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

[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.

[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

21. 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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Dated: February 18, 2025

EXHIBIT 1

DECLARATION OF ERIN J. ADAMS

I, Erin J. Adams, hereby declare:

1. I am the Vice Provost for Research for the University of Chicago ("UChicago"), a position I have held since September 2023. As Vice Provost for Research, I have oversight of UChicago's office for University Research Administration, Research Safety, and Research Computing and am responsible for managing our grant portfolio as well as research compliance. In addition to my current role, I am the Joseph Regenstein Professor of Biochemistry and Molecular Biology and have been a Professor at UChicago for 19 years.
2. As the Vice Provost for Research, I have personal knowledge of the matters set forth below or have knowledge of the matters based on my review of information and records gathered by my staff.
3. I am providing this declaration to explain certain impacts of National Institutes of Health ("NIH") Notice Number NOT-OD-25-068, *Supplemental Guidance to the 2024 NIH Grants Policy Statement: Indirect Cost Rates*, which purports to immediately reduce indirect cost reimbursements to 15%.
4. The NIH funding that UChicago receives funds critical biomedical research that leads to life-saving advances that directly impact the lives of millions of Americans. Below are examples of the impact UChicago research makes:
    a. Cutting-edge research in areas such as pediatric and adult cancer, diabetes, cardiovascular disease, Alzheimer's and aging, and potential treatments for adults and children with a variety of difficult-to-treat diseases and disorders. These include:
        i. Development of the first and only efficacious intervention for individuals with primary progressive aphasia (PPA), a dementia caused by Alzheimer's disease

or related neurodegenerative conditions that impair communication and quality of life.

ii. One of UChicago's active, national clinical trials, 'RADIANT U54', is the leading study in the world in rare and atypical diabetes, which impacts an estimated 300,000 Americans. There are more than 2,000 research participants enrolled across the country.

iii. UChicago has 1,082 federally funded IRB-approved human subjects research studies, of which 111 are focused on disorders that affect children. Of those, 73 are clinical trials for childhood diseases. For example, UChicago is a leader in researching neuroblastoma, an often fatal cancer most commonly affecting children under five years of age. UChicago is currently a participating site in twelve NIH-funded clinical trials focused on understanding and treating this disease. UChicago is also active in NIH-funded clinical trials focused on treating leukemia, lymphoma, and germ cell tumors in children.

b. UChicago's basic research funded by the NIH provides the foundation upon which new therapies and technologies are based. For example, our research into:

i. Engineering hybrid nanomaterials that can be used for biomedical imaging for early diagnosis of cancers as well as targeted delivery of potent drugs for improved cancer therapy.

ii. Elucidating virulence and antibiotic resistance regulation in human pathogens with implications including targeted treatment of antibiotic resistant bacteria in hospitals.

iii. Studying new chemical and biological phenomena that lead to pathological phenotypes and using this knowledge to guide the development of next-generation clinical therapies that harness the immune system to treat cancer, auto-immunity, and infection.

iv. Decoding mutations in human cancers and multi-parameter mapping of human genetic variation and how that is associated with human diseases.

c. UChicago Medicine's Comprehensive Cancer Center (UCCCC), a National Cancer Institute (NCI) designated Cancer Center, supports research relevant to cancer origins, development and spread, prevention, treatment and cures for cancers that affect millions of Americans and their families. These include:

i. A UCCCC initiative known as AI.Oncocure, which takes advantage of advanced artificial intelligence/computational capabilities, X-ray crystallography, and structural chemistry to discover "first-in-class" cancer-targeting compounds to be developed into cancer-treating therapeutics.

ii. Research utilizing artificial intelligence and machine learning approaches to improving cancer care, which leverages UChicago's world-class advanced computing resources and supporting infrastructure for data storage, security, and privacy.

iii. Support of over 600 open clinical trials where patients are receiving new therapies, including approximately 147 interventional trials, of which 138 are therapeutic, through the National Clinical Trials Network, a program run by the NCI to support large-scale cancer clinical trials across the U.S. It brings together researchers, hospitals, and cancer centers to test new treatments,

improve patient care, and advance cancer research. The network focuses on developing innovative therapies, comparing existing treatments, and studying cancer prevention and screening strategies.

5. This cutting-edge research is performed in specialized laboratory space. Maintenance of laboratory buildings equipped with high-tech facilities to support our researchers constitutes a considerable proportion of indirect costs.

6. In addition to supporting UChicago facilities, indirect costs also support staff with the expertise necessary to administer grant proposals and awards, ensure protections for humans involved in clinical trials and animals in research, oversee research laboratory safety and research integrity, and provide cybersecurity for our information technology networks, ensuring that sensitive data (such as identifiable health information) is appropriately protected.

7. UChicago biomedical research is supported by $1,012,945,241 in active award authorizations from the NIH. For UChicago's fiscal year that ended June 30, 2024, NIH reimbursed UChicago for approximately $338 million in research expenditures: $241 million of which was for direct cost charges, and $97 million for indirect costs.

8. UChicago has a Negotiated Indirect Cost Rate Agreement ("NICRA") with the Department of Health and Human Services, ("DHHS") effective as of 04/01/2024. The Indirect Cost ("IDC") Rate in the UChicago's NICRA is 64% of modified total direct costs for on-campus research activity.

9. UChicago negotiates its indirect cost rate with the DHHS every 4-5 years using a detailed and prescriptive methodology outlined in federal regulation. UChicago is also subject to rigorous annual audits pursuant to federal regulation, which help ensure appropriate reimbursement of its direct and indirect costs.

10. NIH's reduction of UChicago's on-campus IDC rate would eliminate approximately $52 million in reimbursement for indirect costs that would support NIH research over the next 12 months. The loss of these funds would immediately impact UChicago's ability to draw critical funds used to pay expenses associated with ongoing maintenance of research buildings and laboratories, purchasing and maintenance of high-tech specialized equipment (such as our Titan Krios cryo-electron microscope, used to visualize protein complexes and dynamics), and support our many core facilities (i.e., shared facilities that provide UChicago biomedical researchers with specialized services and technologies) where researchers perform their experiments and graduate students are trained, among other things.
11. As stated above in 4.c.iii, UChicago currently supports over 600 open clinical trials. Clinical trials require important safety and compliance monitoring to ensure patient safety, data security, and documentation necessary for approval of new treatments. Indirect cost rate reduction will directly impact UChicago's ability to run these clinical trials and will inevitably result in their curtailment, directly impacting the participating patients and their families. Longer term, this would likely negatively impact the translation of promising therapies identified in these trials to the clinic.
12. In addition to the direct economic and scientific impact discussed above, I believe the proposed rate change will materially diminish the talent pipeline that research universities generate. In my view, a 15% indirect cost rate cap would likely result in losing talented scientific faculty to other countries that are investing heavily in research. Furthermore, these cuts are likely to impact universities' ability to train graduate students, as universities would likely limit enrollment. This would mean fewer qualified candidates to be the United States' future academic research leaders, biomedical entrepreneurs and research leads in the biotechnology

and pharmaceutical industries. I believe that curtailment of this pipeline will leave the United States less competitive across all these sectors.

13. If implemented, the NIH reduction in the IDC to 15% would result in a material reduction in research funding for UChicago. UChicago makes long-term, highly-specialized infrastructure investments in the research it supports in connection with its receipt of NIH grants. A mid-stream reduction of indirect costs would create immediate budget deficits.

14. The majority of UChicago's endowment is derived from philanthropic gifts. The use of these gifts is often legally restricted and must be used for designated purposes. Therefore UChicago is unable to use the majority of its endowment funds to offset funding losses caused by a reduced IDC rate.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed this 18th day of February, 2025, in Chicago, Illinois.

Name: Erin J. Adams

Vice Provost for Research

The University of Chicago

EXHIBIT 2

DECLARATION OF JENNIFER LODGE

I, Jennifer Lodge, declare as follows:

1. I am the Vice President for Research & Innovation and Professor of Molecular Genetics and Microbiology at Duke University ("Duke") in Durham, North Carolina. I have held that position since January 2022. Before coming to Duke, I served as the Vice Chancellor for Research and Senior Associate Dean for Research for the School of Medicine at Washington University in St. Louis. My research has been funded continuously by NIH for more than two decades.

2. As Vice President for Research & Innovation, I have personal knowledge of the contents of this declaration, or have knowledge of the matters based on my review of information and records gathered by Duke personnel, and could testify thereto.

3. Duke University receives substantial annual funding from the National Institutes of Health ("NIH"). In Duke's 2024 fiscal year ("FY2024"), which ran from July 1, 2023 through June 30, 2024, Duke held approximately 2,800 individual NIH awards, providing expenditures of approximately $610M in direct costs and $258M in indirect costs (also known as "Facilities and Administrative costs" or "F&A costs"). An indirect rate cap of 15% on all NIH awards to Duke in FY2024 would have resulted in approximately $193M of lost research funding, and a reasonable prediction is that a 15% cap on NIH F&A costs would have immediate impacts of a similar magnitude. These vital funds supported groundbreaking biomedical research that Duke committed to the NIH to perform and that the NIH committed to fund. These NIH awards were made after significant evaluation, are highly competitive, and the research budgets are carefully reviewed by the NIH prior to making the award. Duke also spends substantial funds of its own to further support the NIH sponsored research. In FY2024, Duke provided approximately $239M of its own funds

to support Duke research which, proportional to Duke's sponsored research portfolio, is approximately $186M of Duke funds to support NIH-associated research.

4. The funding that Duke receives from the NIH supports critical and cutting-edge medical research, which millions of Americans benefit from and depend on. For example:

a. Duke is a world leader in cancer research, including cancer prevention and control, precision cancer medicines, cancer detection, neuro-oncology, and immuno-oncology. NIH-funded cancer research projects at Duke range from basic science studying the cells that cause cancer to active clinical trials of new therapies that change the outcome from death sentences to curable diseases. Here are just two examples of cancer research supported over the years by NIH funding to Duke:

i. Metastatic breast cancer: Investigators at Duke have developed an exciting new treatment for patients with metastatic breast cancer for whom all traditional treatments have failed. Elacestrant was approved by the FDA in 2023 and is showing enormous promise in patients.

ii. Brain cancer: Just this year the FDA approved a new drug specifically targeted against brain tumors called low-grade gliomas. The drug, vorasidenib, delays the progression of low-grade gliomas with specific genetic mutations, representing one of the most successful therapies in prolonging survival of brain tumor patients.

b. Duke's pediatrics research is giving kids a better chance at a healthy life. Duke researchers are finding new ways to help babies, children, and teenagers overcome serious illnesses and Duke is a leader in the development of treatments for inherited diseases that have historically been untreatable. Duke's NIH-funded research has led to advancements

in Pompe's disease, thymus transplantation in DiGeorge syndrome, and Krabbe's disease. Duke leads the NIH-funded Pediatric Trials Network (PTN), which focuses on making medications safer and more effective for all children. Under the Best Pharmaceuticals for Children Act (BPCA), the PTN works to provide the Food and Drug Administration (FDA) with information to inform label changes with the necessary information to prescribe the most appropriate doses of the medications to children. As a result of the research conducted by the PTN to date, prescribing information and label changes have been made for twenty medications and two devices. Duke's sustained work on NIH-funded pediatric studies means more children across America will grow up healthy and reach their full potential.

c. At this critical time, NIH-funded Duke researchers are tackling diseases like Alzheimer's Disease and other diseases of the brain and the nervous system, such as epilepsy, stroke, and cerebral palsy. To capitalize on emerging technologies, the Duke-UNC Alzheimer's Disease Research Center, a national leader in developing early diagnostic approaches, is developing an understanding of Alzheimer's root causes. As the population in the United States ages, this critical research will help older Americans stay healthy longer through more effective management strategies, new diagnostics, and new therapeutics that will treat age-related diseases impacting millions of families.

d. Duke is a leader in designing and implementing innovative clinical trials and speeding drugs to market. Duke's physician-scientists expertly manage all aspects of studies, from first in human to marketable drugs. For example, Duke is a leader in an NIH-funded cholesterol-lowering study, (the PREVENTABLE Study), which will evaluate the impact of statin drugs in 20,000 community-dwelling adults aged ≥75 years. PREVENTABLE represents a multi-agency collaboration involving the NIH, the National

Patient-Centered Clinical Research Network (PCORnet), the Veterans Affairs system, and independent health systems to address the leading cause of death in adults.

e. NIH-funded research at Duke is developing a universal flu vaccine to protect against all flu strains and eliminate the need for annual shots with varying effectiveness. In addition, Duke researchers are working hard on furthering our understanding of avian flu and developing a vaccine, which is especially crucial now as avian flu spreads to livestock and humans. This NIH-funded research is essential to our national security to protect our food supply and public health.

5. Facilities and Administrative costs are essential for research. The NIH's proposal to significantly cut F&A cost reimbursement to 15% would devastate the important research described in Paragraph 4. Duke faithfully accounts to the Department of Health and Human Services ("HHS") for these F&A expenses, and only costs that are directly allocable to sponsored research facilities and administration are included. Duke's F&A rate is negotiated with HHS approximately every four years and the proposed rate is carefully examined and audited by the Federal government. Duke relies on its longstanding partnership with the Federal government, including HHS and NIH, to support the actual costs that are recovered through Duke's F&A rate to complete funded research and meet the associated federal requirements.

6. Facility and Administrative (F&A) costs include costs such as:

a. operating and maintaining research facilities with specialized heat, lighting, vacuum, and purified water systems, as well as hazardous waste disposal and security to ensure that biohazards, radioactivity and chemicals are securely used, stored and disposed;

b. upgrading existing lab facilities where NIH sponsored research occurs, to ensure that the plumbing, electric, HVAC, and safety facilities in our laboratories are up to code and safe for Duke researchers and support staff;

c. building new facilities to perform NIH sponsored research;

d. information technology ("IT") networks, high performance computing facilities, and data storage facilities, that enable researchers to analyze large amounts of data, store health data in a secure environment when required, and share certain data to enable other researchers as required by the NIH;

e. over 75 core service facilities, which include high-end equipment and facilities that no single investigator or project could afford to purchase and maintain, and provide efficiencies across NIH-funded projects; and

f. offices that have been put in place to fulfill federally mandated requirements, such as human subject and animal protections, conflict of interest, data security, scientific integrity, financial accounting and auditing, and export controls.

7. Cutting edge biomedical research that is performed at Duke, such as described in Paragraph 4, requires:

a. highly specialized equipment that requires procurement, maintenance, repair and replacement partially supported by F&A cost reimbursement. This includes equipment such as chemical hoods, centrifuges, PCR machines, electrophoresis equipment, microscopes, genomic sequencing equipment, chromatography systems, autoclaves, explosion-proof refrigerators and freezers, incubators, and mass spectrometers.

b. advanced computational resources, involving high-performance and ultra high-speed computing, secure and protected data networks which are essential for the protection

of data. Clinical and genomic data is stored in highly secure environments to ensure the privacy of individuals, and many NIH research projects require secure access to Duke Health patients' clinical and genomic data.

c. managing and conducting clinical trials requires access to appropriate space, clinical equipment and laboratories to perform testing and assessments, and access to secure data environments, networks, and data storage. Duke maintains Good Manufacturing Practice (GMP) facilities to ensure the safe formulation and production of investigational drugs and biologics for human use. Clinical trials also undergo rigorous oversight by program assurance personnel to ensure that the trial is conducted according to approved protocols and requirements.

8. Physical space is one of the largest components of F&A costs, and the amount of space available to researchers has a direct and obvious impact on the amount of research that can be conducted at Duke. A reduction of the reimbursement of the negotiated F&A rate would jeopardize needed upgrades and maintenance of research space, putting the funded research at risk. A roof or pipe leak can destroy hundreds of thousands of dollars of equipment, on-going experiments, and irreplaceable samples. Duke currently has several research buildings that house NIH-funded researchers that are scheduled for major infrastructure upgrades and would have to be shuttered without these upgrades. As a direct result of the proposed NIH F&A rate cap, Duke has halted renovation planning for five research facilities that would be decommissioned over the next two years if a 15% F&A rate is applied. A reduction of functional and safe laboratory space would significantly impede the ability of Duke's researchers to carry out NIH-funded research projects, creating great harm to Duke's research mission.

9. In addition, F&A costs fund the administration of NIH awards, including staff who ensure compliance with a vast number of regulatory mandates from agencies such as NIH. These mandates serve many important functions, including protecting human and animal subjects involved in research, ensuring research integrity, properly managing and disposing of chemical and biological agents used in research, managing financial conflicts of interest, administering and auditing funds, protecting intellectual property, preventing export controlled knowledge from being inappropriately accessed by foreign adversaries, and providing the high level of cybersecurity, data storage, and computing environments mandated for regulated data.

10. If—contrary to the 61.5% indirect cost rate Duke has negotiated with the Federal government—the indirect cost rate is reduced to 15%, this reduction will have deeply damaging effects on Duke University's ability to conduct research from day one. Duke's NIH-funded research expenditures have increased annually for each of the past four years and a 15% F&A rate cap on all NIH awards to Duke in FY2024 would have resulted in approximately $193M of lost research funding. Most critically, an F&A rate cap will necessarily and immediately result in large staffing reductions across the board. Duke has estimated that these reductions in F&A recovery would result in the loss of hundreds and, very likely, thousands of jobs in the coming months, which would harm Duke's ability to conduct currently funded NIH projects and ensure that the research is done with safety, integrity and compliance to the federal regulations and requirements. These specially trained personnel cannot necessarily be rehired in the future, and to even attempt to replace them would require substantial additional effort and cost in recruitment and training, which would in turn take time and money away from other work.

11. Duke University has for decades worked closely with the Federal government on research budgeting and planning in our shared goal of producing world-class research. Operating budgets

are built on an estimate of both direct and indirect sponsored funding to plan for annual staffing needs (*e.g.*, post-docs, PhD students, and other research staff), infrastructure support (*e.g.*, IT networks, regulatory compliance, and grant management support), equipment purchases, and facility operation and maintenance.

12. Disruptions to Duke's research will negatively affect the Durham area, the Research Triangle region, and the State of North Carolina. Duke is the largest employer in Durham County and the second largest private employer in North Carolina. Approximately 47,000 North Carolina residents are directly employed by Duke University and Duke University Health System—and both entities collaborate with state and local partners, including North Carolina state universities and nonprofit research enterprises such as the Research Triangle Institute (RTI), to help solve regional challenges through joint research and innovation. Duke's research also fuels spending in the regional economy, including by driving discoveries that launch new ventures, attract private investment, and make a positive social impact. Duke personnel and inventions have launched 126 active start-ups which raised over $2.4B in funding in the past five years. Over 65% of Duke start-ups in the past five years have been located in North Carolina and a massive reduction in Duke's research budget would immediately and seriously jeopardize these contributions to the local region.

13. Finally, slowdowns or halts in research by Duke and other American universities creates a serious risk that competitor nations that are maintaining their investments in research will surpass the United States on this front, threatening both our Nation's national security, research and development excellence, and its economic competitiveness. Offers of employment to our NIH-funded investigators from institutions in other countries will be highly attractive, and we will lose our best and brightest scientists to other nations.

14. While Duke maintains an endowment, it is neither feasible nor sustainable for Duke to use endowment funds or other revenue sources to offset shortfalls in indirect cost recovery, for several reasons:

a. The majority of Duke's endowment—around 72%—is restricted to specific donor-designated purposes, such as scholarships, faculty chairs, and academic programs. Duke is not legally permitted to use those funds to cover research infrastructure costs.

b. In addition, those endowment funds were donated to Duke with the intention of permanently funding Duke's activities. Fiduciary standards limit the amount of funds available to be spent on the designated purposes to approximately 4-6% per year of the value of the endowment depending on investment performance.

c. As a non-profit institution, Duke reinvests nearly all of its revenue into mission-critical activities, leaving little margin to absorb unexpected funding gaps.

15. The immediate impacts of a proposed 15% indirect rate cap are substantial and irreversible. The short-term budget impacts of the proposed 15% rate cap would require urgent action at Duke to ensure financial stability and would result in the loss of lifesaving research, current and future scientists and trainees, and international competitiveness in health sciences. In addition, the Research Triangle region and North Carolina would experience a very negative economic impact.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on February 18, 2025, at Durham, North Carolina.

/s/ Jennifer Lodge

Jennifer Lodge

EXHIBIT 3

DECLARATION OF THE GEORGE WASHINGTON UNIVERSITY

I, Robert H. Miller, PhD, declare as follows:

1. I am the Interim Vice Provost for Research and the Vice Dean for Research and Academic Affairs in the School of Medicine and Health Sciences at The George Washington University ("GW" or "the University") in Washington, D.C. I have held the Interim Vice Provost for Research position since August 2024 and previously served as the Vice President for Research at GW from August 2018 to August 2020. Before joining GW in 2014 as the Senior Associate Dean for Research in the School of Medicine and Health Sciences, I was the Vice President, Research & Technology Management at Case Western Reserve University.

2. As Interim Vice Provost for Research, I have personal knowledge of the contents of this declaration, or have knowledge of the matters described herein based on my review of information and records gathered by GW personnel, and could testify thereto.

3. GW receives substantial annual funding from the National Institutes of Health ("NIH"). For fiscal year 2024, GW had approximately $87 million in NIH funds, approximately $21 million in indirect costs funded by NIH, and approximately 150 active projects funded by NIH.

4. The funding GW receives from NIH supports critical and cutting-edge biomedical research, which millions of Americans benefit from and depend on. For example:

   a. The University's cancer research includes enabling, targeting, and suppressing the disease at the earliest stages. The GW Cancer Center boasts complex and innovative research facilities dedicated to cancer discovery through interdisciplinary collaboration and partnerships with scientists and clinicians throughout the GW community. These collaborations and partnerships facilitate

novel approaches to cancer diagnosis and treatment in areas such as clinical and translational oncology and cancer biology and immunology. Additionally, GW researchers focus on cancer prevention via understanding how exposure related smoking, vaping and marijuana usage can be prevented.

b. Through NIH funding, GW researchers are making great strides in neuroscience and associated disorders and diseases. For example, a GW researcher is an internationally recognized expert in the care of patients with myasthenia gravis, a chronic autoimmune neuromuscular disease characterized by varying degrees of weakness of the skeletal (voluntary) muscles of the body. His research has been funded by the NIH since 1993 and focuses on understanding the biology and pathogenesis of myasthenia gravis. Other GW researchers are doing groundbreaking research that could be the foundation for novel therapeutics for diseases such as Multiple Sclerosis and Neuroinflammation. Other researchers focus on the epidemiology and prevention of Alzheimers and other causes of dementia.

c. GW advances, develops, and implements innovative practical methods for the design, execution, data monitoring, analyses, and reporting of clinical studies and for the conduct of long-term cohort studies. Current projects include the design and analyses of studies that focus on patient-focused outcome measures that integrate efficacy and safety, personalized treatment, cost-effectiveness analyses, response-adaptive randomization, and pragmatic evaluation of diagnostic technologies. Other studies involve longitudinal analyses of data over many years to understand the progression of disease outcomes and

prevention of adverse consequences like death and disability. An example of both of these types of studies work is the impactful research we have conducted on maternal fetal welfare. The Maternal Fetal Medicine Units Network ("MFMU") has existed since 1986, and GW serves as the data coordinating center and one of 14 clinical centers. The MFMU has a total of 61 studies (33 randomized trials and 28 observational studies) that have been completed or are in process. As of January 2024, MFMU investigators have made over 640 presentations and published over 400 peer-reviewed manuscripts. The major aims of the MFMU are to reduce the rates of preterm birth, fetal growth abnormalities, newborn morbidity, and maternal complications of pregnancy; secondarily to evaluate maternal and fetal interventions for efficacy, safety, and cost-effectiveness; and ultimately to assess the long-term consequences in terms of health and wellbeing over a lifetime.

d. Another example is a large clinical trial – the Glycemia Reduction Approaches in Diabetes: A Comparative Effectiveness Study ("GRADE"), --which compares the effectiveness of the four most commonly used therapies in over 5,000 participants with Type 2 Diabetes over a period of up to ten years. The study is publishing seminal papers to inform clinicians of which combination of diabetes medications achieves the best glycemic control, has the fewest side effects, and is most beneficial for overall good health in terms of preventing the adverse consequences of diabetes (death, vision loss and loss of limbs). This work builds on many years of GW research in prevention of adverse consequences of both Type I and Type II diabetes which have led to current

recommendations not only on therapy but also lifestyle interventions (the "Diabetes Prevention Program") to prevent diabetes.

e. GW's Office of Clinical Research ("GW OCR") provides high-quality support for the efficient execution and management of impactful clinical research while ensuring research participant safety. GW OCR partners with faculty and investigators to coordinate services for:

i. Researchers, by assisting with study start up and quality

ii. Patients, by providing information on ongoing clinical studies

iii. Sponsors, by helping network GW investigators

iv. Training, Education, and Resources

5. Indirect costs are essential for supporting this research. The NIH's proposal to cut indirect cost rates to 15% would end or seriously jeopardize all of the research projects described in paragraph 4 as well as other NIH-funded research projects at GW.

6. Indirect costs include the creation and maintenance of critical infrastructure and facilities required to meet the current technical requirements of research, as well as the procurement and maintenance of equipment necessary to conduct such research. Equipment needed for this ground-breaking research goes beyond the standard lab equipment and may be very specialized, such as certain equipment used in GW's Nanofabrication and Imaging Center and a genomics core. Infrastructure also includes cyber infrastructure and high-performance computing allowing researchers to analyze data and model future outcomes. Without this equipment and infrastructure, GW researchers cannot conduct this research.

7. For example, with respect to some of the areas of research described in Paragraph 4

a. With robust programs in cancer biology; cancer control; cancer engineering and technology; and cancer immunology and microbial oncology, the GW Cancer Center facilities support medical lab functions that require significant lab equipment. Cell sorting/isolation, cell therapies and molecular histology and characterization are core activities of the GW Cancer Center. This work is further supported by the GW Nanofabrication and Imaging Center previously mentioned.

b. The studies on neurological diseases utilize a novel approach to assess the efficacy of drug treatment using high-resolution video recording and specialty-designed computer software analytic tools. This novel approach allows the physician to assess the progress of the patient without the need for the patient to travel to the physician's office. This novel tele-health program is particularly important in rural areas that may be underserved by local medical facilities.

c. The coordination and facilitation of clinical research requires a large investment in systems and infrastructure to safely and securely collect, manage, analyse, transfer and store electronic data. Systems like Encore, Florence and REDCap aid in the compliant use of human subjects data.

8. Physical space costs are one of the largest components of indirect costs which are elevated due to our location, and the amount of space available to researchers has a direct and immediate impact on the amount of research that can be done at GW. GW's urban location poses unique opportunities and challenges. To maximize space utilization, GW has many shared spaces and facilities that require continuous updating to stay on pace with the novel research taking place by multiple investigators. With the reduction in indirect cost funding, GW will be unable to

properly maintain existing equipment and/or would have to reduce procurement of new equipment limiting the type and quantity of research our investigators can pursue. This funding is essential to the maintenance and development of advanced computing and cyber capabilities needed to protect intellectual property and provides support for research security, e.g. data management, security and analysis.

9. In addition, indirect costs fund the administration of awards, including staff who ensure compliance with a vast number of regulatory mandates from agencies such as NIH.[1] These mandates serve many important functions, including protecting human and animal subjects involved in research; ensuring research integrity; properly managing and disposing of chemical and biological agents used in research; assessing, managing, and preventing financial and other types of conflicts of interest; managing funds; preventing intellectual property, technologies, or national security expertise from being inappropriately accessed by foreign adversaries; and providing the high level of cybersecurity, data storage, and computing environments mandated for regulated data. Adherence to these mandates supports a responsible and ethical approach to biomedical research and creates an environment where reproducibility and validity are of great importance.

10. Recovery of GW's indirect costs is based on predetermined rates that have been contractually negotiated with the federal government.

11. Through fiscal year 2025, the predetermined indirect cost rates are 61.5% for the GW On Campus, 26% for the GW Off Campus and the Biostatistics Center, and 36.5% for the Other Sponsored Activities.[2]

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf

[2] GW's average indirect cost rate for fiscal year 2024 was inadvertently misstated in Plaintiffs' Complaint at Paragraph 67. The Complaint states: "GWU receives significant federal funds from NIH—approximately $87 million in fiscal year 2024, at an average indirect cost rate of 24% or

12. The impact of a reduction in the indirect cost rate would be devastating. The NIH sponsors more than one-third of GW's research activity. As of fiscal year 2024, $300 million of NIH funding has been obligated to GW for active awards, spanning current and future performance periods. Of that, for fiscal year 2024, GW has received $87 million in NIH funding, approximately $66 million of which was allocated for direct costs, $22 million of which was allocated for subcontracts (which are not eligible for overhead recovery), and $21 million of which was allocated for indirect costs. Similarly, in fiscal year 2025, GW expects to receive $69 million in NIH funding for direct costs, while $22 million is allocated for indirect costs. Over the next five years, GW anticipates receiving an average of $80 million from the NIH for annual direct costs. Based on the predetermined indirect cost rate of 61.5%, which the federal government agreed upon as of March 29, 2023, GW anticipates receiving approximately $25 million in indirect cost recovery annually, based on current and projected funding levels.

13. If—contrary to what GW has negotiated with the federal government—the indirect cost rate is reduced to 15%, that would reduce the University's anticipated annual indirect cost recovery for fiscal year 2025 to $7 million, instead of the anticipated $22 million, which is a $15 million reduction.

14. This reduction will have deeply damaging effects on GW's ability to conduct research from the day the 15% indirect cost rate goes into effect. Most critically, it will necessarily and immediately result in staffing reductions across the board. For example:

a. GW's Institutional Review Board ("IRB") is charged with reviewing and managing all research involving human subjects to ensure the ethical treatment

$21 million." Compl. ¶ 67. In that sentence, "24%" should instead read "61.5%." All other allegations regarding GW in the Complaint are correctly stated.

of subjects and the protection of their privacy. Without appropriate funding for indirect costs, the University may have to reduce staffing on the IRB, which would immediately impact its ability to promptly review research projects involving human subjects. That would in turn lead to substantial delays in critical research that relies on human subjects, including projects funded by NIH.

b. Additionally, the University's Responsible Conduct of Research ("RCR") team is responsible for ensuring that all individuals engaged in the GW research enterprise understand the importance of adhering to professional standards in specific research fields as well as NIH requirements for training in ethical and responsible conduct of research. The RCR's work enables GW to produce trustworthy research results upon which peers and the general public can rely. A sudden and/or significant reduction of indirect costs will directly impact the number of staff that are dedicated to this integral part of the research ecosystem and GW's ability to support and train its research staff in the ethical and responsible conduct of research.

c. Furthermore, reduction of indirect costs will significantly hamper research administration across the board. GW will have to reduce the number of staff who support the administrative side of doing research. This will hinder proposal review/preparation and slow the review, approval, and posting of allowable charges to awards, all critical to GW's efforts as stewards of federal research funds.

15. The impact of a reduction of the indirect costs on existing awards will immediately result in a budget deficit that will have GW scrambling to cover unplanned expenses. GW will have to make significant adjustments to try to locate other sources of funding to support its research infrastructure. Cross-cutting measures will include a significant reduction in research and research administration staff and the elimination of important research and development ("R&D") projects and programs across the University, including halting studies and clinical trials which may result in safety concerns. Stalling current progress in the development of life-saving drugs and cutting technologies will impact the U.S.'s standing as a global leader in R&D. Cuts in funds for infrastructure maintenance will potentially set back the overall research environment, from existing facilities to ongoing collaborations across institutions to advance U.S. R&D and competitiveness in the world. Lastly, abruptly stopping on-going research projects is essentially throwing away the funding already put forth, particularly for long-term projects and those close to producing outcomes and results.

16. GW has for decades relied on the payment of indirect costs. And until now, it has been able to rely on the well-established process for negotiating indirect cost rates with the government to inform its budgeting and planning. Operating budgets rely on an estimate of both direct and indirect sponsored funding to plan for annual staffing needs (*e.g.*, post-docs, PhD students, and other research staff), infrastructure support (*e.g.*, IT networks, regulatory compliance, and grant management support), and facility and equipment purchases. In some cases, GW has long-term obligations—for example, tenured faculty salaries, graduate research assistants' compensation and tuition packages—and it relies on budgeted grant funding, including associated indirect cost recovery, to fulfill these commitments.

17. In addition to the immediate impacts and reliance interests described above, there are longer-term impacts that are both cumulative and cascading. The longer-term harms are vast and may negate the great strides already made in biomedical research. For example, safety issues from lack of staff/security, as well as the inability to restart clinical trials even if funding were restored, which may put the safety of human subjects at risk through the premature cessation of treatment. Temporary cessation of clinical trials may negate prior work on the trial since patient accrual, reproducibility, and validity of outcomes will be adversely affected. Longer-term effects also include limiting GW's ability: to protect sensitive data from cyberattacks; to comply with U.S. export control laws that secure certain types of information, technologies and commodities, and ensure they are not transmitted overseas to entities and individuals, including U.S. citizens, or made available to foreign nationals on U.S. soil; and to identify, manage and report conflict of interest and other support disclosures in a manner compliant with NIH policies to ensure proper stewardship of NIH funds. The lack of maintenance of lab facilities, compliance and grant management systems, and data repository and cyber infrastructure will further erode the ability to comply with regulations and meet the high standards that lead to research breakthroughs that directly affect society.

18. Disruptions to GW's research will also have negative effects in the Washington Metropolitan area, the District of Columbia, and the broader region. GW employs approximately 11,500 people, with the vast majority residing in the Washington Metropolitan area not including those employed via contractual arrangements. GW collaborates with state and local partners to help solve regional challenges through joint research and innovation. GW's research also fuels spending in the regional economy, including by driving discoveries that launch new ventures, attract private investment, and make a positive social impact. A massive reduction in GW's

research budget would immediately and seriously jeopardize these contributions to the local region.

19. Finally, slowdowns or halts in research by GW and other American universities will allow competitor nations that are maintaining their investments in research to surpass the United States on this front, threatening both our Nation's national security and its economic dominance.

20. Nor can GW cover the funding gap itself. While GW maintains an endowment, it is neither feasible nor sustainable for GW to use endowment funds or other revenue sources, such as student tuition, to offset shortfalls in indirect cost recovery, for several reasons:

a. Approximately 34% of GW's endowment is restricted to specific donor-designated purposes, such as scholarships, faculty chairs, and academic programs. GW is not legally permitted to use those funds to cover research infrastructure costs.

b. Even the portion of the endowment that is unrestricted is subject to a carefully managed annual payout, typically around 4.5%, to ensure long-term financial stability for the institution. The payment from the unrestricted endowment is a critical funding source for GW's annual budget. Using any of this funding for research infrastructure costs would require redirecting it from different University obligations and needs.

c. As a non-profit institution, GW reinvests nearly all of its revenue into mission-critical activities, leaving little margin to absorb unexpected funding gaps. In other words, unlike for-profit organizations, GW does not generate significant

surpluses that could be redirected without impacting core academic priorities such as educational programs and financial aid support for students.

21. Moreover, absorbing the cost of a lower indirect cost rate, even if it were possible, would create long-term budget pressures on GW—which would in turn force reductions in key investments supporting GW's faculty, students, staff, research, and teaching infrastructure, as well as other critical activities needed to maintain GW's academic excellence.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on February 10, 2025, at The George Washington University located in Washington, D.C.

/s/ Robert H. Miller
Robert H. Miller, PhD
Interim Vice Provost for Research
Vice Dean, School of Medicine and Health Sciences
Professor, Anatomy and Cell Biology
Vivian Gill Distinguished Research Professor

Shipment Receipt

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Shipment Information:
Tracking no.: 772157875504
Ship date: 02/18/2025
Estimated shipping charges: 23.22 USD

Package Information
Pricing option: FedEx Standard Rate
Service type: FedEx 2Day
Package type: FedEx Envelope
Number of packages: 1
Total weight: 0.20 LBS
Declared Value: 0.00 USD
Special Services:
Pickup/Drop-off: Drop off package at FedEx location

Billing Information:
Bill transportation to: MyAccount-280
Your reference:
P.O. no.:
Invoice no.:
Department no.:

Thank you for shipping online with FedEx ShipManager at fedex.com.

Please Note

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EXHIBIT 5

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSSETTS

ASSOCIATION OF AMERICAN UNIVERSITIES, AMERICAN COUNCIL ON EDUCATION, ASSOCIATION OF PUBLIC AND LAND-GRANT UNIVERSITIES, BRANDEIS UNIVERSITY, BROWN UNIVERSITY, THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, THE CALIFORNIA INSTITUTE OF TECHNOLOGY, CARNEGIE MELLON UNIVERSITY, THE UNIVERSITY OF CHICAGO, CORNELL UNIVERSITY, THE GEORGE WASHINGTON UNIVERSITY, JOHNS HOPKINS UNIVERSITY, MASSACHUSETTS INSTITUTE OF TECHNOLOGY, TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA, UNIVERSITY OF ROCHESTER, and TRUSTEES OF TUFTS COLLEGE,

Plaintiffs,

v.

DEPARTMENT OF HEALTH & HUMAN SERVICES,

NATIONAL INSTITUTES OF HEALTH,

DOROTHY A. FINK, M.D. in her official capacity as Acting Secretary, Department of Health and Human Services, and

MATTHEW J. MEMOLI, M.D., M.S. in his official capacity as Acting Director, National Institutes of Health,

Defendants.

Case No. 1:25-cv-10346

DECLARATION OF SHASHANK PRIYA

I, Shashank Priya, declare as follows:

1. I am the Vice President for Research and Innovation at the University of Minnesota (the "University"). The University's flagship campus is located in Minneapolis/St. Paul and there are four other campus locations in Minnesota. I have held that position since

September 2022. Prior to that time, I served as Associate Vice President for Research at The Pennsylvania State University.

2. As Vice President for Research and Innovation, I have personal knowledge of the contents of this declaration, or have knowledge of the matters based on my review of information and records gathered by University of Minnesota personnel. I offer this declaration in support of the request of the Association of American Universities (AAU) for judicial relief from the directive issued by the National Institutes of Health (NIH) on February 7, 2024: Supplemental Guidance to the 2024 NIH Grants Policy Statement: Indirect Cost Rates (NOT-OD-25-068).

3. The University of Minnesota receives substantial annual funding from the NIH. In the University's fiscal year 2024 alone, the University received 808 awards directly from NIH which obligated funding to the University of approximately $355.6 million. In addition, the University received NIH subawards from other entities. Awards received are distinct from expenditures incurred.

4. In any given fiscal year, the University of Minnesota is reimbursed for its expenditures on grants that were awarded in that year as well as in preceding years. In fiscal year 2024, the University of Minnesota was reimbursed by NIH for a total of $497.8 million from NIH direct awards and pass-through awards from other entities on which NIH was the prime funder (subawards). Of that, $135.9 million covered allowable indirect costs.

5. Recovery of the University's indirect costs is based on predetermined rates that have been contractually negotiated with the federal government. The University receives indirect costs calculated on a portion of its total direct costs referred to as "Modified Total Direct Costs" (MTDC).

6. Through fiscal year 2028, the University's negotiated indirect cost rate is 54% MDTC for on-campus research activities, 37% MTDC for other sponsored activities, 59% MTDC for the Hormel Institute, and 26% MTDC for all off-campus activities.

7. The impact of any significant reduction in the indirect cost rate would be devastating. For example, for fiscal year 2024, instead of $135.9 million in NIH reimbursement for indirect costs, a 15% MTDC cap on indirect costs would have resulted in the University receiving only $38.4 million in indirect costs. This would have been a loss of $97.5 million in one fiscal year.

8. Over the next five years, the University of Minnesota anticipates approximately $157.7 million in annual indirect costs based on the University's negotiated indirect cost rate. If—contrary to what the University of Minnesota has negotiated with the federal government—the indirect cost rate is reduced to a cap of 15% MTDC, the University's anticipated annual indirect cost recovery for NIH awards would be reduced by 71.8%, an average loss of $113.2 million per year over five years. This could result in a loss to the University of more than $565.7 million from fiscal year 2025 through fiscal year 2029.

9. The funding the University of Minnesota receives from NIH supports critical and cutting-edge medical research, which millions of Americans benefit from and depend on. For example:

a. **Cancer Research**: The University's cancer research includes the Cancer Center Support Grant (P30CA077598), which funds the Masonic Cancer Center to advance cancer prevention, detection, and treatment. This grant enables the development of innovative approaches to suppress the disease at its earliest

stages and fosters collaboration through shared resources and administrative support.

b. **Immunotherapy Research**: The University's immunotherapy research includes the Off-the-Shelf Immune Effector Cells for Hematological Malignancies (P01CA065493), which focuses on developing accessible and effective natural killer (NK) cell therapies for treating blood cancers. These therapies aim to improve patient outcomes by leveraging the immune system's ability to target cancer cells.

c. **Cancer Immunology Research**: The University's cancer immunology research includes NK Cells, Their Receptors, and Cancer Therapy (P01CA111412), which explores the biology of NK cells and their receptors to develop effective cancer therapies. This research seeks to harness NK cells' natural ability to detect and destroy cancer cells, offering new hope for treatment.

d. **Healthy Aging Research**: The University's healthy aging research includes the Minnesota Tissue Mapping Center for Senescent Cells (U54AG076041), which investigates the role of senescent cells in aging-related disorders. This research aims to develop interventions that promote healthier aging by identifying and targeting key mechanisms of cellular aging.

e. **Neurological Research and Imaging**: The University's neurological research (UM1NS132207 and P41EB027061)) leverages state-of-the-art ultra-high-field MRI instrumentation to study brain structure, function, and connectivity in unprecedented detail. This enables early detection of neurodegenerative

diseases (Alzheimer's, Parkinson's, ALS), mapping of brain function in psychiatric disorders (schizophrenia, depression, PTSD), and insights into brain plasticity and development (aging, traumatic brain injury, autism).

10. Indirect costs are essential for supporting this research. The NIH's proposal to cut indirect cost rates to 15% would seriously jeopardize the research projects described in Paragraph 9.

11. Indirect costs include constructing and maintaining state-of-the-art facilities, such as laboratories, cleanrooms, and data centers, that meet the technical requirements of advanced research. They also cover the procurement and upkeep of essential equipment, such as ultra-high-field MRI machines, electron microscopes, advanced computing clusters, and specialized instrumentation for imaging, data analysis, and experimental setups. These investments ensure a safe and compliant environment for researchers to innovate, collaborate, and push the boundaries of discovery. Without these critical facilities and equipment, the research simply cannot be conducted, jeopardizing advancements that benefit society.

12. For example, with respect to the areas of research including those described in Paragraph 9:

a. **Cancer and Immunotherapy Research:** The University's advanced immunotherapy research, including cell-based therapies, relies on highly controlled manufacturing environments (GMP facilities) to ensure compliance with FDA Current Good Manufacturing Practices (cGMP). These facilities are essential for producing safe and effective immune-based treatments. A reduction in the F&A rate to 15% would severely underfund GMP operations, limiting production capacity, delaying patient access to novel treatments, and

jeopardizing quality control. This could increase costs, strain clinical trial infrastructure, slow development of next-generation therapies, and undermine the training of future scientists, ultimately reducing the University's ability to deliver cutting-edge therapies to patients and maintain global leadership in biomedical innovation.

b. **Healthy Aging Research:** Reduced funding due to a lower indirect cost rate could hinder data management, participant tracking, and multi-site diversity, leading to slower progress and diminished impact of these critical age-related interventions.

c. **Neurological Research and Imaging**: A 15% cap on indirect costs would severely impact the maintenance of MRI infrastructure, upgrades to advanced technology, and support for technical staff, leading to delays, data bottlenecks, and limited access to cutting-edge instruments. The massive datasets generated by high-field MRI research, often requiring petabyte-scale, HIPAA-compliant storage, would face funding shortfalls for secure and scalable solutions, increasing risks of data loss. Additionally, AI-powered MRI analysis, which relies on GPU clusters and cloud computing for early disease prediction, would be hampered by insufficient computing resources. These reductions would significantly impede progress in understanding and treating neurological disorders, undermining the University's leadership in MRI-based research and diagnostics.

13. Physical space costs are one of the largest components of indirect costs, and the amount of space available to researchers has a direct and obvious impact on the amount of research

that can be done at the University of Minnesota. The University's planned construction for the Minnesota Bioimaging Center, the BioTechnology and Biomanufacturing Innovation Center, and the Translational Research and Innovation Facility are critical to advancing life-saving research and clinical innovation. However, if a 15% cap on indirect costs were implemented, these projects would face significant delays or very likely cancellation of these projects, causing immediate and long-term harm not only to the University's research capabilities on life-saving technologies but also to the public health outcomes.

14. A critical component of this challenge lies in the facilities reimbursement structure. Facilities costs, which are based on depreciation and interest for investments already made to support research, are not variable costs that can be adjusted based on the volume of research. Over the past several decades, the University has made multi-decade investments totaling hundreds of millions of dollars in research infrastructure, including laboratories, imaging facilities, and advanced capabilities. These are sunk costs, not discretionary expenditures, and they represent essential commitments to supporting the research mission.

15. Changing the reimbursement structure after institutions have made these substantial investments is untenable. Good facilities planning hinges upon reliable and consistent funding sources; sudden and disruptive disturbances to prior funding commitments jeopardizes the financial sustainability of research facilities already in operation.

16. For instance, the Minnesota Bioimaging Center is designed to provide advanced imaging tools essential for understanding diseases such as cancer and chronic and infectious diseases at the molecular and cellular levels. Delays in the construction of this facility would impede researchers' ability to develop new diagnostics and therapies, slowing progress in precision oncology and other fields. The BioTechnology and Biomanufacturing Innovation Center is

designed to address key challenges in therapeutic development, biologics manufacturing, and scalable biomanufacturing processes by fostering collaborations between academic researchers, industry, and government stakeholders. Delaying the construction of this center would impede efforts to develop cutting-edge biologics and therapeutics, slowing the translation of research into scalable treatments and disrupting Minnesota's leadership in biotechnology and biomanufacturing innovation. Similarly, the Translational Research and Innovation Facility is essential for testing new therapeutics and advancing clinical trials. Delays in its completion would reduce the University's capacity to conduct early-phase trials and biomarker validation studies. This would directly impact the development pipeline for life-saving treatments, leading to longer timelines for FDA approval and reduced availability of new therapies for patients.

17. In addition to delaying new construction, the 15% cap would force institutions to reallocate funds to maintain existing facilities at the expense of research productivity and innovation. The depreciation and financing costs associated with decades-long infrastructure investments cannot simply be "turned off" or scaled down without jeopardizing research capacity. This structural shift in reimbursement undermines the foundational investments that make cutting-edge research possible.

18. The combined effect of these delays will hinder the University's ability to maintain its leadership in biomedical research and will negatively impact public health outcomes, patient care, and economic growth driven by biotech innovation. Without sufficient recovery of indirect costs, these crucial facilities and their potential contributions to medical science will remain unrealized.

19. In addition, indirect costs fund the administration of awards, including staff who ensure compliance with the regulatory mandates from agencies such as NIH. These mandates

serve many important functions, including protecting human and animal subjects involved in research; ensuring research integrity; properly managing and disposing of chemical and biological agents used in research; preventing financial conflicts of interest; managing funds; preventing intellectual property, technologies, or national security expertise from being inappropriately accessed by foreign adversaries; and providing the high level of cybersecurity, data storage, and computing environments mandated for regulated data.

20. A reduction in the indirect cost rate will have deeply damaging effects on the University's ability to conduct research from day one of an implemented change to existing and new awards. Most critically, it will necessarily and immediately result in staffing reductions across the board. For example:

> The University's clinical trials program relies heavily on indirect cost recovery to support specialized infrastructure, regulatory oversight, and patient engagement activities. Without appropriate funding, the institution would be forced to implement immediate reductions in essential staffing and resources, causing significant harm to research and patient care outcomes. For example, the University's Institutional Review Board (IRB) oversees the ethical review and compliance of all clinical trials, ensuring patient safety and adherence to federal regulations. A 15% cap on indirect costs would necessitate a reduction of staff members from the IRB. This reduction would delay the review of clinical trial protocols, hindering the timely initiation of critical studies, including early-phase trials for cancer therapies and precision medicine. These delays would also extend FDA approval timelines, slowing the availability of life-saving treatments. Similarly, patient recruitment and retention efforts

would be severely impacted. The University's patient navigator program, which supports rural and underserved populations in accessing clinical trials, would lose funding for navigators and outreach staff. This would result in a decline in recruitment from these populations, reducing trial diversity and generalizability of results. In rare disease and pediatric trials, which require long-term follow-ups and multisite collaborations, indirect cost reductions would force the University to cut back on the coordination staff and specialized research nurses critical to these efforts. This would make participation in multisite trials less viable, jeopardizing advancements in these highly vulnerable patient populations. Finally, the University's ability to ensure data security and deploy AI-driven trial monitoring systems—essential for real-time analysis and adverse event detection—would be impaired by reductions in cloud computing resources. This would increase risks to patient safety and trial reliability, further compromising research integrity.

21. The University has for decades relied on the payment of indirect costs. Until now, we have been able to rely on the well-established process for negotiating indirect cost rates with the government to inform our budgeting and planning. Operating budgets rely on an estimate of both direct and indirect sponsored funding to plan for annual staffing needs (*e.g.*, post-docs, PhD students, and other research staff), infrastructure support (*e.g.*, IT networks, regulatory compliance, and grant management support), and facility and equipment purchases. In some cases, University of Minnesota has long-term obligations for which it relies on budgeted grant funding, including associated indirect cost recovery, to fulfill these commitments.

22. In addition to the immediate impacts and reliance interests described above, there are longer term impacts that are both cumulative and cascading.

23. The University's research also fuels spending in the regional economy, including by driving discoveries that launch new ventures, attract private investment, and make a positive social impact. A massive reduction in the University of Minnesota's research budget would immediately and seriously jeopardize these contributions to the local region.

24. Finally, slowdowns or halts in research by the University of Minnesota and other U.S. universities will allow competitor nations that are maintaining their investments in research to surpass the United States on this front, threatening both our Nation's national security and its economic dominance.

25. If required to absorb the cost of a reduced indirect cost rate, the University of Minnesota would be forced to immediately reduce key investments supporting the University of Minnesota's faculty, students, staff, research, and teaching infrastructure, as well as other critical activities needed to maintain academic excellence.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on February 17, 2025, at Minneapolis, Minnesota.

/s/ Shashank Priya
Shashank Priya

EXHIBIT 6

DECLARATION OF ERIC PERREAULT

I, Eric J. Perreault, declare as follows:

1. I am the Vice President for Research at Northwestern University ("Northwestern" or "the University") in Evanston, Illinois. I have held this position since September 2023. I am also a biomedical engineer who has been a faculty member at Northwestern since 2002, holding appointments in the McCormick School of Engineering, the Feinberg School of Medicine, and the Shirley Ryan AbilityLab. My research is focused at the convergence of rehabilitation medicine and engineering, addressing fundamental challenges of human movement control relevant to individuals who have suffered from a stroke or spinal cord injury. This work has been funded by the National Institutes of Health ("NIH") for more than 22 years. I am therefore personally familiar with the NIH and its positive impact on fundamental and translational science relevant to human health.

2. As Vice President for Research, I have personal knowledge of the contents of this declaration or have knowledge of the matters based on my review of information and records gathered by Northwestern personnel and could testify thereto.

3. Northwestern receives substantial annual funding from the NIH. Northwestern currently has approximately 1,425 active NIH awards. In fiscal year 2024, the University received approximately $519 million in funding from the NIH; this represents both direct awards to Northwestern and subawards from other entities where the prime sponsor was NIH. Of this amount, approximately $365.4 million was allocated to the direct costs for research and approximately $153.6 million was allocated to the indirect costs supporting our overall research enterprise.

4. The funding Northwestern receives from the NIH supports critical, cutting-edge medical research benefitting millions of Americans. A few from among many examples are:

a. **Alzheimer's disease research** at Northwestern encompasses all aspects of the disorder, from genetics, molecules, and cells to the individual patient, their families, and their communities. Our goal is to understand the cause of Alzheimer's and then to target the cause with novel therapeutic approaches for the treatment and ultimate prevention of the disease. For example, we investigate the enzymes that initiate the production of the β -amyloid peptide that plays a central early role in the pathogenesis of Alzheimer's. We also study rare genetic mutations that increase the risk of late-onset Alzheimer's disease. Further, we investigate how the microbiome affects inflammation in Alzheimer's disease. Together, these studies are informing current clinical care and the development of future interventions. This multifaceted research requires the involvement of specially trained neurologists, neuropsychologists, pathologists, social workers, basic and clinical scientists, and high-quality research facilities. The multidisciplinary approach of our research is unique and helps us advance toward the day when we can say Alzheimer's disease is just a memory.

b. **Cardiology Clinical Trials**. Cardiovascular disease remains a potentially devastating condition impacting the entire U.S. population. Appropriately, focused investigation by research-intensive institutions, like Northwestern, informs treatment decisions and public health. At Northwestern, we host an

expansive cardiovascular research portfolio. Our discoveries now reduce the burden of disease, save lives and promote better cardiovascular health. For example, genomic variation contributes to nearly every cardiovascular disease. We are interfacing bioengineering techniques with human-induced pluripotent stem cell technologies to develop precision models of heart disease, enabling the testing of new therapies and improving the safety of existing and novel drugs. We also study inflammation, a central but poorly understood cause of cardiometabolic diseases. We are using cutting-edge instrumentation from Northwestern's core facilities to understand how inflammation is regulated, when it is beneficial, and when it can lead to deadly disease. Finally, nearly 60% of patients with heart failure have "heart failure with preserved ejection fraction," meaning the global contractile function of the left ventricle is not severely impaired. This form of heart failure disproportionately affects older individuals and women. Northwestern investigators have been at the forefront of developing four classes of therapies that are now proven to be beneficial in lowering cardiovascular morbidity and mortality.

c. **The Robert H. Lurie Comprehensive Cancer Center** is a National Cancer Institute designated Comprehensive Cancer Center. It supports prostate cancer studies to better understand the underlying causes of prostate cancer as well as to improve diagnoses and treatment. It also supports detailed studies of brain cancer and in particular several clinical trials testing novel therapies for the almost always fatal glioblastoma multiforme.

5. Indirect costs are essential for supporting this research. The NIH's proposal to cut indirect cost rates to 15% would seriously jeopardize all NIH-funded research projects at Northwestern, including those described in Section 4. This work is critical to the continued understanding and treatment of disease for all Americans.

6. Indirect costs include expenses incurred for the operation, maintenance, preservation, and protection of the institution's assignable space to perform research. Indirect costs also include ***partial reimbursement*** for expenses incurred for general and utility services, repairs and alterations of buildings, furniture and equipment, environmental safety, and hazardous waste disposal, all necessities for performing research. These costs are considered indirect because they are not directly tied to a specific project but are required to ensure safe and functional spaces to carry out research and related activities.

7. Research performed at Northwestern relies on shared equipment and resources supported through indirect costs charged to NIH. These resources are shared across many research studies, creating efficiencies that would not be possible if they were allocated to a single project. Research could not be completed without the indirect costs that help maintain and support these resources. These resources include shared administrative resources, such as regulatory coordinators and clinical research coordinators, and highly specialized research equipment.

8. Physical space costs are one of the largest components of our federally negotiated indirect cost rate and the amount of space available to researchers has a direct and obvious impact on the amount of research that can be done. Northwestern is currently upgrading a generator to serve research facilities in Cook Hall and performing improvements in our building at 1801 Maple to support research translation. Both projects are on our Evanston campus. Reimbursements for this ongoing work would be jeopardized by a reduction in our negotiated indirect cost rate.

Additionally, we are in the late planning stages for adding 18 floors onto the Simpson Querrey Biomedical Research Building in downtown Chicago. This addition would add 560,000 gross square feet of space, bringing the total in the building to 1.2 million square feet. The construction is critical for the continued growth of Northwestern's biomedical research enterprise. We are also in the early stages of planning for a new engineering building to support laboratory research, including for medical technologies, on our Evanston campus. Both projects would be supported in part through indirect cost recovery and may not be able to move forward with a reduction in indirect costs for facilities and operations.

9. In addition, indirect costs fund the administration of awards, including professional staff who ensure compliance with a vast and growing number of federal regulatory mandates. These mandates serve important functions, including protecting human and animal subjects involved in research; ensuring research integrity; properly managing and disposing of chemical and biological agents used in research; preventing financial conflicts of interest; managing funds; preventing intellectual property, technologies, or national security expertise from being inappropriately accessed by foreign adversaries; and providing the high level of cybersecurity, data storage, and computing environments mandated for regulated data.

10. Through fiscal year 2026, the federally negotiated indirect cost rate for Northwestern is 60%. This rate is negotiated between Northwestern and the Department of Health & Human Services ("HHS") and is supported by evidence of actual costs incurred by the University. The negotiation includes documentation of operations and maintenance costs, square footage of buildings used for research, and administrative salaries. A reduction in the indirect cost rate would be devastating.

11. Based on Northwestern's fiscal year 2024 NIH funding, a reduction in the indirect cost rate from what Northwestern has negotiated with the federal government (60%) down to 15%, would reduce the University's maximum indirect cost recovery from these awards by approximately $115.2 million, from approximately $153.6 million down to approximately $38.4 million. This reduction will have deeply damaging effects on Northwestern's ability to conduct research from day one. Northwestern relies on its indirect cost rates negotiated with HHS to inform its budgeting and planning. An abrupt and significant change to that rate would require corresponding adjustments to the University's budgets across campus. In fact, on February 12, 2025, Northwestern's senior leadership announced several cost-cutting measures in response to the potential impacts of this indirect cost rate reduction and other emerging federal directives and proposals. These measures include a 10% reduction in all non-personnel expense budgets for the current fiscal year, and a review of all pending and future personnel actions, including hiring, compensation increases, additional payments and other related actions. If the indirect cost rate reductions proposed by NIH are implemented, we expect this announcement to be just the first step in what could be drastic budget and personnel cuts in the upcoming fiscal year.

12. The significant reduction in the indirect cost rate proposed by NIH would also lead to other immediate harms to the University. For example:

a. As mentioned above, Northwestern has already implemented across-the-board reductions in budgeted non-personnel expenditures, including capital expenditures. This would impact our ability to acquire and maintain state of the art equipment and facilities that are necessary to support Northwestern's cutting-edge research, including those impacts described in Paragraphs 7 and 8 above.

b. The administrative burden of converting the indirect cost rate on the University's approximately 1,425 NIH active awards will be significant and costly. For instance, Northwestern's financial systems allow an indirect cost rate to be applied to an award budget and it then auto-calculates that rate as expenditures occur. If an indirect cost rate change of the kind proposed by NIH were to occur immediately, it would require IT personnel and resources to modify our systems to ensure accurate reimbursements, which has typically taken weeks (or even months) even with planned changes related to renegotiated rates.

c. Northwestern collaborates with other institutions by means of subcontracts. All subcontracts (both incoming and outgoing) would require rebudgeting and renegotiation, requiring significant personnel time and effort. Additionally, it is likely that institutions would require changes to their scope of work as the amount of funding (if reduced) would not support the project. Other administrative challenges will occur with an abrupt reduction in IDC due to the inability to maintain staffing at our current levels, as most administrative staff in the research infrastructure are funded through IDC reimbursements.

13. Indirect costs represent reimbursements for actual costs associated with conducting research, not extra revenue to research institutions. Reducing the indirect cost rate paid to research institutions like Northwestern will not reduce the costs of research, but will instead create operating losses for research projects that Northwestern accepts from NIH. This is not

sustainable and could result in halts to existing NIH-funded research projects and reductions in future NIH awards accepted by the University.

14. Northwestern has for decades relied on the payment of indirect costs, and until now, we have been able to rely on the well-established process for negotiating indirect cost rates with the government to inform our budgeting and planning. Operating budgets rely on an estimate of both direct and indirect sponsored funding to plan for annual staffing needs (*e.g.*, postdoctoral fellows, PhD students, and other research staff), infrastructure support (*e.g.*, IT networks, regulatory compliance, and grant management support), and facility and equipment purchases.

15. In addition to the immediate impacts and reliance interests described above, there are longer-term impacts that are both cumulative and cascading. A reduction in staffing will limit the scale and scope of research Northwestern faculty can pursue, including human subjects and animal studies, clinical trials, and large-scale healthcare informatics studies. All require substantial regulatory infrastructure and oversight to ensure safety and confidentiality. Many studies paused even for a short time would be difficult to restart without significant loss of time due to interruptions in the treatment protocol.

16. Disruptions to Northwestern's research will have negative effects across Chicago, the state of Illinois, and the broader region. There are currently 2,859 Faculty and 11,742 non-faculty staff employed by the University, which collaborates with state and local partners to help solve regional challenges through joint research and innovation. Northwestern's research also fuels spending in the regional economy, including by driving discoveries that launch new ventures, attract private investment, and make a positive social impact. The University's Innovation and New Ventures Office helps to facilitate start-up companies. There are currently over 500 people

employed at such companies. A massive reduction in Northwestern's research budget would immediately and seriously jeopardize these contributions to the local region.

17. Finally, slowdowns or halts in research by Northwestern and other American universities will allow competitor nations that are maintaining their investments in research to surpass the United States on this front, threatening both our nation's national security and its economic dominance.

18. Northwestern cannot cover this funding gap alone. While the University maintains an endowment, it is neither feasible nor sustainable for the University to use endowment funds or other revenue sources to offset shortfalls in indirect cost recovery, for several reasons:

a. The majority of Northwestern's endowment—around 52%—is restricted to specific donor-designated purposes, such as scholarships, faculty chairs, and academic programs. The University is not legally permitted to use those funds to cover research infrastructure costs.

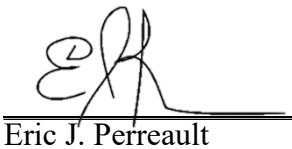
b. Even the portion of the endowment that is unrestricted supports mission-critical activities of the University, such as financial aid for undergraduate and graduate students and faculty recruitment. Moreover, this unrestricted portion of the endowment is subject to a carefully managed annual payout, typically around 5%, to ensure long-term financial stability for the institution.

c. As a non-profit institution, Northwestern invests nearly all its revenue into mission-critical activities, leaving little margin to absorb unexpected funding gaps. In other words, unlike for-profit organizations, Northwestern does not generate significant surpluses that could be redirected without impacting core academic priorities such as educational programs and financial aid for students.

19. Moreover, absorbing the cost of a lower indirect cost rate, even if it were possible, would create long-term budget pressures on Northwestern—which would in turn force reductions in key investments supporting the University's faculty, students, staff, research, and teaching infrastructure, as well as other critical activities needed to maintain Northwestern's academic excellence.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on February 18, 2025, at Evanston, Illinois.



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