certain whether Plaintiffs intend to press their non-APA claims in phase 2 of this case but, to the extent they do, those claims should be dismissed for purposes of phase 2.

A. No separation of powers concern exists here.

As an initial matter, the Court has already dismissed the separation-of-powers argument made in the related case, *APHA v. NIH*, -- F. Supp. 3d --, 1:25-cv-10787, 2025 WL 1548611 (D. Mass. May 30, 2025), which challenged identical agency action, *see APHA v. NIH*, 1:25-cv-10787, Doc No. 41 at 11, 12 17- 21. It should reject the separation of powers argument in the States' case for the same reasons. Although Defendants maintain that this case may only be properly brought in the Court of Federal Claims, now that this Court has asserted jurisdiction under the APA, "plaintiffs' concerns are better addressed by other counts of their complaint, that is, their APA claims." *APHA v. NIH*, 2025 WL 1548611 at *15 (internal citations omitted). As this Court already noted, it "must take care not to transform every claim that an agency action conflicts with a statute into a freestanding separation of powers claim." *Id.* So, because the APA "appears to provide an avenue for complete relief," *id.*, the Court need not (and should not) entertain Plaintiffs' extraneous separation of powers argument. That view applies equally well here.

But if the Court chooses to consider separation-of-powers, Plaintiffs' argument fails for an additional independent reason: the Executive has both express and implied authority to terminate individual grants.

Congress has 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); *see also* 42 U.S.C. § 282(b)(3). This broad grant of discretion permits the Director of NIH to set NIH's priorities and to not enter grants unaligned with these priorities.

The Executive also has implicit authority to not enter 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.C. § 241(a)(3). Indeed, the appropriation for each institute of NIH is breathtakingly capacious. *See, e.g.*, H.R. 2882, 118th Cong., 138 Stat. 460, 656 (2024) (appropriating funds to the National Cancer Institute "[f]or carrying out section 301 and title IV of the PHS Act."). Congress knows how to write laws that constrain Executive Branch discretion. *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 enter grants, no separation of powers concern exists.

B. Plaintiffs' *ultra vires* claim fails.

Plaintiffs *ultra vires* claim also fails because the APA provides an alternative procedure for review, in addition to the claim's failure on the merits. To establish an *ultra vires* claim, Plaintiffs must show that: "(1) equitable review is not expressly precluded, (2) there is no alternative procedure for review, and (3) the Executive plainly acts in excess of its delegated powers and contrary to law." *New Mexico v. Musk*, -- F. Supp. 3d --, 2025 WL 1502747, at *17

(D.D.C. May 27, 2025); *see also Dalton v. Specter*, 511 U.S. 462, 472 (1994) ("Our cases do not support the proposition that every action by the President, or by another executive official, in excess of his statutory authority is *ipso facto* in violation of the Constitution."). This Court has ruled that it can review Plaintiffs' claims under the APA. Doc. 105. As such, because there is an alternative procedure for review, the Court should dismiss Plaintiffs' *ultra vires* claim.

The *ultra vires* claim should also be dismissed because Plaintiffs failed to show that NIH's actions were contrary to law. Moreover, it would be absurd to claim that the agency exceeded its authority to act when it allegedly failed to take an action. For all these reasons, the court should dismiss the *ultra vires* claim.

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 reciprocal to the 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.

Defendants asked Plaintiffs for their position on this proposal. State Plaintiffs did not agree and insisted on the 10-day response deadline proposed by Defendants in the parties' joint statement, and previously unaltered by the Court. Defendants respectfully submit that ten days is inappropriate because Defendants proposed more reciprocal deadlines (Defendants had 7 days to move while Plaintiffs had 10 days to respond) and—most important—in Defendants' proposal, the decision on the motion to dismiss triggered the deadline for the administrative record.

Plaintiffs requested and the Court entered significantly more expedited deadlines for Defendants, including a fixed date to produce 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.

Respectfully submitted,

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Dated: June 20, 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).

Dated: June 20, 2025

/s/ Thomas W. Ports, Jr.
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