IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS, *et al.* Plaintiffs, v. NATIONAL INSTITUTES OF HEALTH, *et al.*, Defendants.	Case No. 1:25-cv-10338 Leave to File Granted Feb. 13, 2025
ASSOCIATION OF AMERICAN MEDICAL COLLEGES, *et al.* Plaintiffs, v. NATIONAL INSTITUTES OF HEALTH, *et al.*, Defendants.	Case No. 1:25-cv-10340 Leave to File Granted Feb. 14, 2025
ASSOCIATION OF AMERICAN UNIVERSITIES, *et al.* Plaintiffs, v. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, Defendants.	Case No. 1:25-cv-10346 Leave to File Granted Feb. 14, 2025

DEFENDANTS' OPPOSITION TO MOTIONS FOR TEMPORARY RESTRAINING ORDER

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INTRODUCTION

In these lawsuits, three separate groups of Plaintiffs[1] challenge a Supplemental Guidance announcing a new policy of the National Institutes of Health, under which NIH will use a 15% rate in paying for "indirect costs"—overhead costs relating to research grants that are not directly tied to the research performed under those grants. To be clear, the Supplemental Guidance will not change NIH's total grant spending; rather, it simply reallocates that grant spending away from indirect costs and toward the direct funding of research.

In adopting the Supplemental Guidance, NIH sought to further its mission of advancing public health in a manner reflecting wise stewardship of the public money entrusted to it: The Supplemental Guidance, NIH explained, would ensure that its grants fund the research at the core of its mission by: minimizing payments for indirect costs that are difficult for NIH to oversee and bringing NIH's indirect cost rates into line with the lower (and thus less expensive) indirect cost rates provided by private grantors and accepted by grantees. Still, Plaintiffs invite this Court to upend NIH's effort to administer its grants in a way that it has concluded best furthers public health—all so that they and the incumbent grantees they represent may receive larger indirect cost payments they claim are owed to them under the original indirect-cost terms of their grants.

The Court should reject the invitation for several different and independent reasons. *First*, the Court lacks jurisdiction to do what Plaintiffs ask. Under binding First Circuit precedent, the Tucker Act vests exclusive jurisdiction over this case in the Court of Federal

[1] Unless otherwise noted, "Plaintiffs" here refers to the named plaintiffs in *Commonwealth of Massachusetts, et al. v. National Institutions of Health, et al*. (1:25-cv-10338-AK), *Association of American Medical Colleges et al. v. National Institutes of Health, et al.* (1:25-cv-10340), and *Association of American Universities et al. v. Department of Health & Human Services, et al.* (1:25-cv-10346-AK), collectively.

Claims because Plaintiffs are effectively seeking damages for breach of contract—the regulations incorporated into their grant agreements. *See, e.g.*, *Burgos v. Milton*, 709 F.2d 1, 3 (1st Cir. 1987); *American Sci. & Eng'g, Inc. v. Califano*, 571 F.2d 58, 62 (1st Cir. 1978). *Second*, even if this Court did have jurisdiction to consider Plaintiffs' claims under the Administrative Procedure Act, those claims have no merit: In issuing the Supplemental Guidance, NIH acted in accordance with the governing regulations (which, again, are incorporated into the grants), ran afoul of no statute, and provided a reasoned explanation of its action. And, *third*, Plaintiffs have failed to show that they would suffer an irreparable injury without a temporary restraining order.

For any and all of these reasons, as explained below, the Court should deny Plaintiffs' motions and vacate the temporary injunctions that have already been issued in these cases.

BACKGROUND

I. Factual and Regulatory 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.[2] 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").

Generally speaking, these grants include two kinds of costs: "direct costs" that are directly tied to a specific research project or activity and "indirect costs" that are not tied to a specific research project or activity. Indirect costs include "facilities," "defined as depreciation

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

on buildings, equipment and capital improvements, interest on debt associated with certain buildings, equipment and capital improvements, and maintenance expenses." 45 C.F.R. § 75.414(a). Indirect costs also include "administration," defined as "general administration and general expenses such as the director's office, accounting, personnel, and all other types of expenditures not listed specifically under one of the subcategories of "Facilities." *Id.* A grantee draws down its grant on a periodic basis, based on the direct and indirect costs it has incurred during the relevant period. *See generally* NIH Grants Policy Statement, Part 6 (Payment), *available at* https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

This case concerns payments for indirect costs. By default, NIH pays indirect costs based on an indirect cost rate negotiated with the grantee. 45 C.F.R. § 75.414. The indirect cost rate reported by NHS has averaged between 27% and 28% over time, with some organizations using indirect rates of 50% or 60%.[3] Supplemental Guidance at 1. Private foundations generally provide much lower rates for the research they fund: Some of the largest foundations use indirect cost rates of 10% to 15%. *See* Supplemental Guidance at 2 & n.3. And many foundations do not fund indirect costs at all. *Id.* Thus, at the least, NIH's average indirect cost rate is nearly double the indirect cost rates used by private grantors. Nevertheless, research institutions consistently agree to the indirect cost rates provided by private grantors: Harvard, for example accepts indirect cost rates of 15%, and some institutions are willing to accept funds that do not cover indirect costs at all. *See id.* at 2.

Indirect costs consume a lot of NIH grant funding, particularly at the rates historically paid by NIH. Indeed, of the $35 billion spent by NIH on grants in Fiscal Year 2023, more than

[3] *See* Harvard University, FAS Office of Research Administration, https://research.fas.harvard.edu/indirect-costs-0 (Harvard reporting its federally negotiated indirect cost rate of 69% for on campus research) (last visited Feb. 14, 2025).

$9 billion was spent paying grantees for indirect costs. *Id.* In addition to consuming resources, indirect costs are difficult to track, making it hard for a grantor like NIH to determine whether the money—in the case of NIH, public money—it provides is actually funding the research it intends to fund under the terms of the grant. *See* Supplemental Guidance. And, of course, because NIH has a limited budget each year, the money it spends on indirect costs cannot be used to pay for more medical research.

In light of all this, NIH on February 7, 2025, released the Supplemental Guidance, in which it announced its policy that "[f]or any new grant issued, and for all existing grants to [institutes of high education (IHEs)] retroactive to the date of issuance of this Supplemental Guidance, award recipients are subject to a 15 percent indirect cost rate." *Id.* at 3. The Supplemental Guidance explains that the new policy "shall be applied to all current grants for go forward expenses from February 10, 2025 forward as well as for all new grants issued." *Id.*

NIH set out three reasons for the policy. *First*, NIH explained that it was capping indirect cost rates to "ensure that as many funds as possible go towards direct scientific research costs rather than administrative overhead" which is, "by [its] very nature, not readily assignable to the cost objectives specifically benefitted." Supplemental Guidance at 2. *Second*, NIH explained that it was focusing its payments on direct costs of research because indirect costs are "difficult for NIH to oversee." *Id.* *Third*, NIH sought to bring its indirect cost rates into line with the indirect cost rates paid by grantors in the private sector which, as just explained, are substantially lower than the indirect costs rates historically paid by NIH. *Id.* at 2-3.

NIH issued the policy under existing federal regulations that are incorporated into every Notice of Award that finalizes a grant. Specifically, NIH relied on 45 C.F.R. § 75.414(c)(1) and (3), which together authorize NIH to "use a rate different from the negotiated federal rate for a

class of Federal awards so long as it "implement[s], and make[s] publicly available, the policies procedures and general decision making criteria" it "will follow to seek and justify deviations from negotiated rates." *See* Supplemental Guidance at 1 (citing these provisions and 45 C.F.R. Appendix III to Part 75, § C.7.a).

II. Procedural History

Three groups of Plaintiffs filed suit on February 10, 2025, seeking injunctive and declaratory relief, each alleging that the Supplemental Guidance violates the APA because it exceeds statutory authority and is arbitrary and capricious. The Plaintiff groups each moved for *ex parte* temporary restraining orders (TROs). The Court granted a TRO in *Massachusetts v. NIH*, restraining Defendants from implementing the Supplemental Guidance in the Plaintiff States. Doc No. 25. The Court then entered a nationwide TRO in *Association of American Medical Colleges (AAMC) v. NIH*, 25-cv-10340. Doc No. 8. And the Court then denied the injunction sought in *Association of American Universities (AAU) v. HHS*, 25-cv-10346, as moot. Doc No. 45.

The TROs required Defendants to file status reports confirming their compliance with the TROs and describing steps taken to ensure compliance. *See Mass. v. NIH*, Doc No. 25; *AAMC v. NIH*, Doc No. 8. Defendants filed reports on February 11 and 12, confirming that they would not implement the Supplemental Guidance until further notice from the Court. *Mass. v. NIH*, Doc No. 46; *AAMC v. NIH*, Doc No. 15. The TROs also require Defendants to submit additional status reports on a bi-weekly basis confirming Defendants' continued compliance with the TROs. *See Mass. v. NIH*, Doc No. 25; *AAMC v. NIH*, Doc No. 8.

On February 13, 2025, the Court directed Defendants to submit a single consolidated opposition to the pending motions for temporary restraining orders, to be filed in each case.

Mass. v. NIH, Doc No. 60. The Court also granted Defendants' unopposed requests for leave to file an over-length opposition brief in the three cases. *Mass. v. NIH*, Doc No. 57; *AAMC v. NIH*, Doc No. 26; *AAU v. HHS*, Doc No. 71.

LEGAL STANDARD

A TRO, like 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. 2021). 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 burden of establishing (1) a likelihood of success on the merits, (2) irreparable harm in the absence of preliminary relief, (3) the balance of the equities favor the movant, and (4) 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).

ARGUMENT

I. Plaintiffs Are Not Likely to, and Indeed Cannot, Succeed on the Merits.

A. This Court lacks jurisdiction to enter a preliminary injunction because the lawsuits stem from agreements and thus are governed by the Tucker Act's restrictions.

Plaintiffs in these lawsuits seek to force the payment of "many millions of dollars," *Mass. v. NIH*, Doc No. 12 at 27, that they claim are due to them under NIH grants. Plaintiffs, in other words, are seeking money based on a claim that the Government breached the terms of its

contracts with them. *See* Complaint*, Mass v. NIH*, Doc. No. 1, ¶ 42*, MANIH*, ("Once the NOA is signed or money is drawn, the NOA and the grant terms are binding on the grantee and the government."); *U.S. ex rel. Bauchwitz v. Holloman*, 671 F. Supp. 2d 674, 681 (E.D. Pa. 2009) (cleaned up); *accord Henke v. U.S. Dep't of Com.*, 83 F.3d 1445, 1450 (D.C. Cir. 1996) ("An NSF grant agreement includes the essential elements of a contract and establishes what would commonly be regarded as a contractual relationship between the government and the grantee."). This Court has no jurisdiction over these contract-based claims.

"Under the Tucker Act, 28 U.S.C. § 1491(a)(1), the Court of Federal Claims has *exclusive* jurisdiction over non-tort claims against the United States where the amount in controversy exceeds $10,000." *Tortorella v. United States*, 486 F. Supp. 2d 159, 161 (D. Mass. 2007) (emphasis added); *see Burgos*, 709 F.2d at 3 (Tucker Act "vests the Claims Court with exclusive jurisdiction over contract actions against the United States."). Consequently, "a breach of contract claim under the Tucker Act is an 'adequate remedy in a court,' precluding APA review." *Glaskin v. Klass*, 996 F. Supp. 67, 71-72 (D. Mass. 1998) (citing *Califano*, 571 F.2d at 62). In other words, any claim that sounds in contract and seeks over $10,000 must be brought to the Court of Federal Claims. Both conditions are met here.

First, "the essence of the [Plaintiffs'] action is in contract, and [Plaintiffs] cannot 'by the mystique of a different form of complaint' make it otherwise." *Califano*, 571 F.2d at 63 (quoting *Sprague Electric Co. v. Tax Court*, 340 F.2d 947, 948 (1st Cir. 1965)); *see Diaz v. Johnson*, No. 19-1501, 2020 U.S. App. LEXIS 42196, at *5 (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"). The elements of a contract with the United States are well-settled: there must be "a mutual intent to contract, including an offer, an acceptance, and

consideration passing between the parties." *Stark v. Bunch*, No. 19-cv-12109-ADB, 2020 U.S. Dist. LEXIS 135258, at *16 (D. Mass. July 30, 2020).

All elements are present in the Notices of Award at issue here. Each Notice of Award contains the same material terms: an offer by NIH to fund a grantee's project in exchange for the grantee's agreement to perform the project and comply with the terms and conditions of funding. By way of example, the Notice of Award to the University of Connecticut provides that the NIH "hereby awards a grant in the amount of $322,000" in support "of the above referenced project," *i.e.*, work related to "Cytoskeletal compartmentalization of apoptotic signaling." Declaration of Liza Bundesen ("Bundesen Decl."), Exh. B, Notice of Award at 1-2. The "[a]cceptance of this award, including the 'Terms and Conditions'" is acknowledged by the grantee "when funds are drawn down or otherwise requested from the grant payment system." *Id.* at 1.

Under these circumstances, courts have routinely held that "grant agreements [are] contracts when the standard conditions for a contract are satisfied." *Columbus Reg'l Hosp. v. United States*, 990 F.3d 1330, 1338 (Fed. Cir. 2021); *see also San Juan City Coll. v. United States*, 391 F.3d 1357, 1360-62 (Fed. Cir. 2004) (treating a "Program Participation Agreement" and related grants under the Higher Education Act as a contract); *Henke*, 83 F.3d at 1450 ("An NSF grant agreement includes the essential elements of a contract and establishes what would commonly be regarded as a contractual relationship between the government and the grantee."); *Thermalon Indus., Ltd. v. United States*, 34 Fed. Cl. 411, 415 (1995) ("Viewing the grant terms and conditions in their entirety, the court concludes that the parties intended to be bound contractually.").[4]

[4] Conversely, courts have held that federal funding grants, without these contract hallmarks, cannot give rise to enforceable contract claims. *See, e.g.*, *Imaginarium, LLC v. United States*, 166

The Notices of Award specifically incorporate regulations in 45 C.F.R. Part 75, which authorizes NIH to deviate from the negotiated rates. Each Notice of Award provides:

> The award is . . . subject to the terms and conditions incorporated either directly or by reference in the following:
>
> a. The grant program legislation and program regulation cited in this Notice of Award.
> b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
> c. *45 CFR Part 75*.
> d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
> e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
> f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

Bundesen Decl., Exh. B, Notice of Award at 3. Accordingly, the parties—NIH and each Plaintiff here—agreed that the HHS regulations, 45 C.F.R. Part 75, the NIH Grants Policy Statement, and grant program legislation, *inter alia*, would be incorporated as contract terms.

Plaintiffs claim that NIH breached these contract terms—either directly by alleging that NIH breached the Notice of Award or indirectly by alleging that NIH failed to comply with the regulations within 45 C.F.R. Part 75, the NIH Grants Policy Statement, or grant program legislation. For example, the State Plaintiffs expressly allege that NIH violated its obligations under the Notice of Award:

> Once the [NOA] is signed or money is drawn, the [NOA] and the grant terms are binding on the grantee and the government." *U.S. ex rel. Bauchwitz v. Holloman*,

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Fed. Cl. 234, 241 (2023) (holding that the plaintiff "cannot prove a contract exists between it and the SBA" under the Shuttered Venue Operators Grant program "because it cannot show mutuality of intent to contract"); *see also Simmons v. United States*, No. 21-2271, 2022 U.S. Claims LEXIS 2593, at *9 (Fed. Cl. Nov. 30, 2022) ("The issuance of a social security number does not create a contract with the United States."); *Gravatt v. United States*, 100 Fed. Cl. 279, 286 (2011) ("Neither birth certificates nor social security numbers recognize or impose contractual rights, obligations, or duties.").

> 671 F. Supp. 2d 674, 681 (E.D. Pa. 2009). *"An [NOA] constitutes an 'obligation,'"* and the NIH is "committed to funding the grant for the current budget period due to dependency upon the annual Congressional appropriations process." *Id.* Accordingly, *any failure of the NIH to comply with the terms of an NOA in the middle of a budget period—such as by modifying payment of "go forward expenses"—would constitute a breach of the NIH's obligations*.

Mass. v. NIH, Doc No. 1 at ¶ 47 (emphasis added). And all Plaintiffs allege the Supplemental Guidance violated 45 C.F.R. § 75.414(c)—an HHS regulation within 45 C.F.R. Part 75 and thus incorporated into their NOAs. *See, e.g.*, *Mass. v. NIH*, Doc No. 1, at ¶¶ 188-196; *AAU v. HHS*, Doc No. 1, at ¶¶ 109-114; *AAMC v. NIH*, Doc No. 1, at ¶¶ 50-52. Although Plaintiffs frame their claims as violations of the APA, the success of those claims turns on establishing NIH breached terms listed within the Notices of Award—all of which are legally binding contracts. Plaintiffs therefore assert claims for breach of contract.[5]

Second, Plaintiffs seek monetary relief greater than $10,000 for NOA's reduction of the indirect cost rate to 15%. *See, e.g.*, *Mass. v. NIH*, Doc No. 1, at ¶ 94 ("The Rate Change Notice [Supplemental Guidance], cutting indirect cost rates to 15%, would result in a loss to UMass Chan Medical School of $40 to $50 million annually. . . ."); *id.* at ¶ 98 ("University of Michigan has negotiated an Indirect Cost Rate of 56%. A reduction to 15% would eliminate approximately $181 million in funding."); *see also AAU v. HHS*, Doc No. 1, at ¶ 60 ("Brandeis has relied on the well-established process for negotiating grant funding to prepare its operating budget. The Guidance's reduction would eliminate $7.5 million in indirect cost recovery on an annual

[5] For at least two reasons, *Bowen v. Massachusetts*, 487 U.S. 879 (1988), is inapposite. *First*, unlike this case, *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 features of the Medicaid Act specifically—underscoring that the case (unlike this case) did not implicate the Tucker Act's application to contract claims. *Id.* at 900 n.31. *Second*, the Court emphasized that suits under the Medicaid Act generally arise between the federal government and a State, implicating federalism concerns that generally do not arise in disputes over the terms of grants. *Id.* at 900 n.31, 904 n.39, 907-08.

basis."); *AAMC v. NIH*, Doc No. 1, at ¶ 1 (describing the Supplemental Guidance as a "fundamental change implicating $36 billion in federally funded research"). The remedy for this alleged harm is purely monetary and well beyond the $10,000 threshold requiring Plaintiffs to file suit in the Court of Federal Claims.

In sum, "despite [Plaintiffs'] valiant effort to frame the suit as one for declaratory or injunctive relief, 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 it therefore belongs in that court." *See Suburban Mortg. Assocs. v. U.S. Dep't Hous. and Urban Dev.*, 480 F.3d 1116, 1118 (Fed. Cir. 2007). For that reason alone, the Court should deny Plaintiffs' motions and dismiss these cases.

B. The governing regulations specifically authorized the Supplemental Guidance.

1. Existing regulations, 45 C.F.R. § 75.414(c)(1), allow NIH to set an indirect cost rate other than the NICRA rate.

a. In issuing the Supplemental Guidance, NIH acted under authority expressly granted in 45 C.F.R. § 75.414(c). Subsection (c)(1) establishes that NIH must by default "accept[ ]" "negotiated" indirect cost rates—but then, crucially, sets forth exceptions, including Section 75.414(c)(3): "An HHS awarding agency may use a rate different from the negotiated rate for a class of Federal awards or a single Federal award only when required by Federal statute or regulation, *or when approved by a Federal awarding agency head or delegate based on documented justification as described in paragraph (c)(3) of this section*." (emphasis added). Here, NIH issued the Supplemental Guidance under Paragraph (c)(3). Paragraph (c)(3) provides that:

> The HHS awarding agency must implement, and make publicly available, the policies, procedures and general decision making criteria that their programs will follow to seek and justify deviations from negotiated rates.

Id. That is precisely what NIH did when it issued the Supplemental Guidance: In that publicly available document, NIH set forth the policy and decision-making criteria that it will now use in seeking and justifying its deviation from negotiated rates, and the procedure it would use for applying the new policy—application of a 15% rate for ICRs. As the Plaintiff States put it, the Supplemental Guidance publicly sets forth the "new decision-making criterion." *Mass. v. NIH*, Doc No. 12, at 22.

In short, NIH followed the plain terms of Section 75.414(c) in announcing the Supplemental Guidance.

b. Plaintiffs' counterarguments misread the governing regulations.

First, Plaintiffs take issue with the Supplemental Guidance's across-the-board deviation from negotiated rates, as distinguished from case-by-case deviations. *See Mass. v. NIH*, Doc No. 12, at 22. But nothing in Section 75.414 imposes a case-by-case requirement that would preclude NIH from "seek[ing] and justify[ing]" a deviation from negotiated rates across the board. *See Fourstar v. Garden City Grp., Inc.*, 875 F.3d 1147, 1153 (D.C. 2017) (Kavanaugh, J.) ("It is not a judge's job to add to or otherwise re-mold statutory text to try to meet a statute's perceived policy objectives. Instead, we must apply the statute as written."). Indeed, the plain language of Section 75.414(c) forecloses Plaintiffs' argument: Subsection 75.414(c)(1) provides that, so long as it complies with Subsection 75.414(c)(3), "[a]n HHS awarding agency may use a rate different from the negotiated rate *for a class of Federal awards*"—without in any way limiting the size of that class. Here, NIH complied with 75.414(c)(3) to deviate from negotiated rates for the class of Federal awards made by NIH, exactly as the regulations allow. *See Gen. Med., P.C. v. Azar*, 963 F.3d 516, 521 (6th Cir. 2020) (Courts "should not add language that Congress has not included"); *Fourstar v. Garden City Grp., Inc.*, 875 F.3d 1147, 1153 (D.C.

2017) (Kavanaugh, J.) ("It is not a judge's job to add to or otherwise re-mold statutory text to try to meet a statute's perceived policy objectives. Instead, we must apply the statute as written.").

Second, Plaintiffs claim that the information in the Supplemental Guidance should have been included in the Notice of Funding Opportunity that led to the grant. *Mass. v. NIH*, Doc No. 12, at 22-23. Of course, that argument would apply only to existing grants rather than future ones. But even for those grants, the argument has no merit. The regulations Plaintiffs cite concern what NIH must disclose to grant applicants, stating that the then-existing "policies relating to indirect cost reimbursement" should be "include[d] in the notice of funding opportunity." 45 C.F.R. § 75.414(c)(4); *see* 45 C.F.R. § 75.203(c)(2) (requiring the inclusion of "Federal award information, including sufficient information to help an applicant make an informed decision about whether to submit a funding application."). The regulation does not purport to prevent the awarding agency from changing its policies or procedures for deviating from negotiated rates. That authority is, after all, disclosed in the very previous subsection. 45 C.F.R. § 75.414(c). For its part, the Notice of Funding Opportunity that led to each Plaintiff's grant refers to the grant policy, which describes that each recipient will execute a Notice of Award with terms governing the grant. *See* NIH Grant Policy Statement at IIA-60; *see also id.* at IIA-61 ("Once the award is accepted by the recipient, the contents of the NoA are binding on the recipient unless and until modified by a revised NoA signed by the GMO."). And Plaintiffs' Notices of Award expressly incorporate 45 C.F.R. Part 75, including Section 75.414(c)(1) and (3), which explicitly authorize the awarding agency to change the "policies, procedures and general decision-making criteria" that it will use to "seek and justify deviations from negotiated rates." If confirmation is needed, it can be found in Appendix III to Part 75, which provides that

the rates for indirect costs may change during the life of the award so long as the awarding agency complies with Section 75.414(c)—which is exactly what NIH did here.

Third, contrary to Plaintiffs' suggestions, nothing in the regulations requires use of negotiated and audited indirect costs. *Mass. v. NIH*, Doc No. 12 at 16. Again, Section 75.414 expressly says otherwise, allowing "deviation[s]" from negotiated rates.

* * *

At bottom, Plaintiffs ask this Court to ignore a regulatory provision that has led to a result they do not like. The Court should reject the invitation. Section 75.414(c) serves an important function, ensuring that the politically accountable Executive branch has superintendence over how its funds are spent. NIH abided by that provision, which fully supports the Supplemental Guidance.

2. The Supplemental Guidance is consistent with NIH's process governing the recovery of indirect costs.

The Supplemental Guidance is consistent with all other relevant regulations relating to indirect costs. The first regulation cited by the AAU Plaintiffs (*AAU v. HHS*, Doc No. 16 at 27), 45 C.F.R. § 75.402, simply defines the "total costs of a Federal award" as "the sum of the allowable direct and allocable indirect costs less any applicable credits." But that provision speaks only to the "total cost," without purporting to dictate the rate of payment for indirect costs. It does not require the Government to pay for the entirety of a recipient's costs—a result that would be flatly inconsistent with NIH's authority to negotiate a rate for indirect costs and its authority to "deviate" from negotiated rates under Section 75.414(c).

The Supplemental Guidance likewise does nothing to contravene Appendix III to Part 75. That Appendix "provides criteria for identifying and computing indirect . . . rates at IHEs (institutions)." In doing so, it simply (i) defines categories of indirect costs, such as

"Depreciation," "Interest," and "Operation and Maintenance Expenses"; (ii) requires those costs to be "distributed to the major functions of the institution"; and (iii) further defines each of the "major functions of the institution." It does not purport to require NIH to pay for all of a grantee's costs, or even to adhere to the "negotiated rate" for indirect costs. In fact, it expressly notes that the grantor may deviate from the negotiated rate under Section 75.414(c)(1)—precisely as NIH did in the Supplemental Guidance.

Nor does the Supplemental Guidance somehow contravene the regulations relating to audits and the negotiation of indirect cost rates. *See AAU v. HHS*, Doc No. 16 at 28-29. Nothing about a change in indirect cost rates precludes NIH from auditing a grant recipient to ensure that the recipient is properly using the federal funds. *See* 45 C.F.R. §§ 75.501(b), 75.504, and 75.514. And to invalidate the Supplemental Guidance's "deviation from negotiated rates" on the ground that it is inconsistent with the provisions governing negotiations of indirect cost rates would be to read Section 75.414(c) into nonexistence. *See* 45 C.F.R. § 75.2 (defining "indirect cost rate proposal"); *see also id.* § 75.414(e) (listing Appendices "for development and submission of indirect (F&A) cost rate proposals and cost allocation plans"). The provisions governing negotiation of rates will continue to apply when and if NIH uses negotiated indirect cost rates—but under the plain terms of Section 75.414(c) NIH is not bound to do so.

C. Neither the Appropriations Rider Nor the Appropriations Clause Precludes the Supplemental Guidance.

All Plaintiffs invoke Section 224 or the Continuing Appropriations Act of 2024, Public Law 118-47. And, based entirely on the alleged violation of that Rider, the AAU Plaintiffs argue

that the Supplemental Guidance violates the Appropriations Clause. U.S. Const. Art. I, § 9, cl. 7.6 Those arguments fail because the Supplemental Guidance in no way violates Section 224.

Section 224 imposes three prohibitions:

> [1] In making Federal financial assistance, the provisions relating to indirect costs in part 75 of title 45, Code of Federal Regulations, including with respect to the approval of deviations from negotiated rates, shall continue to apply to the National Institutes of Health to the same extent and in the same manner as such provisions were applied in the third quarter of fiscal year 2017. [2] None of the funds appropriated in this or prior Acts or otherwise made available to the Department of Health and Human Services or to any department or agency may be used to develop or implement a modified approach to such provisions, or [3] to intentionally or substantially expand the fiscal effect of the approval of such deviations from negotiated rates beyond the proportional effect of such approvals in such quarter.

The Supplemental Guidance does not run afoul of any of those prohibitions.

Start with the first sentence of Section 224. That provision establishes only that the then-existing regulations in part 75 of Title 45 of the Code of Federal Regulations will continue to apply to NIH as they did in the third quarter of 2017. NIH agrees: It acknowledges those regulations continue to apply the same way they did back then which is precisely why NIH complied with one of those regulations—Section 75.414(c)—in issuing the Supplemental Guidance.

Consider next the prohibition on using funds "to develop or implement a modified approach" to the regulatory provisions that were in place in 2017. NIH has done no such thing: It has not sought to modify those regulations or how they apply. Rather, it has *complied* with them by using the very procedure those regulations provide to issue the Supplemental Guidance.

[6] The AAU Plaintiffs also raise "the Anti-Deficiency Act," although they "do not seek relief based on that violation." *AAU v. HHS*, Doc No. 15 at 19. Defendants therefore do not further address that provision.

Finally, there is the prohibition on using appropriated funds to "intentionally or substantially expand the fiscal effect of the approval of such deviations from negotiated rates beyond the proportional effect of such approvals" in the third quarter of 2017. In the AAU and State Plaintiffs' view, this means NIH may not deviate from negotiated rates in a way that reduces payments of indirect costs. *See Mass. v. NIH*, Doc No. 12 at 21; *AAU v. HHS*, Doc No. 1 at ¶ 101; *AAU v. HHS*, Doc No. 16 at 17-18. But Plaintiffs ignore that context—a statute discussing appropriations of *government* funds—and the statutory language—which speaks only to "*fiscal* effects," using a word that generally refers to *government* finances. *See, e.g.*, "fiscal," Merriam-Webster Online Dictionary ("of or relating to taxation, public revenues, or public debt"), *available at* https://www.merriam-webster.com/dictionary/fiscal; "fiscal," Collins Online Dictionary ("having to do with the public treasury or revenues"), *available at* https://www.collinsdictionary.com/us/dictionary/english/fiscal. Both text and context thus confirm that Section 224 was concerned with the impact of indirect cost deviations on public funds. And that should come as no surprise: Congress enacted Section 224 in response to an earlier budget proposal that would have reduced NIH's funding while capping indirect costs at 10% to "achieve significant savings." *Mass. v. NIH*, Doc No. 6, Exh. 2 at 43 (OMB, *Major Savings and Reforms, Budget of the U.S. Government, Fiscal Year 2018*). But that concern—and Section 224—has no application here, because the Supplemental Guidance does *not* seek to save the government money; rather, it takes the appropriations to NIH as a given and *allocates* the grants made with that money so that more of the money is spent on the direct costs of the projects NIH is funding—*i.e.*, medical research costs—in keeping with the approach taken by private grant-makers. Because the Supplemental Guidance does not increase the "fiscal effects" of deviations from negotiated indirect cost rates, it does not run afoul of Section 224.

D. The Supplemental Guidance does not conflict with the Public Health Service Act.

The AAU Plaintiffs include in their Memorandum a two-paragraph contention that the Supplemental Guidance violates the Public Health Service Act. *AAU v. HHS*, Doc No. 16 at 31-32, which authorizes the Secretary of Health and Human Services to "make grants-in-aid … for … research projects" concerning "the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man." 42 U.S.C § 241(a). The AAU Plaintiffs raise two arguments on this score, both meritless.

First, the AAU Plaintiffs assert without elaboration that the Supplemental Guidance will not support public health. But NIH concluded otherwise, reasoning that reducing indirect costs would serve the public health by "ensur[ing] that as many funds as possible go towards direct scientific research rather than administrative overhead." Supplemental Guidance at 1. The AAU Plaintiffs cite no authority whatsoever for their implicit claim that the Public Health Services Act—which does not require grants-in-aid at all—authorizes private litigants to use the courts to substitute their private views concerning how best to use public dollars to promote public health for the views of the politically accountable Executive Branch of the United States Government. *See Apter v. Richardson*, 510 F.2d 351, 355 (7th Cir. 1975) (The Public Health Services Act "confer[s] broad discretion in the funding of training programs," which "leads to the conclusion that the medical merits of NIH decisions on training grants may be committed to the unreviewable discretion of the agency.").

Second, the AAU Plaintiffs invoke the major questions doctrine, contending that, despite authorizing the Secretary of Health and Human Services to make grants, Congress did not intend to give the Secretary the power to determine what those grants would pay for. This is plainly incorrect. If Congress intended to provide a block funding award to Harvard University or some

other school, it would earmark money for Harvard University. The appropriation of funds to NIH to administer a multi-billion-dollar grant program plainly includes the provision of discretion to NIH in how to achieve the purposes of that program—here, by channeling as much taxpayer money as possible to medical research rather than overhead. Otherwise, NIH would not have the authority to negotiate over indirect cost rates *at all*.

Besides, the AAU Plaintiffs' argument has no stopping point: On their logic, the Secretary (or NIH) could be held incapable of declining to fund certain projects because the power to refuse funding is "sweeping" and of great "economic and political significance." *AAU v. HHS*, Doc No. 16 at 31-32 (quoting *West Virginia v. EPA*, 597 U.S. 697, 721 (2022)). And in any event, NIH's long-exercised power under the Public Health Services Act to decide how best to allocate research funding is wholly unlike the policies that have been invalidated under the major questions doctrine. *See EPA*, 597 U.S. at 725 (shifting the energy market "from dirtier to cleaner sources"); *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 125-26 (2000) (newly claimed power to regulate the tobacco industry).

E. NIH Complied with the APA in Issuing the Supplemental Guidance.

1. The Supplemental Guidance did not require notice-and-comment rulemaking.

For at least two reasons, NIH was not required to follow the notice-and-comment process prior to issuance of the Supplemental Guidance.

First, the Supplemental Guidance "relat[es] to . . . grants" and is therefore exempt from notice-and-comment rulemaking under the plain terms of the APA. 5 U.S.C. § 553(a)(2); *see also Opelika Nursing Home, Inc. v. Richardson*, 356 F. Supp. 1338, 1342 (M.D. Ala. 1973) ("[T]he requirement of notice in the Administrative Procedure Act, 5 U.S.C. § 553(b), is inapplicable when regulations concern matters relating to grants, as do the instant ones."

(quotation marks and citation omitted)). While the Secretary the Department of Health and Human Services predecessor department voluntarily agreed to follow notice and comment rulemaking, he did so "as a matter of policy"—not in a binding regulation. *See* 36 Fed. Reg. 2,532 (Feb. 5, 1971). There is thus no binding requirement of notice-and-comment rulemaking here—and, in any event, no matter what the executive branch says as a matter of policy discretion, the Court should not extend the APA's notice-and-comment requirements to a context, *i.e.*, grant making, that Congress expressly dictated they should not reach.

Second, the agency did not need any additional rulemaking because the independent reason that NIH followed the process set out in a validly promulgated regulation—45 C.F.R. § 75.414(c). That regulation itself went through notice-and-comment rulemaking (79 Fed. Reg. 75,871, 75,873), and Plaintiffs have offered no justification for effectively unwinding that (Dec. 19, 2014). Merely applying this existing regulation requires no further rulemaking. And Plaintiffs voluntarily agreed to the application of Section 75.414(c) when they agreed to grants expressly incorporating that provision. Thus, the requirements of notice-and-comment do not apply.

2. The reasoned Supplemental Guidance is not arbitrary and capricious.

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).

a. Contrary to Plaintiffs' suggestions, the Supplemental Guidance is both reasoned and rational. "The task of a court reviewing agency action under the APA's 'arbitrary and capricious' standard is to determine whether the agency has examined the pertinent evidence, considered the relevant factors, and 'articulate[d] a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *Penobscot Air Servs., Ltd. v. F.A.A.*, 164 F.3d 713, 719 (1st Cir. 1999) (quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)) (further citations omitted). The agencies reasoning need only be "rational" and a court should disrupt agency action only if it "is too unreasonable . . . for the law to permit it to stand." *Penobscot Air Servs.*, 164 F.3d at 720.

Here, NIH provided three separate reasons for its Supplemental Guidance.

First, NIH explained that it was capping indirect cost rates to "ensure that as many funds as possible go towards direct scientific research costs rather than administrative overhead" which is, "by [its] very nature, not readily assignable to the cost objectives specifically benefitted." Supplemental Guidance at 1, 2. Plaintiffs offer no response to this justification, which is perfectly rational: It is certainly reasonable for NIH to steer its money directly toward the very research it seeks to fund. Plaintiffs may disagree with NIH's choice, but that does not suffice to establish that it is arbitrary and capricious. *See Penobscot Air Servs.*, 164 F.3d at 720.

Second, NIH explained that it was focusing its payments on direct costs of research because indirect costs are "difficult for NIH to oversee." Supplemental Guidance at 2. While Plaintiffs argue that the Supplemental Guidance "does not explain why [NIH's] audit system would not accomplish the task of preventing administrative waste," their extensive citations to audit and calculation requirements for indirect costs confirm NIH's position. *AAU v. HHS*, Doc No. 16 at 24. Rather than divert funds to difficult-to-oversee, subject-to-abuse, and difficult-to-

standardize-across-institutions indirect costs, NIH is focusing its grants on funding work with the highest return on the government's investment—direct spending for medical research. *See* Supplemental Guidance at 2. This is an entirely rational choice for NIH to make as a steward of public funds. To deploy those funds in ways that will be easier for NIH to oversee for the benefit of the public. Again, Plaintiffs disagree with that choice, but it is certainly not arbitrary or capricious. *Penobscot Air Servs.*, 164 F.3d at 720.

Third, NIH sought to bring its indirect costs rates in line with the indirect cost rates paid by grantors in the private sector. Supplemental Guidance at 2. Most private foundations that fund research provide substantially lower indirect costs than the federal government, and most commonly, foundations do not fund indirect costs at all. *Id.* at 2. In addition, many of the nation's largest funders of research—such as the Bill and Melinda Gates Foundation—have a maximum indirect rate of 15%. *Id.* NIH reasonably decided to bring its indirect cost rates in line with indirect cost rates paid by private grantors, so as to avoid disproportionately subsidizing indirect costs and instead fund costs more directly attributable to research. While Plaintiffs would undoubtedly like those subsidies to continue, it is certainly *rational* for NIH to decline to disproportionately subsidize indirect costs. And while Plaintiffs complain about NIH's across-the-board 15% market-derived rate, they ignore that that rate was actually generous, exceeding the maximum indirect cost rates paid by many private grantors. Given the rationality of NIH's decision to bring its practices into line with private grantors, the Court should reject Plaintiff's argument that NIH's generosity is somehow irrational.

b. The NIH did not "fail to consider" important aspects of the problem." *Mass. v. NIH*, Doc No. 12 at 16. *First*, Plaintiffs contend that the Supplemental Guidance failed to consider "fact-findings as to actual indirect costs, memorialized in NICRAs." *Mass. v. NIH*, Doc

No. 12 at 19; *AAU v. HHS*, Doc No. 16 at 23, 26-27. But NIH did not ignore those findings. Rather, those negotiated rates served as the starting point that NIH was deviating from, for all the reasons already given. To say that the deviation ignored the NICRA is like saying that the runners in a race ignore the starting line. Indeed, on Plaintiff's theory, it would be impossible to "deviate from negotiated rates," as expressly permitted under Section 75.414(c)—a provision incorporated into the Notices of Award setting out the negotiated indirect cost rate. Bundesen Decl., Exh. B, Notice of Award at 1, 5. To deviate from a baseline is always to consider it, and the Court should reject Plaintiffs' atextual attempt to freeze in place the excessive indirect cost rates they previously charged to taxpayers.

Second, Plaintiffs argue that NIH failed to consider their reliance interests in their current indirect cost rates and, relatedly, the ways in which the Supplemental Guidance's 15% rate would affect their ongoing work. *Mass. v. NIH*, Doc No. 11 at 17; *AAU v. HHS*, Doc No. 16 at 32. This argument, of course, relates only to existing grants, because Plaintiffs can have no legally protectible reliance interests in grants that they have not yet been awarded. *Accord Lemon Bay Cove, LLC v. United States*, 160 Fed. Cl. 593, 613 (2022) ("A property owner who acquires land with knowledge of a regulatory restraint could be said to have no reliance interest or to have assumed the risk of any economic loss."). And with respect to existing grants, NIH did note that "grant recipients use grant funds to cover indirect costs. Supplemental Guidance at 2. It simply concluded that the other interests justifying the Supplemental Guidance outweighed that interest. *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 (CKK), 2022 U.S. Dist. LEXIS 174212, at *49 (D.D.C. Sep. 23, 2022) ("Even if the agency considers the any reliance interests to be serious, it my nonetheless determine that other interests and policy concerns outweigh any reliance interests.") (cleaned up).

NIH likewise considered that grantees often accept grants with lower indirect cost rates, demonstrating that those rates are generally acceptable to the grantees and would not unduly upset their reliance interests. Supplemental Guidance at 2 (recounting both maximum indirect cost rates paid by private grantors and discussing the indirect expense rates commonly accepted by institutions "from funders of research"—with the vast majority of institutions "willing to accept grants that had 0% indirect cost coverage"). While Plaintiffs no doubt dislike the change worked by the Supplemental Guidance, that does not mean that their reliance interests went unconsidered.

* * *

In sum, NIH considered the relevant issues and offered a reasoned and rational justification for its Supplemental Guidance. That Guidance is eminently sensible, and it certainly sets out a reasonably discernible path, *see Fox Television Stations, Inc.*, 556 U.S. at 514 (quotation marks and citation omitted), that meets the "minimum rationality standard." *Sierra Club v. EPA,* 353 F.3d 976, 978 (D.C. Cir. 2004) (citation omitted). The Court therefore should resist Plaintiffs' calls to "substitute its judgment for that of the agency." *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43.

3. The Supplemental Guidance is not impermissibly retroactive.

The Court should reject Plaintiffs' argument that the Supplemental Guidance is impermissibly retroactive. *See Mass. v. NIH*, Doc No. 12, at 23; *AAU v. HHS*, Doc No. 16, at 32.

First, the Supplemental Guidance makes clear that it applies only to future payments for costs incurred after its issuance—"go forward expenses"—and "all new grants issued." Supplemental Guidance at 3. This case is thus wholly unlike the cases cited by Plaintiffs, where an agency attempted to claw back money that already had been paid out. *See Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988); *Brimstone R.R. & Canal Co. v. United States*, 276 U.S. 104, 122 (1928). In *Bowen*, for example, the HHS Secretary promulgated a rule in 1984 that applied retroactively to Medicare payments made by HHS starting in 1981, allowing HHS to recoup millions of dollars. 488 U.S. at 207. The Supreme Court held that the Medicare Act did not give the Secretary that authority. *Id.* at 215. Unlike the HHS rule in *Bowen*, the Supplemental Guidance here has only prospective application: It applies to all "go forward expenses" from "February 10, 2025 forward as well as new grants issued."

Second, even if there were impermissible retroactivity, that would be limited only to existing grants—and not to new grants that will be made subject to the Supplemental Guidance. As a result, it would be improper to leave the temporary restraining orders in place insofar as they apply to new grants under the Supplemental Guidance. *See, e.g.*, *Hayes v. North State Law Enf't Officers Ass'n*, 10 F.3d 207, 217 (4th Cir. 1993) (An injunction "should not go beyond the extent of the established violation.").

II. Plaintiffs Have Not Shown Irreparable Injury.

The Court should deny Plaintiffs' motions, and vacate the existing TROs, for the additional, independently sufficient reason that Plaintiffs have not shown irreparable harm. *See 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).

Plaintiffs' primary claimed injury is the delayed payment of money—a standard part of litigation and a quintessential example of what does *not* count as irreparable injury. *See United States v. Michigan*, 230 F.R.D. 492, 495 (E.D. Mich. 2005) (ruling county did not suffer irreparable harm from state-agency directive to make certain payments where any overpayment could "be legally remedied by employing the standard procedure of look-back adjustments to future . . . rates"). Although the AAMC points out that a plaintiff cannot recover money damages for an APA violation, Plaintiffs could receive reimbursement for past indirect costs over the 15% cap if they prevail on their claims and the Supplemental Guidance were set aside. *See AAMC v. NIH*, 1:25cv10340, ECF No. 5, ¶¶ 10, 11. This delay in receiving funds is not enough. *Merit Energy Co. v. Bernhardt*, No. 20-cv-32, Dkt. 22 at *15-16 (D. Wyo. Apr. 29, 2020) (finding delay in recovering money from the government was insufficient to warrant preliminary injunction).

Indeed, Plaintiffs' declarations demonstrate that the immediate effects of reduced reimbursements are not irreparable. *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."). Here, some declarants explicitly acknowledge that they could "cover obligations with other funds" and fund near-term operating deficits from "reserves." *Mass. v. NIH*, Doc No. 6, Barton Decl., Ex. 19 ¶ 17. And even where plaintiffs do not have ready reserves, courts regularly reject assertions that a delay in receiving funds is irreparable harm. *E.g. Michigan*, 230 F.R.D. at 495 n.1 ("[Movant] argues that its ratepayers are low-income and do not have the luxury of saying, 'It's only money.' The rule that equitable

remedies cannot issue when the damages are monetary in nature has been ingrained in law for 'half a millennium or so,' and no judge within the English common law tradition has the luxury of ignoring it.") (internal citations omitted).

Moreover, where declarants assert that reducing funds is likely to harm research or clinical trials, they generally do not assert that those harms are *imminent* as opposed to eventual reductions in their capacity that would occur from sustained diminished funding after a ruling on the merits. *See Pub. Serv. Co. of New Hampshire v. Town of W. Newbury*, 835 F.2d 380, 382 (1st Cir. 1987) (affirming denial of preliminary injunction in the absence of indication that the merits of the case would not be decided before harms occurred). The declaration from Donald M. Elliman Jr. of the University of Colorado provides a useful example: In paragraph 9 of his declaration he states, without saying "when," that reduced funds "*will cause* partial elimination of clinical trial activity." Elliman Decl., Ex. 11 ¶ 9 (emphasis added), *Mass v. NIH*, Doc No. 6-11. In paragraph 11, however, Mr. Elliman specifically discusses the immediate impacts of reduced reimbursement and, there, he says that impacts on personnel and clinical trial activity are only "potential." *Id.* ¶ 11. It is clear that Plaintiffs believe that their programs would be harmed by reduced funding, but they do not establish that any irreparable impacts would occur before this case can proceed to the merits.

Beyond delayed disbursement, Plaintiffs have not shown that claimed imminent harms are likely to occur. "Plaintiffs must show that irreparable harm is *likely*, not merely possible." *In re TelexFree Sec. Litig.*, Civil Action No. 4:14-md-02566-TSH , 2021 WL 11604879, at *7 (D. Mass. Apr. 21, 2021) (citing *Steir v. Girl Scouts of the USA*, 383 F.3d 7, 16 (1st Cir. 2004)). That showing "must be grounded on something more than conjecture, surmise, or a party's unsubstantiated fears of what the future may have in store." *Charlesbank Equity Fund II v.*

Blinds To Go, Inc., 370 F.3d 151, 162 (1st Cir. 2004). Many of Plaintiffs' declarations never even assert a harm is "likely" to occur. *See, e.g.*, *Mass. v. NIH*, Doc No. 6, Dill Decl., Ex. 7 ¶ 11 (asserting reduction will be "devastating," without saying how any harm is imminent and irreparable); *Mass. v. NIH,* Doc No. 6, Jaime Decl., Ex. 8 ¶ 4 (asserting training will be "at risk"; asserting clinical trials "may" be disrupted); *Mass. v. NIH,* Doc No. 6, Alpay Decl., Ex. 13 ¶¶ 9, 10 (asserting reduced funding "may" result in job loss and "may" result in insufficient cash to meet obligations). And where declarants assert harms are "likely," they provide no facts to show why irreparable harm cannot be avoided. *See Augusta News Co. v. News Am. Pub. Inc.*, 750 F. Supp. 28, 32 (D. Me. 1990) (finding "bare conclusory assertions" insufficient to support preliminary injunction).

In short, Plaintiffs have failed to carry their burden of showing imminent irreparable harm warranting equitable relief.

III. Even if the Court Declines to Vacate the Existing TROs in their Entirety, the Court Should Vacate Them In Part Because They Are Overbroad.

For all the reasons already given, the Court should vacate the existing TROs in their entirety. But even if the Court disagrees, it should vacate the TROs in part because they are overbroad.

"Injunctive relief should be no more burdensome to the defendant than necessary to provide complete relief to plaintiffs[.]" *Tamko Roofing Prods., Inc. v. Ideal Roofing Co*., 282 F.3d 23, 40 (1st Cir. 2002) (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). Courts must "closely tailor injunctions to the harm that they address[.]" *Tamko Roofing Prods., Inc*., 282 F.3d at 40 (quoting *ALPO Petfoods, Inc. v. Ralston Purina Co.*, 913 F.2d 958, 972 (D.C. Cir. 1990)); *see also Nat. Res. Def. Council, Inc. v. Winter*, 508 F.3d 885, 886 (9th Cir. 2007)

("[I]njunctive relief must be tailored to remedy the specific harm alleged, and an overbroad preliminary injunction is an abuse of discretion.") (citation omitted) (alteration in original). And nationwide injunctions "take a toll on the federal court system—preventing legal questions from percolating through the federal courts, encouraging forum shopping, and making every case a national emergency for the courts and for the Executive Branch." *Trump v. Hawaii*, 585 U.S. 667, 713 (2018) (Thomas, J., concurring); *see also Free Speech Coal., Inc. v. Att'y Gen. United States*, 974 F.3d 408, 431 (3d Cir. 2020) (vacating nationwide injunction and remanding for entry of relief limited to successful as-applied plaintiffs).

Here, at most, any remedy should address only any sufficiently proven harms of the Plaintiffs in these cases, or those they represent: the members of the Plaintiff organizations and the public institutions of the Plaintiff States. Significantly, the States of Arizona, Hawai'i, and North Carolina did not submit any declaration in support of their claimed irreparable harms. *See Mass. v. NIH*, Doc. No. 6. And the sole declarant for the Association of American Medical Colleges asserted two immediate impacts insufficient for emergency relief, that members would draw less money and that unidentified members said they planned a hiring freeze. *See AAMC v. NIH*, Doc No. 5-1 ¶¶ 6, 8. Moreover, a nationwide injunction would speculatively address hypothetical harms suffered by parties not before the Court. The fact that some of the Plaintiffs are States claiming harm to their public institutions does not warrant extending injunctive relief to every institution within those States. Similarly, that the private organizations have many members does not warrant extending injunctive relief nationwide or to non-members.

Furthermore, agencies are entitled to a presumption of regularity—that "in the absence of clear evidence to the contrary, courts presume that [public officials] have properly discharged their official duties." *United States v. Chem. Found.*, 272 U.S. 1, 47 (1926). An injunctive

remedy requiring NIH to submit regular status reports, as requested by Plaintiffs, is inappropriate. The NIH and its officials are entitled to a presumption that they will properly comply with an injunction providing regular status reports.[7]

CONCLUSION

Defendants respectfully request that the Court dissolve the temporary restraining orders and deny Plaintiffs' motions.

Dated: February 14, 2025

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[7] On February 10, this Court entered two TROs without briefing from the Defendants. *See* Fed. R. Civ. P. 65(b). By the time this Court holds its hearing on February 21, Defendants will have been subject to a TRO for 11 days, almost all of the 14-day period contemplated in Rule 65(b)(2). And this Court has now received a full round of briefing on the merits of the parties' dispute a week in advance of that hearing. Regardless of the label Plaintiffs use, this matter is now effectively in a preliminary injunction posture. *Cf.* Fed. R. Civ. P. 65(b)(3). This Court lacks jurisdiction, and plaintiffs have not met the high showing necessary to obtain relief. Their motions should be denied.