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-AK
ASSOCIATION OF AMERICAN MEDICAL COLLEGES, *et al.* *Plaintiffs*, v. NATIONAL INSTITUTES OF HEALTH, *et al.*, *Defendants*.	Case No. 1:25-cv-10340-AK
ASSOCIATION OF AMERICAN UNIVERSITIES, *et al.*, *Plaintiffs*, v. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, *Defendants*.	Case No. 1:25-cv-10346-AK **Leave to File a Consolidated Brief Granted on Feb. 18, 2025**

PLAINTIFFS' REPLY IN SUPPORT OF A TEMPORARY RESTRAINING ORDER

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NIH's Rate Change Notice violates bedrock legal principles and will have grave consequences for science and medicine. The government posits that neither NIH regulations nor the Administrative Procedure Act ("APA") constrain NIH in the least, and the appropriations rider Congress repeatedly enacted is meaningless. NIH claims that it has carte blanche to do whatever it wants with reimbursement rates for facilities and administrative costs ("F&A" or "indirect costs") no matter how disruptive, and no matter how inconsistent with existing laws and regulations. The Executive, however, is not so unbound by law.

The government's attempts to evade legal constraints runs through its Tucker Act argument too. Plaintiffs challenge illegal—indeed, unconstitutional[1]—agency action, not breaches of contracts. These claims belong in Article III district courts. The government's arguments would deny Plaintiffs any adequate remedy.

The equities are not close. The government's insistence that these cases are just about delayed payments utterly disregards the realities of NIH funding. Yes, the Rate Change Notice will destroy budgets nationwide, but the consequences—imminent, certain, and irreparable—extend far beyond money, including lost human capital, shuttering of research projects and entire facilities, stalling or ending clinical trials, and forgoing advances in medical research, all while ending the Nation's science leadership.

ARGUMENT

I. The Tucker Act Does Not Divest This Court of Jurisdiction.

District courts have jurisdiction over "all civil actions arising under the Constitution, laws,

[1] Only the *AAMC* (Count V) and *AAU* Plaintiffs (Count II) assert constitutional claims.

or treaties of the United States." 28 U.S.C. § 1331. This case—an action under the APA alleging violations of the federal Constitution, laws, and regulations—falls squarely within that statute. And the Tucker Act does not implicitly eliminate that jurisdiction. Plaintiffs allege illegal agency action, not breach of contract, and those claims belong in Article III courts.

Like any argument inviting courts to divine an implicit exception from an express statute, the government's argument faces a steep climb. The Tucker Act's implied divestiture applies only when the plaintiff's claim is "essentially a contract dispute," *Am. Sci. & Eng'g, Inc. v. Califano*, 571 F.2d 58, 61 (1st Cir. 1978), and is "*at its essence* a contract claim," *Megapulse, Inc. v. Lewis*, 672 F.2d 959, 967 (D.C. Cir. 1982) (emphasis added). That implied exception is narrow; courts routinely reject the "'broad' notion 'that any case requiring some reference to or incorporation of a contract is necessarily on the contract and therefore directly within the Tucker Act.'" *Crowley Gov't Servs., Inc. v. GSA*, 38 F.4th 1099, 1107 (D.C. Cir. 2022) (quoting *Megapulse*, 672 F.2d at 967); *see Fairholme Funds, Inc. v. United States*, 26 F.4th 1274, 1298 (Fed. Cir. 2022); *Atterbury v. U.S. Marshals Serv.*, 805 F.3d 398, 407-08 (2d Cir. 2015). A broader approach would improperly "deny a court jurisdiction to consider a claim that is validly based on grounds other than a contractual relationship with the government." *Megapulse*, 672 F.2d at 967-68. And the existence of a contract in the background does not insulate the government from challenges to illegal or unconstitutional agency action. *See, e.g.*, *Crowley*, 38 F.4th at 1102 (APA claim challenging agency's authority belonged in district court because plaintiff "d[id] not seek to enforce or recover on [a] contract" and did not "seek monetary relief"); *Normandy Apartments,*

Ltd. v. HUD, 554 F.3d 1290, 1300 (10th Cir. 2009) (similar).[2]

In assessing whether the Tucker Act impliedly precludes jurisdiction, courts consider "both . . . the source of the rights upon which the plaintiff bases its claims, and . . . the type of relief sought (or appropriate)." *Megapulse*, 672 F.2d at 968. Both factors favor this Court's jurisdiction.

First, Plaintiffs root their claims in the Constitution, federal statutes, and federal regulations, not contract terms. They claim NIH's actions violate Section 224 of the Continuing Appropriations Act ("Section 224") and the Appropriations Clause, the statutes and regulations governing NIH grants, and the APA. *Commonwealth* Compl. ¶¶ 9 (*Commonwealth* Doc. No. 1), 157-221; *AAMC* Compl. ¶¶ 13, 47-74 (*AAMC* Doc. No. 1); *AAU* Compl. ¶¶ 9, 93-152 (*AAU* Doc. No. 1).[3] Plaintiffs do not base their claims on the terms of any contract. Indeed, Plaintiffs contend that the Rate Change Notice is illegal as applied to *all* NIH grants, including future grants for which no contract exists. The "source of the rights" here, *Megapulse*, 672 F.2d at 968, is thus not contractual. These cases instead challenge agency overreach—the heartland of the APA. *See Bowen v. Massachusetts*, 487 U.S. 879, 904-05 (1988).

Even as to existing grants, Plaintiffs' claims could not be meaningfully vindicated in the Court of Federal Claims. For example, Section 224 explicitly prohibits NIH from spending funds

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[2] Circuits nationwide have followed *Megapulse*'s test for determining whether the Tucker Act impliedly precludes district court jurisdiction. *See Atterbury*, 805 F.3d at 408; *Robbins v. U.S. Bureau of Land Mgmt.*, 438 F.3d 1074, 1083 (10th Cir. 2006); *B&B Trucking, Inc. v. USPS*, 406 F.3d 766, 768 (6th Cir. 2005); *N. Star Alaska v. United States*, 14 F.3d 36, 37 (9th Cir. 1994).

[3] Pursuant to this Court's Standing Order issued on February 11, 2025, for every first full citation to a document that has already been filed on at least one of the three related dockets, this Reply appends the respective docket number citation. This Reply uses the following short form labels for the respective dockets: "*Commonwealth* Doc. No. __," "*AAMC* Doc. No. __," and "*AAU* Doc. No. __."

to take the precise action it just took. That claim is not a contract claim, and retrospective damages in the Court of Federal Claims could not vindicate it. The same is true of the *AAU* Plaintiffs' Appropriations Clause claim and Plaintiffs' claims that the government violated the governing statute and the APA's substantive and procedural mandates. *See Bowen*, 487 U.S. at 905. Indeed, Plaintiffs' irreparable injury arguments underscore that an after-the-fact Tucker Act remedy is a misfit for the injuries inflicted by the action challenged here. More than that: Accepting the government's argument would allow it to avoid judicial review of its illegal action in *any* forum.

Nor does the Tucker Act bar Plaintiffs' claims based on the regulations in 45 C.F.R. Part 75 simply because those regulations may be incorporated by reference into grant agreements. Opp. 9-10 (*Commonwealth* Doc. No. 73; *AAMC* Doc. No. 30; *AAU* Doc. No. 74). The government argues that Plaintiffs could bring hypothetical breach-of-contract claims premised on NIH's violation of those regulations. *Id.* But even leaving aside the narrowness of this argument (which applies only to existing grants and only to claims under 45 C.F.R. Part 75), courts routinely reject the notion that the government could exempt itself from APA review by simply incorporating regulatory terms into a contract. "APA jurisdiction does not turn on whether the plaintiff could conceivably have based his claim on a government contract." *Atterbury*, 805 F.3d at 407. Likewise, "the mere fact that a court may have to rule on a contract issue does not, by triggering some mystical metamorphosis, automatically transform an action . . . into one on the contract and deprive the court of jurisdiction it might otherwise have." *Megapulse*, 672 F.2d at 968. Here, Plaintiffs contend that the Rate Change Notice violated *the regulations themselves*, not the grants in which those regulations are incorporated. Indeed, Plaintiffs would have exactly the same argument even if no grants incorporated the regulations.

Second, "the type of relief sought (or appropriate)" here differs from the relief available from a Tucker Act claim. *Megapulse*, 672 F.2d at 968. Plaintiffs seek neither a money judgment nor an injunction directing the government to pay money. Instead, they seek declaratory and injunctive relief returning the parties to the pre-existing status quo by requiring the government to respect negotiated rates for indirect costs. The Supreme Court has made clear this type of suit may proceed in district court, because it "is not a suit seeking money in *compensation* for the damage sustained by the failure of the Federal Government to pay as mandated; rather, it is a suit seeking to enforce the statutory [and regulatory] mandate itself." *Bowen*, 487 U.S. at 900. The fact that an injunction may later cause the government to honor its obligation to make payments does not strip this Court of jurisdiction. *See Crowley*, 38 F.4th at 1108 ("[E]ven if the plaintiff filed the complaint with an eye to future monetary awards, a district court with otherwise appropriate jurisdiction may hear the claim and grant the proper equitable relief." (quotation omitted)).

None of the government's cases supports its position. Opp. 7-9. In those cases, the plaintiffs asked the district courts to award them money—either via money judgments or via "injunctions" that commanded payment of specific sums.[4] Here, Plaintiffs seek the quintessential APA remedy

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[4] *See, e.g.*, *Diaz v. Johnson*, No. 19-1501, 2020 WL 9437887, at *2 (1st Cir. 2020) (individual plaintiff's bid protest that was "pecuniary in nature" and "at bottom . . . seeks . . . monetary relief"); *Am. Sci.*, 571 F.2d at 61 (claim was "essentially a contract dispute" seeking compensation following HHS's cancellation of an individual's license); *Suburban Mortg. Assocs. v. HUD*, 480 F.3d 1116, 1117 (Fed. Cir. 2007) (claim that government breached "contractual obligations" under an insurance agreement and owed the plaintiff "specific performance" and "the money . . . due it under [the agreement]"); *Burgos v. Milton*, 709 F.2d 1, 2 (1st Cir. 1983) (individual claim for $15,000 in damages against individual IRS officers); *Tortorella v. United States*, 486 F. Supp. 2d 159, 161 (D. Mass. 2007) (employment contract dispute where damages award remedied alleged injury); *Glaskin v. Klass*, 996 F. Supp. 67, 70 (D. Mass 1998) ("requested relief [that] would restore bonds to [the plaintiff's estate]" as a substitute for "provid[ing] compensation for the loss of the bonds").

of vacatur, as well as declaratory and injunctive relief prohibiting NIH from relying on the Notice and requiring it to comply with Congress's direction to follow the existing approach to negotiated cost rates. That is nothing like an injunction to pay a specific sum. *See Crowley*, 38 F.4th at 1110-12; *Normandy Apartments*, 554 F.3d at 1296-97.

Finally, the Court should exercise jurisdiction because "the doubtful and limited relief available in the Claims Court is not an adequate substitute for review in the District Court." *Bowen*, 487 U.S. at 901. NIH awards over 60,000 grants annually at more than 2,500 different institutions.[5] The government apparently believes each of those institutions should file thousands of separate Tucker Act claims. Worse, because Tucker Act relief is retrospective, the government apparently would require each institution to file a new lawsuit every time NIH refuses to reimburse indirect costs. Such litigation would not just be massively wasteful but would also utterly fail to remedy Plaintiffs' injuries from NIH's unlawful across-the-board policy that wreaks havoc on institutions *right now*. *See infra* Part III (describing imminent irreparable harm).

II. Plaintiffs Are Likely to Succeed on the Merits.

A. The Rate Change Notice Is Unlawful Under the Plain Language of Section 224 of the Continuing Appropriations Act of FY 2024 and the Appropriations Clause.

The government's claim that it has complied with Section 224 ignores that provision's plain text and unmistakable purpose. After the Executive Branch proposed slashing NIH F&A rates in 2017,[6] Congress immediately adopted a bipartisan appropriations rider designed to prevent

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[5] National Institutes of Health, *Impact of NIH Research*, https://www.nih.gov/about-nih/what-we-do/impact-nih-research/serving-society/direct-economic-contributions (last visited on Feb. 18, 2025).

[6] *See* Office of Management & Budget, *Major Savings and Reforms: Budget of the U.S.*

NIH from doing so, which is in effect to this day. Yet here we are again. In open defiance of that rider, NIH slashed F&A rates. The government's only response is an interpretation that would impose no restrictions on its discretion whatsoever. The Court should reject that argument because Congress does not enact meaningless statutes. *See, e.g.*, *Plaut v. Spendthrift Farm*, *Inc.,* 514 U.S. 211, 216 (1995); *Rumsfeld v. FAIR*, 547 U.S. 47, 57 (2006).

Section 224 contains *three separate* prohibitions (numbering added for convenience):

> **[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 [NIH] 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 [HHS] 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.

Further Consolidated Appropriations Act, 2024, Pub. L. No. 118-47, § 224, 138 Stat. 460, 677. This belt-and-suspenders-and-drawstrings approach reflects Congress's effort to leave no doubt that NIH cannot slash F&A rates without authorization. Here, NIH violated all three prohibitions.

First, when NIH abruptly switched from case-by-case deviations from negotiated rates to an across-the-board 15% F&A rate, it violated Congress's mandate that, "with respect to the approval of deviations from negotiated rates," NIH must apply 45 C.F.R. Part 75's provisions "to

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Government Fiscal Year 2018, at 43 (2017), https://www.govinfo.gov/content/pkg/BUDGET-2018-MSV/pdf/BUDGET-2018-MSV.pdf ("The Budget includes an indirect cost rate for NIH grants that will be capped at 10 percent of total research. This approach would be applied to all types of grants with a rate higher than 10 percent currently . . . .").

the same extent and in the same manner" as it did previously. The government responds that this prohibition has nothing to say so long as NIH purports to apply its existing regulations, and those regulations do not constrain NIH's discretion. Opp. 11-16. But if Congress wanted only to prevent NIH from changing its regulations, it could have said so. Instead, it enacted a much broader prohibition. And indisputably, NIH has never applied the regulations to enact a single fixed F&A rate, aside from in the discredited 2017 budget proposal and in the Notice. Congress included the key language—"same extent" and "same manner"—precisely to preclude what the Notice attempts. *See infra* 10-12. Moreover, as explained in Part II.B.1, the government is wrong that the regulations gave NIH carte blanche to cap indirect costs across the board. So the government's insistence that it complied with 45 C.F.R. § 75.414(c)(3) gets it nowhere.

Second, NIH illegally used appropriated funds "to develop or implement a modified approach to [the provisions relating to F&A rates]." It is hard to imagine what the Notice could be described as doing *other than* implementing a "modified approach" to F&A rates. Again, the government's only argument is to insist that the rider prohibited it from changing the regulations, and because the regulations always gave it the power to impose a cap, it has not "modified" its approach. Opp. 16-17. Here too, the government's theory would render the rider meaningless. The rider does not just prohibit changes to the regulations but any modified "*approach*" to the indirect cost "provisions." *See Approach*, *The American Heritage Dictionary* (5th ed. 2016) (defining "approach" as "the method used in dealing with or accomplishing"). Even the government cannot claim that the Notice does not at least "modify" the approach to negotiated costs that preceded it.

Third, NIH has twice over "expand[ed] the fiscal effect" of its deviations from the negotiated rates. NIH unveiled this new policy in an X post that proudly declared: "This change

will save more than $4B a year effective immediately."[7] And declaration after declaration in these cases underscores the Rate Change Notice's cataclysmic fiscal effects on institutions.[8] The government incorrectly claims both that the rider's reference to "fiscal effects" includes only the government, not institutions, and that there will be no net "fiscal effects" on the government because it will redirect, rather than pocket, F&A expenditures. Opp. 17. Both arguments fail.

As to the first, the phrase "fiscal effects" plainly encompasses—indeed, focuses on—effects on institutions. The government cites a Merriam-Webster definition of "fiscal" that refers to public revenues. But Merriam-Webster includes a second definition that is much broader: "of or relating to financial matters." *Fiscal*, *The Merriam-Webster Dictionary* (2022). Other dictionary definitions are similarly general. *See Fiscal*, *The American Heritage Dictionary* (5th ed. 2016) (defining "fiscal" as "[o]f or relating to finance or finances"); *Fiscal, The Oxford English Dictionary Online*, https://www.oed.com/dictionary/fiscal_adj (last visited Feb. 17, 2025) (similar). In NIH regulations governing F&A recovery, the word "fiscal" is invariably and repeatedly used according to the second, broader definition.[9] In context, the rider—which

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[7] *Commonwealth* Doc. No. 6-5 (NIH, X (Feb. 7, 2025, 6:19 PM), https://x.com/NIH/status/1888004759396958263).

[8] *See, e.g.*, Columbia Decl. ¶ 13 (*AAU* Doc. No. 2-10) (estimated annual loss of $180 million); Univ. of Florida Decl. ¶ 13 (*AAU* Doc. No. 2-13) ($70 million); JHU Decl. ¶ 15 (*AAU* Doc. No. 2-15) ($200 million); Univ. of Kansas Decl. ¶ 13 ($30 million); MIT Decl. ¶ 10 (*AAU* Doc. No. 2-17) ($113 million); Univ. of Michigan Decl. ¶ 6 (*Commonwealth* Doc. No. 6-23; *AAU* Doc. No. 2-18) ($181 million); Univ. of Penn Decl. ¶ 10 (*AAU* Doc. No. 2-21) ($170.9 million); Rochester Decl. ¶ 14 (*AAU* Doc. No. 2-24) (over $40 million); Rutgers Decl. ¶ 9 (*Commonwealth* Doc. No. 6-27; *AAU* Doc. No. 2-25) ($57.5 million); USC Decl. ¶ 12 (*AAU* Doc. No. 2-28) ($93.7 million); Vanderbilt Decl. ¶ 12 (*AAU* Doc. No. 2-29) ($33 million); Washington Univ. St. Louis Decl. ¶ 12 (*AAU* Doc. No. 2-30) ($87 million).

[9] *See, e.g.*, 45 C.F.R. § 75.415 (setting forth certification requirement for the "annual and final

specifically refers to those regulations—plainly includes fiscal effects on universities.

And even if "fiscal effect" referred only to effects on the government, NIH would still be violating the rider's third command. The rider focuses on the "the fiscal effect of the approval of such deviations from negotiated rates." In other words: did the deviations *themselves* have a fiscal effect? Here, the answer is yes, to the tune of $4 billion.[10] Nothing in the rider suggests that the Executive may try to make up for that forbidden effect through separate grants.

Moreover, the government's interpretation would once again render the rider meaningless. It effectively says that the Notice had no "fiscal effect" because NIH spends all its appropriated funds anyway. But NIH was *already required* to do that. *See* 2 U.S.C. § 683(b) (barring President from rescinding appropriated funds without congressional approval). Even though the rider refers specifically to indirect costs, NIH interprets it merely to require that NIH spend all its appropriated funds on *something*, which was a requirement even before the rider. Thus, under the government's interpretation, the rider added nothing to preexisting law.

The government's theory is especially untenable given the rider's history as a direct

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fiscal reports" from funding recipients); *id.* Appendix III to Part 75 (same, with respect to the "annual and/or final *fiscal* reports" from funding recipients); *id.* § 75.419(a) (setting forth accounting standards for institutions of higher education who receive aggregate federal funding totaling $50 million or more "in [their] most recently completed *fiscal* year"); *id.* § 75.501(a) (setting forth audit requirements for funding recipients that expend "$750,000 or more during the non-Federal entity's *fiscal* year in Federal awards"); *id.* § 75.510(a) (requiring information about "cash flows for the *fiscal* year audited" in an auditee's financial statements (emphases added)).

[10] NIH touted the savings on social media when it announced the Rate Change Notice. *See Commonwealth* Doc. No. 6-5 (NIH, X (Feb. 7, 2025, 6:19 PM), https://x.com/NIH/status/1888004759396958263). The Department of Government Efficiency (or "DOGE") made the same point. *See* Department of Government Efficiency, X (Feb. 7, 2025, 4:10 PM) https://x.com/DOGE/status/ 1887972340446683576.

response to the last proposal to impose a one-size-fits-all regime for F&A rates. In 2017, the Republican-controlled Senate Appropriations Committee explained what the rider sought to do. The Committee observed that the approach to "negotiating indirect costs has been in place since 1965"; that "Administration's proposal would radically change" this approach; and that this proposal would "throw[] research programs across the country into disarray." S. Rep. No. 115-150, at 109 (2017); *see Commonwealth* TRO Br. at 7 (*Commonwealth* Doc. No. 12). "To avoid this possibility," the Committee continued, it was "prohibit[ing] HHS from developing or implementing a modified approach"—*i.e.*, an across-the-board approach—to "F&A costs." S. Rep. No. 115-150, at 109 (2017).

The Republican-controlled House Appropriations Committee similarly stated that the proposal was "misguided and would have a devastating impact on biomedical research across the country." H.R. Rep. No. 115-244, at 50 (2017). The Committee explained the rider's purpose: "To ensure that NIH can continue supporting both direct *and F&A costs* as is their current practice, the bill includes a new general provision directing NIH to continue reimbursing institutions for F&A costs according to the rules and procedures described in 45 CFR 75." *Id.* (emphasis added). And further, the rider "also prohibits funds in this Act from being used to implement any further caps on F&A cost reimbursements." *Id.* By imposing an across-the-board rate of 15%, the Notice effectively implements exactly the type of cap that Congress enacted the rider to bar.

This rider, grounded in an unequivocal congressional rebuke of an across-the-board F&A rate, has been repeatedly reenacted year after year.[11] The Court should reject NIH's efforts to

[11] Further Consolidated Appropriations Act, 2024, Pub. L. No. 118-47, § 224, 138 Stat. 460, 677;

ignore Congress's express prohibitions and deprive Congress of its power of the purse.

B. The Rate Change Notice Violates the Regulations Governing the Reimbursement of F&A Rates.

NIH's own regulations independently bar it from jettisoning its decades-old approach to F&A rates and replacing it with an across-the-board cap. That should not be a surprise: When the Executive Branch sought to do so in 2017, it proposed that Congress enact a statute. Had NIH's existing regulations permitted the same result, the Executive would not have bothered with Congress. Now, the government has no adequate answer to the Rate Change Notice's illegality.

1. The Rate Change Notice Violates 45 C.F.R. § 75.414(c).

The Rate Change Notice violates 45 C.F.R. § 75.414(c). That regulation allows NIH to "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 by paragraph (c)(3)." 45 C.F.R. § 75.414(c)(1). Paragraph (c)(3), in turn, provides that NIH "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.* § 75.414(c)(3). The government asserts that the Notice's reversal of NIH's decades-old approach is a mere "deviat[ion]" from negotiated rates for a "class of Federal awards." Opp. 12-13. But NIH's

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see Dept. of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019, Pub. L. No. 115-245, § 224, 132 Stat. 2981, 3094 (2018); Further Consolidated Appropriations Act, 2020, Pub. L. No. 116-94, § 224, 133 Stat. 2534, 2582 (2019); Consolidated Appropriations Act, 2021, Pub. L. No. 116-260, § 224, 134 Stat. 1182, 1594 (2020); Consolidated Appropriations Act, 2022, Pub. L. No. 117-103, § 224, 136 Stat. 49, 470-71; Consolidated Appropriations Act, 2023, Pub. L. No. 117-328, § 224, 136 Stat. 4459, 4883-84 (2022).

regulations impose real constraints—the government cannot simply wave them away.

First, the regulation's authorization of "deviations" from negotiated rates for "a class of Federal awards" does not authorize NIH's categorical repudiation of negotiated F&A rates for *all* grants. A "deviation" is a "[d]ivergence from an accepted idea, policy, or norm of behavior,"[12] which requires a standard or norm that *still exists* and is the default rule from which deviations occur. "Deviation" does not mean the replacement of one norm (negotiated rates) with an entirely different approach (a single 15% rule). *See Biden v. Nebraska*, 143 S. Ct. 2355, 2369 (2023) ("The authority to 'modify' statutes and regulations allows [an agency] to make modest adjustments and additions to existing provisions, not transform them."); *MCI Telecomms. Corp.*, 512 U.S. at 228.

Similarly, that the regulation allows deviation only for a designated "*class* of Federal awards," 45 C.F.R. § 75.414(c)(1) (emphasis added), underscores that it contemplates individualized or group-based determinations, not a blanket rule. The government's position that the entire universe of NIH grants is a "class" of HHS grants, Opp. 12, ignores the regulatory definition. A "Class of Federal awards" means "a group of Federal awards either awarded *under a specific program or group of programs* or to a specific type of non-Federal entity or group of non-Federal entities to which *specific provisions or exceptions may apply*." 45 C.F.R. § 75.2 (emphases added). The category of "all NIH grants" cannot fairly be characterized as a "group of programs . . . to which specific provisions or exceptions may apply."

Second, the Notice violates the regulation's procedural requirements. Paragraph (c)(3)

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[12] *Deviation*, *The American Heritage Dictionary* (5th ed. 2016); *see also Deviate*, *The Merriam-Webster Dictionary* (defining "deviate" as "to turn aside from a course, standard, principle, or topic").

requires the awarding agency to "implement" and make "publicly available" the policies, procedures and decision-making criteria used in assessing whether to deviate from a negotiated rate. 45 C.F.R. § 75.414(c)(3). The government did not do that here. Instead, it claims that the Notice, with its 15% F&A rate, constitutes the relevant "policies, procedures and decision-making criteria." Opp. 12. But the Notice's 15% F&A rate is not a policy, procedure or criterion for making a decision—it is the decision itself. The regulation requires a two-step sequence: first, implement and publicize the criteria and process, and then, later, apply those criteria and follow that process to justify the deviation. The regulation's use of tenses makes this point clear: the agency "must" first, in the present, "implement, and make publicly available" its "policies, procedures and general decision making criteria," which it then "will," in the future, "follow to seek and justify deviations from negotiated rates." 45 C.F.R. § 75.414(c)(3). Here, the Notice announced the repudiation of negotiated rates in one fell swoop without any prior identification of the criteria it would apply.

2. The Rate Change Notice Violates the Regulation Governing Changes for Existing Grants.

The Notice also violated 45 C.F.R. § 75.414(c)(4), which requires NIH to "include in the notice of funding opportunity the policies relating to F&A rate reimbursement." This information must be "sufficient . . . to help an applicant make an informed decision about whether to submit an application." *Id.* § 75.203(c)(2); *see id.* § 75.414(c)(4) (cross-referencing this requirement). No notices issued before February 7, 2025, reflect the Rate Change Notice. The government argues that § 75.414(c)(3) allows NIH to change F&A rates any time, even if not included in the notice of funding opportunity. Opp. 13-14. But nothing in § 75.414(c)(3) authorizes NIH to adjust the terms of existing grants. And—picking up on a recurring theme—the government's reading would render § 75.414(c)(4) meaningless: Why require NIH to publicize "policies relating to indirect cost

rate reimbursement," 45 C.F.R. § 75.414(c)(4), if the agency can change them at will and without warning? Any such "policies" would not be "sufficient" to allow for informed decisions. *Id.* § 75.203(c)(2). Nor does Appendix III help the government: It requires compliance with 45 C.F.R. § 75.414(c)(1), which requires compliance with 45 C.F.R. § 75.414(c)(3) where a rate change is not "required by Federal statute or regulation." 45 C.F.R. § 75.414(c)(1); *see* 45 C.F.R. Appendix III to Part 75, § C.7a. And as explained, NIH did not comply with those provisions.

C. The Notice Has Retroactive Effects That Congress Has Not Authorized.

The Notice is also impermissibly retroactive because it saddles Plaintiffs with paying for critical F&A costs that NIH previously committed to reimburse. *See Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988) (agencies may not "promulgate retroactive rules unless that power is conveyed by Congress in express terms"). The government does not dispute that NIH lacks statutory authority to engage in retroactive rulemaking, arguing instead that the Notice applies only to "go forward expenses from February 10, 2025 forward." Opp. 25 (quoting Notice at 3). But the relevant question is "whether [the change] would impair rights a party possessed when he acted, increase a party's liability for past conduct, or impose new duties with respect to transactions already completed." *Landgraf v. USI Film Prods.*, 511 U.S. 244, 280 (1994). Here, the Notice impairs institutions' rights to recover costs for existing grants and imposes new duties to pay for these costs. By altering existing grants, the Notice violates settled anti-retroactivity principles.

D. The Rate Change Notice Is Arbitrary and Capricious in Violation of the APA.

NIH violated the APA's reasoned-decision-making mandate by unilaterally and abruptly capping at 15% all F&A rates for all current and future grantees. None of NIH's attempts at a justification withstands scrutiny, underscoring the lack of "a rational connection between the facts

found and the choice made." *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221 (2016) (quoting *Motor Vehicle Mfrs. Ass'n of the U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). And NIH's failure of reasoned decision-making is especially egregious because it failed to consider the individualized circumstances that formed the basis for institutions' evidence-based rates, or how institutions nationwide have relied on NIH's decades-old approach. *See FCC. v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009).

1. Defendants' Purported Reasons for the Rate Change Notice Are Inadequate.

First, NIH asserts that it must "ensure that as many funds as possible go towards direct scientific research costs rather than administrative overhead." Opp. 21 (quoting Notice at 2). But the Notice is simply a decision to fund *less research*. F&A rates are calculated and negotiated based on each institution's *actual* indirect costs for NIH-funded research. So imposing a 15% cap is a decision to *not compensate* research institutions for the indirect costs that support (and are necessitated by) NIH's specific research projects, meaning recipients will simply lose the funding necessary to cover the various facilities and administration costs required for their research. NIH's failure to even acknowledge this obvious fact is classic arbitrary decision-making. And NIH offers no support for its apparent assumption that institutions will pick up the tab for the F&A shortfall—as opposed to no longer accepting grants that do not even begin to cover their actual costs.

Moreover, contrary to the government's claims, the Notice does nothing to "steer" money to the research it seeks to fund or direct more funds "towards direct scientific research."[13] Opp. 21.

[13] Indeed, the government touts that the Rate Change Notice will save it $4 billion dollars—not that the savings will be redirected to research. *Commonwealth* Doc. No. 6-5 (NIH, X (Feb. 7, 2025, 6:19 PM), https://x.com/NIH/status/1888004759396958263). The Notice could be upheld only on

Nothing in the Notice directs more money to direct expenses; it simply caps F&A rates. And under the regulations, reducing the F&A rates would not increase the base amount available for direct costs because they represent distinct pools of funding. *See* 45 C.F.R. part 75, Appx. III, § C.2. So the Notice's policy change again bears no rational connection to NIH's stated goal.

Second, NIH declares that indirect costs are "difficult . . . for NIH to oversee" and that direct costs are "easier . . . to oversee." Rate Change Notice 2. But NIH did not explain why expenses related to "facilities" and "administration" are supposedly difficult to track. Indeed, these categories are well defined by federal regulations, 45 C.F.R. § 75.414(a), and NIH's Grants Policy Statement. Supp. Dirks Decl. Ex 44. Moreover, indirect costs are subject to close supervision "to ensure that Federal sponsors do not in any way subsidize the indirect (F&A) costs of other sponsors." 45 C.F.R. part 75, Appx. III, § C.1(a)(3); *see* Tran Decl. ¶ 8. Because the Notice does not address this oversight structure, it fails the APA's requirement of reasoned decision-making.

Third, NIH's move to a 15% across-the-board metric relies entirely—and improperly—on a comparison to private foundations. Rate Change Notice 2; Opp. 22. But such foundations often deploy different definitions of "direct" and "indirect" costs, such that a cap of 15% on indirect costs does not have the same fiscal import as the Notice. Tran Decl. ¶ 14.[14] In addition, foundations

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the agency's stated rationale. *See Johnson v. Copyright Royalty Bd.*, 969 F.3d 363, 390 (D.C. Cir. 2020).

[14] For example, the Gates Foundation's Indirect Cost Policy, cited by NIH in its notice (Doc. No. 6-1 at 2 n.3), specifies that "utilities and communications expenses that are required to execute the project, such as . . . project office costs," are *direct* costs. Supp. Dirks Decl. Ex. 45 (Gates Policy) at 5. Thus, a project manager that serves multiple projects would be an "indirect cost" under federal regulations, 45 C.F.R. § 75.414(a), but a "direct cost" in a Gates grant. Similarly, the Robert Wood Johnson Foundation, cited by NIH (Rate Change Notice 2), permits these types of expenses as direct costs, delineating within direct costs a subcategory of "Shared Costs," which "benefit

are more likely to fund more discrete research projects that do not involve laboratory infrastructure.[15] And the F&A rates listed in the Notice for several private foundations are simply wrong.[16] These distinctions would have been obvious to any reasonable observer of the 2017 proposal: At that time, the Executive similarly invoked the comparison to foundations, including the Gates Foundation[17]—and in response, these foundations and others explained why the comparison was inapt. *See AAU* TRO Br. at 25 (*AAU* Doc. No. 16).

2. Defendants Did Not Consider Plaintiffs' Reliance Interests.

NIH also failed to adequately address Plaintiffs' reliance interests. The government does not—and could not—dispute that those interests, based on decades of NIH policy, are substantial. Opp. 23. And the government points only to a passing statement that NIH found such interests are "outweighed" by other considerations. *Id.* But "conclusory statements do not suffice." *Encino Motorcars*, 579 U.S. at 224. NIH failed to explain how it "weigh[ed] [reliance] interests against competing policy concerns" or considered obvious ways of "accommodating [those] reliance interests." *Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 591 U.S. 1, 33 (2020).

The government confuses retroactivity and reliance in arguing that Plaintiffs' reliance

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multiple programs or projects." Supp. Dirks Decl. Ex. 46 (RWJF Indirect Cost Rate Policy).

[15] For example, the Smith Richardson Foundation and the Carnegie Corporation of New York, both cited by NIH as comparators (Doc. No. 6-1 at 2), do not appear to offer any grants related to lab-based research. *See* Supp. Dirks Decl. Ex. 47 (SRF Policy); Ex. 48 (Carnegie Policy).

[16] The Robert Wood Johnson Foundation's typical ICR is 15%, not 12%. *Compare Commonwealth* Doc. No. 6-1 at 2, *with* Supp. Dirks Decl. Ex. 46 (RWJF Indirect Cost Rate Policy). The Packard Foundation, which NIH describes as providing a 15% ICR, offers ICRs of up to 25%. *Compare Commonwealth* Doc. No. 6-1 at 2 & n.3, *with* Supp. Dirks Decl. Ex. 49 (Packard Foundation Notice).

[17] Major Savings and Reforms at 43, *supra* note 6.

interests extend only to existing grants—although the reliance-destroying effects on existing grants alone suffice to render the policy arbitrary. While Plaintiffs may have no *property* interest in future grants, they have structured their operations with the reasonable expectation that NIH would maintain its longstanding policy, and the Supreme Court has held that agencies must consider such forward-looking reliance interests. *See, e.g.*, *Encino Motorcars*, 579 U.S. at 222-23.

E. NIH Cannot Adopt the Rate Change Notice Without Notice and Comment.

The government offers two responses to Plaintiffs' showing that the Rate Change Notice failed to comply with the APA's notice-and-comment requirement. Neither is persuasive.

First, the government cannot rely on the APA's "grant" exception, 5 U.S.C. § 553(a)(2), because HHS in 1971 "waived the § 553(a)(2) exception and subjected itself to the [APA's] procedural requirements." *Clarian Health W., LLC v. Hargan*, 878 F.3d 346, 356-57 (D.C. Cir. 2017) (citing *Public Participation in Rule Making*, 36 Fed. Reg. 2532 (Feb. 5, 1971)). And while the government says HHS originally did so as a matter of "policy" (Doc. No. 73 at 20), the D.C. Circuit "and the Supreme Court's cases [have] treat[ed] this or other such waivers as binding," *Clarian*, 878 F.3d at 356-57 (citing cases). They have been right to do so: "An agency has an obligation to abide by its own regulations," *Rotinsulu v. Mukasey*, 515 F.3d 68, 72 (1st Cir. 2008) (citing *United States ex rel. Accardi v. Shaughnessy,* 347 U.S. 260, 265–67 (1954)), and may not "depart from a prior policy *sub silentio*," *Fox Television Stations, Inc.*, 556 U.S. at 515. Having chosen to waive reliance on § 553(a)(2), HHS cannot disregard that commitment. HHS itself has recognized as much: When HHS has previously changed its grant rules, it has either done so through notice and comment or asserted good cause. *See AAU* TRO Br. 30 & n.6.

Second, the government claims that the agency did not need "any additional rulemaking

because . . . NIH followed the process set out in a validly promulgated regulation—45 C.F.R. § 75.414(c).” Opp. 20. As explained, the Notice is inconsistent with § 75.414(c). *Supra* 12-14. But more fundamentally, a regulation cannot excuse the agency from complying with the APA. And under the APA, the Notice is a legislative rule, as the government has not tried to dispute. Such rules require notice and comment. *See N.H. Hosp. Ass’n v. Azar*, 887 F.3d 62, 70 (1st Cir. 2018).

III. Without Injunctive Relief, Plaintiffs Will Suffer Imminent, Irreparable Harm.

On irreparable harm, the government’s brief is largely an exercise in misdirection: It cherry-picks particular declarations (often incorrectly) that it says do not establish a particular point, and then ignores how myriad *other* pieces of evidence expressly address the same point. The government simply has no answer to the immediate harms the Rate Change Notice will inflict on this country’s research institutions—and on the country as a whole. The 83 unique declarations submitted in these three related cases establish that, if the Court permits the government to enforce the Rate Change Notice, Plaintiffs, their members, other research institutions, and the patients that depend on them will suffer irreparable harms.[18]

To demonstrate that irreparable harm, Plaintiffs must show merely that “legal remedies are inadequate.” *Ross-Simons of Warwick, Inc. v. Baccarat, Inc.*, 102 F.3d 12, 18 (1st Cir. 1996).[19]

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[18] In addition to the original 61 unique declarations submitted in these cases, Plaintiffs have supplemented the record with the 22 additional declarations. In fast-moving litigation for injunctive relief, courts routinely allow movants to add to the record by attaching additional evidence to their reply. *See, e.g.*, *Vicor Corp. v. FII USA, Inc.*, No. 24-10060, 2024 WL 3548786, at *3-4 (D. Mass. June 24, 2024) (denying motion to exclude preliminary injunction evidence submitted for the first time with the movant’s reply brief).

[19] Although Plaintiffs bear the burden of proof, their evidence need only “possess *some* substance” and be more than “a tenuous or overly speculative forecast of anticipated harm.” *Ross-Simons*, 102 F.3d at 19 (emphasis added). And when, as is the case here, the party seeking preliminary relief

Plaintiffs easily meet that burden, and then some. Unlike in the government's cited cases,[20] Plaintiffs have articulated specific, tangible, and immediate effects the Rate Change Notice will have on Plaintiffs, their members, and the public. And in considering temporary injunctive relief, the "Court may accept as true well-pleaded allegations in the complaint and uncontroverted affidavits." *Parexel Int'l LLC v. Signant Health Holding Corp.*, No. 1:22-CV-11896-AK, 2023 WL 2938073, at *4 (D. Mass. Apr. 13, 2023) (Kelley, J.).

1. *Cessation of clinical trials*: The ability of Plaintiffs and their members to offer clinical trials will immediately suffer, impeding medical progress and ending hope for those patients without available effective clinical treatments. The University of Washington, for example, will need to "scale back ongoing clinical trials and stop enrolling new patients in clinical trials for diseases where there is no good treatment available outside of trials." Univ. of Washington Decl. ¶ 7 (*Commonwealth* Doc. No. 6-39). The University of Wisconsin-Madison similarly expects these cutbacks to "necessitate programmatic downsizing . . . including potentially terminating some clinical trials, thereby leaving a population of patients with no viable alternative." Univ. of Wisconsin-Madison Decl. ¶ 9 (*Commonwealth* Doc. No. 6-41; *AAU* Doc. No. 2-31).[21] Many of

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is especially likely to succeed on the merits, the burden to demonstrate irreparable harm is even lighter. *See, e.g.*, *Vaqueria Tres Monjitas, Inc. v. Irizarry*, 587 F.3d 464, 485 (1st Cir. 2009); *Worthley v. Sch. Comm. of Gloucester*, 652 F. Supp. 3d 204, 208 (D. Mass. 2023).

[20] *See In re TelexFree Securities Litigation*, No. 4:14-md-02566, 2021 WL 11604879, at *7-8 (D. Mass. Apr. 21, 2021) (plaintiffs failed to support with evidence claim that irreparable harm "may" occur); *Charlesbank Equity Fund II v. Blinds To Go, Inc.*, 370 F.3d 151, 162-63 (1st Cir. 2004) (nothing in evidentiary record suggested "anything resembling a realistic prospect of irreparable harm"); *Augusta News Co. v. News Am. Pub. Inc.*, 750 F. Supp. 28, 32-33 (D. Me. 1990) ("bare conclusory assertions of Plaintiff's president" contradicted by record evidence).

[21] *See also* Brown Decl. ¶ 13 (*Commonwealth* Doc. No. 6-34; *AAU* Doc. No. 2-5) ("At a 15%

these clinical trials will be impossible to restart. *See, e.g.*, Harvard Decl. ¶ 17 (*AAU* Doc. No. 2-14); GW Decl. ¶ 17.

2. *Harm to research more broadly*: If the Notice goes into effect, existing research projects at leading institutions will immediately be paused, delayed, curtailed, or cancelled. *See, e.g.*, Washington State Univ. Decl. ¶ 16 (*Commonwealth* Doc. No. 6-40) ("With the mass loss of facilities, employees, and staff that will result from NIH's guidance, WSU would be functionally unable to proceed with many of the life-saving research projects that are currently the subject of NIH's various grants."); Morehouse Decl. ¶¶ 13-14; Univ. of Chicago Decl. ¶ 11; Colorado State Univ. Decl. ¶ 12 (*Commonwealth* Doc. No. 6-10); Duke Decl. ¶¶ 8-10; Rutgers Decl. ¶ 11 (*Commonwealth* Doc. No. 6-27; *AAU* Doc. No. 2-25). And the Rate Change Notice will affect not just existing grants, but also budget decisions institutions are *currently making* about future grants. *See* Caltech Decl. ¶ 13 (*AAU* Doc. No. 2-7); Columbia Decl. ¶ 14 (*AAU* Doc. No. 2-10); Tufts Decl. ¶ 11 (*AAU* Doc. No. 2-27). At a 15% rate, research institutions across the country will be unable to cover F&A costs for projects that are yet to begin; they will thus need to take on fewer research projects or scale them back, irreparably harming the continued pace of scientific development in this country. *See* GW Decl. ¶ 8; Univ. of Minn. Decl. ¶¶ 11-12; Meharry Decl. ¶ 18.

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indirect cost rate, many of Brown's current research projects and clinical trials will be forced to cease abruptly."); Univ. Nevada, Las Vegas Decl. ¶¶ 7-8 (*Commonwealth* Doc. No. 6-37) ("ongoing clinical trials . . . would be severely diminished by the [Rate Change Notice]"); Univ. Vermont and State Agric. Coll. Decl. ¶ 10 (*Commonwealth* Doc. No. 6-38) ("As the state's only research university and university affiliated hospital/health network, declines in NIH indirect support for clinical trials facilities will lessen our ability to provide medical advancement to the people of Vermont.").

3. *Deprivation of other patient care*: Due to financial constraints, many NIH funding recipients will be forced to alter patient care programs. As the government recognizes (Opp. 26), only "some" of Plaintiffs' members anticipate being able to "cover obligations with other funds and fund near-term operation deficits from reserves." Indeed, many lack access to or are prohibited from drawing from endowments or other funding sources to fill their immediate funding gap. *See, e.g.*, Univ. of Kansas Decl. ¶ 18; CMU Decl. ¶ 18 (*AAU* Doc. No. 2-8); Univ. of Oregon Decl. ¶ 20 (*AAU* Doc. No. 2-20). And even for institutions that can redirect funds, doing so will force sacrifices elsewhere, including necessary cuts in patient care. As Dr. Gyongi Szabo, the Chief Academic Officer at Beth Israel Deaconess Medical Center and Beth Israel Lahey Health, put it, it is "not an exaggeration to say that patient care will suffer from the NIH's proposed funding reduction and that such reduction could even cause the avoidable loss of patients' lives." BIDMC Decl. ¶ 7; *see* Univ. of California Decl. ¶ 20 (*Commonwealth* Doc. No. 6-9; *AAU* Doc. No. 2-6); Brown Decl. ¶ 18. This harm will be particularly severe in underserved areas, where institutions like Morehouse College of Medicine and Meharry Medical College are often the only providers of critical, lifesaving care and will be forced to redirect resources away from patients. Meharry Decl. ¶ 11; Morehouse Decl. ¶¶ 11-12.

4. *Negative impacts to research buildings, supplies, and materials*: Without NIH funding to cover F&A costs, research institutions will immediately cancel or delay capital improvement and building projects, terminate leases, and allow research equipment and materials to deteriorate or be destroyed. For example, Beth Israel Deaconess Medical Center will need to "terminate its leases for laboratory buildings" immediately. BIDMC Decl. ¶ 5. Michigan State University and Henry Ford Health will "likely" pause or abandon their joint construction of a new $330 million

research facility in Detroit that will house 80 research terms and create nearly 500 new jobs "support[ing] innovative research efforts in cancer, cardiovascular, and neurosciences." Michigan State Univ. Decl. ¶ 13 (*Commonwealth* Doc. No. 6-24; *AAU* Doc. No. 2-19); *see also* BIDMC Decl. ¶ 6; Vanderbilt Decl. ¶ 13 (*AAU* Doc. No. 2-29); MIT Decl. ¶ 14 (*AAU* Doc. No. 2-17); Northwestern Decl. ¶ 8. Such losses are irreparable.

5. *Degradation of human capital*: Institutions will immediately be forced to lay off trained and highly skilled researchers and support personnel—a loss of human capital that can never be fully replaced. The Morehouse School of Medicine, for instance, "will quickly need to impose a hiring freeze" and "lay off approximately 66 employees," including "not only research, but also clinical staff." Morehouse Decl. ¶ 11. The University of Florida will need to reduce critical research staffing by an estimated 45 individuals. Univ. of Florida Decl. ¶ 14 (*AAU* Doc. No. 2-13); *see also, e.g.*, Tulane Decl. ¶ 5; Brown Decl. ¶ 13; Univ. of Penn Decl. ¶ 19 (*AAU* Doc. No. 2-21). That loss of human capital also irreparably harms economies and communities.

6. *Threats to continued operations*: Finally, for some institutions, the loss of F&A grant funding at negotiated rates poses an existential threat. At the Meharry Medical College, the rate cut would threaten the medical college's "stability" because researchers there also teach medical students and, if some of them are laid off, it threatens medical education and the college more generally, not just the important research projects it undertakes with NIH funding. Meharry Decl. ¶ 5. That sort of threat justifies emergency relief.[22]

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[22] As to the final two factors that the Court must consider in granting preliminary injunctive relief—the balance of the equities and the public interest—the parties agree that the factors "merge when the Government is the party opposing the preliminary injunction." *Nken v. Holder*, 556 U.S.

IV. Relief Should Apply to the Scope Requested by Plaintiffs.

The *AAMC* Plaintiffs and *AAU* Plaintiffs maintain[23] that the Court should preliminarily enjoin the government from taking any steps to implement the Rate Change Notice in its entirety for all grant recipients, rather than limiting relief either to the Plaintiff States or to members of the Plaintiffs' organizations as the government suggests.[24] "[W]hen a reviewing court determines that agency regulations are unlawful, the ordinary result is that the rules are vacated—not that their application to the individual petitioners is proscribed." *Victim Rights Law Center v. Cardona*, 2021 WL 3516475, at *1 (D. Mass. Aug. 10, 2021) (citation omitted). A preliminary injunction against implementation of the Rate Change Notice as a whole would reflect the relief Plaintiffs would receive at the end of this case.

Further, the *AAU* and *AAMC* Plaintiffs maintain that there are compelling equitable reasons to enjoin the implementation of the Notice in its entirety. The proposed Notice will have a substantial detrimental effect nationwide. *See* Tran Decl. ¶ 19. "[O]ne of the recognized bases for an exercise of equitable power was the avoidance of 'multiplicity of suits.'" *Trump v. Hawaii*, 585 U.S. 667, 717 (2018) (Thomas, J., concurring) (quoting Samuel L. Bray, *Multiple Chancellors:*

418, 435 (2009); Opp. 6. And, here, the analysis is easy. "[T]here is a substantial public interest 'in having governmental agencies abide by the Federal laws that govern their existence and operations.'" *League of Women Voters v. Newby*, 838 F.3d 1, 12 (D.C. Cir. 2016) (quoting *Washington v. Reno*, 35 F.3d 1093, 1103 (6th Cir. 1994). Courts readily conclude that the public "benefit[s] from ensuring public health and safety." *Jones v. Wolf*, 467 F. Supp.3d 74, 94 (W.D.N.Y. 2020). And the Federal government faces no "harm from an injunction that merely ends an unlawful practice or reads a statute as required." *R.I.L-R v. Johnson*, 80 F. Supp. 3d 164, 191 (D.D.C. 2015) (quoting *Rodriquez v. Robbins*, 715 F.3d 1127, 1145 (9th Cir. 2013)).

[23] The 22 Plaintiff States have not requested nationwide relief, and instead have requested relief "within Plaintiff States." *Commonwealth* Doc. No. 4 at 3.

[24] Plaintiffs would not object to the Court's treating their motions as requesting preliminary injunctive relief under Federal Rule of Civil Procedure 65(a).

Reforming the National Injunction, 131 Harv. L. Rev. 417, 426-27 (2017)). Courts should also avoid issuing an injunction that "lop[s] a state off" thereby "entirely undercut[ting] that injunction's effectiveness." *DraftKings Inc. v. Hermalyn*, 118 F.4th 416, 424 (1st Cir. 2024).

Here, in addition to the 22 States that are Plaintiffs,[25] Plaintiff AAMC has over 650 member institutions—members whose research, educational, and clinical activities span every State, Puerto Rico, and the District of Columbia; Plaintiff AAU has 71 member institutions; Plaintiff APLU has over 230 member institutions across the United States; and Plaintiff ACE has nearly 1,400 member institutions. AAMC Decl. ¶ 3 (*AAMC* Doc. No. 5-1); AAU Decl. ¶ 3 (*AAU* Doc. No. 2-1); ACE Decl. ¶ 3 (*AAU* Doc. No. 2-2); APLU Decl. ¶ 3 (*AAU* Doc. No. 2-3). All those institutions are entitled to relief by virtue of their participation (either directly or through States or membership organizations) in this case. And with direct relief so broad, it would create needless confusion to try to carve out institutions not already covered. Judicial economy also counsels in favor of nationwide relief here to stave off the raft of lawsuits that would surely follow as others seek to protect themselves from the existential threat visited by the Notice.

Collaboration across research institutions underscores the inadequacy of more tailored relief. *See* Univ. Nevada, Reno Decl. ¶ 9 (*Commonwealth* Doc. No. 6-37); Univ. of Massachusetts, Amherst Decl. ¶ 36 (*Commonwealth* Doc. No. 6-19); Princeton Decl. ¶ 7 (*Commonwealth* Doc. No. 6-26; *AAU* Doc. No. 2-22); Univ. of Rhode Island Decl. ¶ 21 (*Commonwealth* Doc. No. 6-33).

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[25] The government claims that Arizona, Hawai'i, and North Carolina are not entitled to relief because they did not submit declarations in the TRO motion that the State Plaintiffs filed on an emergency basis one business day after the Rate Change Notice issued. *Commonwealth* Doc. No. 73 at 29. The impact on State Plaintiffs is self-evident from the Rate Change Notice and the declarations submitted with the State Plaintiffs' motion, but in any event, the government's concerns are moot. *See* Supp. Dirks Decl. Ex. 50 (Hawai'i); 51 (North Carolina); 52-53 (Arizona).

An injunction that extended only to members of Plaintiffs' organizations would not adequately remedy the Rate Change Notice's harm because other institutions with which those members collaborate would be unprotected and possibly unable to fulfill their critical part of, or cover their share of costs for, the coordinated research project.

Finally, it bears emphasis that the government is poorly positioned to complain about extending relief to all affected institutions when it is the government itself that tried to superimpose a one-size-fits-all solution in an area where both longstanding regulations and statutes express a decided requirement for institution-specific negotiated rates. Having unlawfully deviated from that institution-specific regime by lumping every grant recipient together, the government can hardly complain when the remedy for its violation is equally comprehensive.

CONCLUSION

Plaintiffs respectfully urge this Court to maintain the temporary restraining order.

[signatures on following page]

Dated: February 18, 2025

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CERTIFICATE OF SERVICE

Counsel for Plaintiffs certify that they have submitted the foregoing document with the clerk of court for the District of Massachusetts, using the electronic case filing system of the Court. Counsel for Plaintiffs hereby certify that they have served all parties electronically or by another manner authorized by Fed. R. Civ. P. 5(b)(2).

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CERTIFICATE OF SERVICE

I hereby certify that this document will be served on all registered parties through the court's CM/ECF system.

/s/ John P. Bueker
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