UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASACHUSETTS

COMMONWEALTH OF MASSACHUSETTS, ATTORNEY GENERAL DANA NESSEL ON BEHALF OF THE PEOPLE OF THE STATE OF MICHIGAN, STATE OF ILLINOIS, STATE OF ARIZONA, STATE OF CALIFORNIA, STATE OF CONNECTICUT, STATE OF COLORADO, STATE OF DELAWARE, STATE OF HAWAI'I, STATE OF MAINE, STATE OF MARYLAND, STATE OF MINNESOTA, STATE OF NEW JERSEY, STATE OF NEW YORK, STATE OF NEVADA, STATE OF NEW MEXICO, STATE OF NORTH CAROLINA, STATE OF OREGON, STATE OF RHODE ISLAND, STATE OF VERMONT, STATE OF WASHINGTON, and STATE OF WISCONSIN,

Plaintiffs,

v.

NATIONAL INSTITUTES OF HEALTH; MATTHEW MEMOLI, M.D., M.S., in his official capacity as Acting Director of the National Institutes of Health; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; and DOROTHY FINK, in her official capacity as Acting Secretary of the U.S. Department of Health and Human Services,

Defendants.

Case No. 1:25-cv-10338

(Leave to File Granted Feb. 10, 2025)

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' *EX PARTE* EMERGENCY MOTION FOR TEMPORARY RESTRAINING ORDER

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INTRODUCTION

The National Institutes of Health is the largest single public funder of biomedical and behavioral research in the world.[1] The majority of its nearly $50 billion annual budget is awarded through nearly 50,000 competitive grants to institutes of higher education throughout the country—including those operated by and in every Plaintiff State.[2] The typical grant provides for two types of costs: direct costs, attributed to a specific research project; and indirect costs, necessary for the institution to carry out cutting-edge research, but attributable to multiple projects (e.g., laboratory and health care infrastructure costs, staffing, and administration). The portion of a grant allocated to indirect costs—known as the indirect cost rate (ICR)—is centrally important to the research institution because each particular research project rests on an institutional foundation that can be established and maintained only with adequate funding. Unsurprisingly, then, how the ICR is established for each research institution—and when and how it may be changed—is the subject of extensive regulation.[3] And the issue has been the focus of sustained Congressional attention, resulting in statutory language that binds NIH.[4]

[1] National Institutes of Health, "Direct Economic Contributions," https://www.nih.gov/about-nih/what-we-do/impact-nih-research/serving-society/direct-economic-contributions.

[2] The Plaintiff States are the Commonwealth of Massachusetts, the State of Illinois, Attorney General Dana Nessel on behalf of the People of Michigan, the State of Arizona, the State of California, the State of Colorado, the State of Connecticut, the State of Delaware, the State of Hawai'i, the State of Maine, the State of Maryland, the State of Michigan, the State of Minnesota, the State of New Jersey, the State of New York, the State of Nevada, the State of New Mexico, the State of North Carolina, the State of Oregon, the State of Rhode Island, the State of Vermont, the State of Washington, and the State of Wisconsin.

[3] *See generally* 2 C.F.R. Pt. 200, Subpts. C-F, Appx. II,; 45 C.F.R. Pt. 75, Subpts. C-F, Appx. III.

[4] *See* Further Consolidated Appropriations Act, 2024, Pub. L. No. 118-47, § 224 (2024); Consolidated Appropriations Act ("CAA"), 2023, Pub. L. No. 117-328, § 224, 138 Stat. 4883-884 (2022); CAA, 2022, Pub. L. No. 117-103, § 224, 136 Stat. 471, (2022); CAA, 2021, Pub. L. No. 116-260, § 224, 134 Stat. 1594 (2020); Further CAA, 2020, Pub. L. No. 116-94, § 224, 133 Stat. 2582 (2019); CAA, 2018, Pub. L. No. 115-141, § 226, 132 Stat 348, (2018).

In disregard of that controlling law, on Friday night, February 7, the Acting Director of NIH issued a Notice (the "Rate Change Notice") purporting to restructure the agency's funding of research at "more than 2,500 universities, medical schools, and other research institutions across all 50 states and the District of Columbia." Ex. 1 to Decl. of Katherine Dirks ("Dirks Decl."). Though ICRs for institutions of higher education (IHEs) performing world-leading biomedical research commonly exceed 50 or 60%, NIH purports to now cap those rates across the board at 15%—not only for future grants, but also for existing ones. *Id*. The Notice itself recognizes that this cap is about half of the existing average of incidental costs across all NIH grants. *Id.* Unless it is enjoined, the Rate Change Notice is to take effect today, February 10. *Id.*

NIH issued the Rate Change Notice in the face of statutory language expressly prohibiting it from doing so—language that was first enacted by Congress in response to a 2017 effort to cap ICRs and that has been repeatedly readopted in appropriations legislation ever since. Even were NIH to have the authority it claims, a demanding regulatory process would be required; but NIH took none of the steps mandated by that process. In addition, the agency did not consider the detrimental effect of its decision on ongoing research that NIH itself has determined is integral to public health. Nor did NIH address the considerable reliance interests that are impaired when thousands of existing grants, totaling billions of dollars, are changed unilaterally over a weekend.

Even more striking than NIH's flagrant disregard of the controlling law are the immediate and irreparable harms caused by its action. Were the Rate Change Notice permitted to take effect, ongoing clinical research at Plaintiff States' IHEs would be disrupted, interrupting ongoing trials in which countless patients are receiving experimental treatments for innumerable diseases. Cutting-edge laboratory research would be impeded—with millions of Americans left

waiting for life-saving experimental treatments because IHEs will be unable to meet the costs imposed by the considerable infrastructural and administrative demands of that work.

Because the Plaintiff States are likely to succeed on their claims that the NIH Guidance is arbitrary and capricious, contrary to law, *ultra vires*, and improperly promulgated; because NIH's actions would jeopardize ongoing, life-saving medical care and research; and because the public interest and the equities favor the continued provision of essential healthcare and continuation of world-changing research, this Court should issue a temporary restraining order pursuant to Fed. R. Civ. P. 65 to prevent the Rate Change Notice from taking effect today.

BACKGROUND

A. The NIH Grant Process

The NIH competitive grantmaking process begins with a notice of funding opportunities for a specific topic followed by new application submissions. *See* NIH Grants Policy Statement, U.S. Dep't of Health & Hum. Servs. (rev. Apr. 2024) ("NIHGPS"),[5] at I-51. After a formal peer review process, NIH issues a legally binding Notice of Award ("NOA") to selected grant recipients stating that funds may be requested. *Id.* at IIA-59.[6] The grant awards typically are not lump-sum awards. Rather, they are grant amounts using cost-based accounting systems, under which grant recipients are authorized to recover their actual, documented costs for conducting research after the grant is awarded. *E.g.*, Declaration of Denise Barton ("Barton Decl."), ¶ 18.

After receiving an NIH grant, a grantee periodically submits a research performance progress report outlining their "direct costs" and their "indirect costs" to NIH. 2 C.F.R.

[5] https://grants.nih.gov/policy-and-compliance/nihgps.
[6] "Once the [NOA] is signed or money is drawn, the [NOA] and the grant terms are binding on the grantee and the government." *U.S. ex rel. Bauchwitz v. Holloman*, 671 F. Supp. 2d 674, 681 (E.D. Pa. 2009). "An [NOA] constitutes an 'obligation,'" and NIH is "committed to funding the grant for the current budget period due to dependency upon the annual Congressional appropriations process." *Id.*

§ 200.329. "Direct costs" are attributed directly to a specific research project supported by the grant (e.g., specialized staff, equipment, and materials for the discrete project). 45 C.F.R. § 75.413. "Indirect costs" are needed for research but cannot be attributed and allocated exclusively to a specific research project. *See* 45 C.F.R. § 75.414(a); 2 C.F.R. Pt. 200, Appx. III, § A ("Indirect costs . . . are incurred for common or joint objectives and therefore cannot be identified readily and specifically with a particular sponsored project . . . ."). Indirect costs include expenses such as building construction and maintenance, utilities, maintaining laboratory equipment, compliance infrastructure, and faculty and personnel responsible for of multiple research projects. Barton Decl. ¶ 10; Declaration of Leslie Anne Brunelli ("Brunelli Decl."), ¶ 8; Declaration of Theresa A. Maldonado ("Maldonado Decl."), ¶ 15; Declaration of Cassandra Mosely ("Mosely Decl.") ¶ 7; Declaration of Mari Ostendorf ("Ostendorf Decl.") ¶ 6. Indirect costs "quite literally 'keep the lights' on." Declaration of Ben Friedman ("Friedman Decl.") ¶ 7. Indirect costs are based on each institution's unique needs and cost structure; they are not theoretical, and instead are documented, actual costs incurred by the IHE. *See, e.g.*, Brunelli Decl. ¶ 8; Ostendorf Decl. ¶ 6.

B. Regulatory Framework

Federal regulations require research institutions to express their indirect costs as a proportion of their total costs that cannot be attributed or allocated to individual research projects. 45 C.F.R. §§ 75.306, 75.414. For example, a federal grant may award $100,000 to a recipient to conduct a specific research project. Compl. ¶ 62. If the grant recipient's indirect cost rate is 20%, then the grant award becomes $120,000, after adding the indirect costs. *Id.*

Federal regulations prescribe a detailed methodology for negotiating ICRs. Typically, a single agency, such as HHS, negotiates an ICR with a research institution. 2 C.F.R. Pt. 200,

Appx. III, § C.11(a)(1). As part of those negotiations, federal regulations require institutions to conduct comprehensive cost analyses that follow detailed federal directions governing reasonable and allowable indirect costs. 2 C.F.R. Pt. 200, Appx. III, § C.11(a)(1), (f)(1). For example, if an institution seeks to recover the cost of building maintenance, it must document those costs and then attribute those costs to their research programs; the attribution is then subject to federal audit. 2 C.F.R. Pt. 200, Appx. III, § D.2(b)(2); *see id.*, § C.11(d).

Once the ICR for a research institution is negotiated, the research institution and the federal agency enter into a Negotiated Indirect Cost Rate Agreement ("NICRA"). *See* 2 C.F.R. Pt. 200, Appx. III, § C.11(g). That ICR is then binding on the entire federal government during the period that the negotiated rate is in effect. 2 C.F.R. § 200.414(c)(1) (generally); *see* 45 C.F.R. § 75.414(c)(1) (for agencies with HHS). After the ICR is agreed upon and the actual indirect costs are incurred, federal agencies conduct audits to ensure that the negotiated ICR conforms to the actual indirect costs that are incurred and address any amounts called into question by the audit. 2 C.F.R. Pt. 200, Appx. III, § C.11(2)(c). The ICR must be adjusted if the audit indicates that the institution has recovered excess costs. 2 C.F.R. § 200.411(a).

NIH is required to use the ICR negotiated with a research institution in its NICRA, unless a deviation from that rate is "required by statute or regulation" or is "approved by a Federal awarding agency head or delegate based on documented justification as described in [45 C.F.R. § 75.414(c)(3)]." 45 C.F.R. § 75.414(c)(1); *see* 45 C.F.R. Pt. 75, Appx. III, § C.7 ("Except as provided in paragraph (c)(1) of § 75.414, Federal agencies must use the negotiated rates for indirect (F&A) costs in effect at the time of the initial award throughout the life of the federal award"). To deviate from a negotiated ICR, 45 C.F.R. § 75.414(c)(3) requires that "[t]he HHS awarding agency must implement, and make publicly available, the policies, procedures and

general decision making criteria that their programs will follow to seek and justify deviations from negotiated rates." Pursuant to 45 C.F.R. § 75.414(c)(4), "the HHS awarding agency must include in the notice of funding opportunity the policies relating to indirect cost rate reimbursement, matching, or cost share as approved." Moreover, "the HHS agency should incorporate discussion of these policies into their outreach activities with non-Federal entities prior to the posting of a notice of funding opportunity." *Id.* That is because all factors pertinent to allowing a research institution to "make an informed decision" about whether to seek funding must be identified before a grant is made available for competition. 45 C.F.R. § 75.203(c)(2).

The NIHGPS sets out for NIH grant recipients "the policy requirements that serve as the terms and conditions of NIH grant awards." NIHGPS at ii. Regarding reimbursement of indirect costs, the NIHGPS confirms that ICRs are to be negotiated with one of several "agenc[ies] with cognizance for . . . indirect cost rate (and other special rate) negotiation." *Id*. at IIA-68. The NIHGPS further provides that "[i]f a subrecipient already has a negotiated indirect cost rate established with their cognizant agency for indirect cost, the negotiated rate must be used." *Id.* at IIA-69.

C. 2017 Budget Proposal and Congressional Response.

In May 2017, as part of its fiscal year 2018 budget proposal, the first Trump Administration proposed establishing a 10% across-the-board ICR cap for NIH grants. *See* OMB, *Major Savings and Reforms: Budget of the U.S. Government Fiscal Year 2018*, at 43 (2017) (attached as Dirks Decl. Ex. 2). In explaining the proposal, the first Trump Administration asserted without elaboration that NIH's funding of indirect costs should mimic that of private foundations. *Id.*

The proposal drew widespread, bipartisan criticism.[7] The Association of American Universities explained that, were the ICR cap to be adopted, it would "cripple our nation's scientific efforts, undermining our economic growth, public health, and national security," and hobble the ability of ongoing research to "provide tomorrow's cures and technologies."[8]

Congress was similarly unimpressed with the proposed cuts and acted promptly to preserve NIH's then-existing approach to ICRs. The Senate Committee on Appropriations reported that the Administration's proposal would "radically change the nature of the Federal Government's relationship with the research community," would "abandon[]" the Government's "long-established responsibility" for research infrastructure, and would jeopardize "biomedical research nationwide." S. Rep. No. 115-150, at 109 (2017). The Committee further noted that it "had not seen any details of the proposal" that would explain "how it could be accomplished without throwing research programs across the country into disarray." *Id.* "To avoid this possibility," the Committee proposed, and Congress later enacted, the following restriction barring NIH or any other department or agency from restructuring or modifying the existing approach to indirect costs:

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

[7] *See, e.g.*, Paul Basken, "Trump Proposal to Cut Indirect Research Payments Would Hit State Universities Hardest," *Chronicle of Higher Ed*. (Mar. 31, 2017), https://www.chronicle.com/article/trump-proposal-to-cut-indirect-research-payments-would-hit-state-universities-hardest/; Jocelyn Kaiser, "NIH plan to reduce overhead payments draws fine," *Science* (June 2, 2017), https://www.science.org/content/article/nih-plan-reduce-overhead-payments-draws-fire.

[8] *Statement on Administration's FY18 Budget Proposal*, Ass'n of Am. Univs. (May 23, 2017), https://www.aau.edu/newsroom/press-releases/aau-statement-administrations-fy18-budget-proposal-1.

> 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.

CAA, 2018, Pub. L. No. 115-141, § 226, 132 Stat 348. Two years later, when the Trump Administration proposed eliminating this self-described "*prohibit[ion] by law from reducing grantee administrative* costs," Congress rejected that proposal, too. *Compare* OMB, *Major Savings and Reforms, Budget of the U.S. Government, FY 2020*, at 43 (2019) (emphasis added) (Dirks Decl. Ex. 3), *with* Further Consolidated Appropriations Act, 2020, Pub. L. No. 116-94, § 224, 133 Stat. 2582 (2019); *see also* Hr'g before Subcomm. of the House Comm. on Appropriations, at 236 (Apr. 2, 2019) (Rep. Tom Cole, Ranking Subcommittee member, cautioned against changing ICRs which he described as "a foundational element for research").

This statutory language has been readopted in HHS and NIH appropriations provisions ever since. *Supra* note 4; *see* CAA, 2025, Pub. L. No. 118-83, §§ 101, 106 and Further CAA, 2025, Pub. L. No. 118-158, § 101 (continuing Section 224 in effect).[9] It remains in force today as Section 224 of the Further Consolidated Appropriations Act, 2024, Pub. L. No. 118-47. NIH itself recognizes Section 224 as a legislative mandate binding on the issue of indirect costs. NIH Notice NOT-OD-24-110 (Dirks Decl. Ex. 4).

[9] Legislative history indicates a continued Congressional focus on ensuring continued NIH funding of indirect costs. In a February 2020 House Committee hearing on appropriations for HHS in 2021, Congressman Tom Cole, Ranking Member of the Subcommittee with jurisdiction, reiterated his caution against changing indirect cost negotiations. Hr'g before Subcomm. of the House Comm. on Appropriations, at 228 (Mar. 4, 2020) https://www.congress.gov/116/chrg/CHRG-116hhrg43462/CHRG-116hhrg43462.pdf. In the ensuing 2020 House Committee Report on HHS appropriations, the Committee noted the proposed (and later adopted) statutory language "continues a provision relating to indirect cost negotiated rates." Rep. of the Comm. on Appropriation, House of Representatives, on H.R. 7614, H. Rep. 116-450 (July 15, 2020) (116th Cong.).

D. Rate Change Notice.

On February 7, 2025, the Acting Director of NIH issued the Rate Change Notice. The Rate Change Notice announced that "[f]or any new grant issued, and for all existing grants to [IHEs] retroactive to the date of issuance of this Supplemental Guidance, award recipients are subject to a 15 percent indirect cost rate." The Notice further stated that "[p]ursuant to this Supplemental Guidance, there will be a standard indirect rate of 15% across all NIH grants for indirect costs in lieu of a separately negotiated rate for indirect costs in every grant." The Rate Change Notice purports to rely on 45 C.F.R. § 75.414(c)(1), (3) as authority.

The Rate Change Notice, which by NIH's own telling affects more than $4 billion in grant funding to support life-saving and life-extending medical research, *see* NIH Statement (Dirks Decl. Ex. 5), spans only two pages. It identifies, at most, two reasons for setting a categorical ICR cap: that NIH should follow the approaches of a handful of private foundations, which subsize a lower rate of indirect costs; and that indirect costs are "difficult for NIH to oversee." The Rate Change Notice does not explain why a uniform ICR cap of 15% was chosen; discuss whether other rates were considered; or consider the extent to which immediately setting a global ICR of roughly half the "average indirect cost rate reported by NIH" will compromise NIH's mission or the purpose of tens of billions of dollars in existing grant funding.

E. Institutes of Higher Education in the Plaintiff States.

Plaintiff States' IHEs depend heavily on NIH funding to support medical research, and the Rate Change Notice will significantly impact them. These IHEs not only contribute significantly to protecting the health of the Plaintiff States' residents through their research and administration of clinical trials, but are also important economic drivers for the plaintiff states – employing thousands of people and leveraging additional investment in the states. At any given

time, individual IHEs may depend on thousands of NIH grants, amounting to billions of dollars, that support biomedical research projects across 100s of university facilities.

In just Massachusetts, for example, 219 organizations received NIH funding to support 5,783 projects in Federal fiscal year 2024. The total funding in Massachusetts during that time was $3.46 billion, of which approximately $1 billion supported support indirect research costs.[10] The University of Massachusetts ("UMass") system alone received 501 awards for a total of $248 million, of which more than $80 million were for indirect costs. Barton Decl. ¶ 7.

The same is true across Plaintiff States. In the same or previous fiscal year, the University of California received $2 billion; the California State Universities system received $158 million in NIH funding; Colorado State University received $203.3 million; Delaware State University received over $9.3 million; the University of Hawai'i's system received $211 million; the University of Illinois received more than $325 million, and the Southern Illinois University received $20.2 million; Oregon Health and Science University ("OHSU") received $297 million; Wayne State University in Michigan received $80 million; the University of Washington system received nearly $669 million, including flow-through funding via partner institutions, and Washington State University received approximately $44 million. [11] These IHEs, including UMass, have collectively received over *$4.1 billion* in NIH funding in the past Federal fiscal year alone. This funding supports groundbreaking, lifesaving research that saves lives, including

[10] NIH Awards by Local & Organization, Location: Massachusetts, https://report.nih.gov/award/index.cfm?ot=&fy=2025&state=MA&ic=&fm=&orgid=&distr=&rfa=&om=n&pid=&view=statedetail (last visited Feb. 9, 2025).

[11] Declaration of Dr. Tony Allen ("Allen Decl."),¶ 4; Declaration of Dr. Peter G. Barr-Gillespie, ("Barr-Gillespie Decl."), ¶ 10; Brunelli Decl. ¶ 4; Dr. Gireesh Gupchup ("Gupchup Decl."), ¶ 5; Declaration of Jani Kitchell, ¶ 12; Maldondo Decl. ¶ 8-9, 16; Moseley Decl. ¶ 4; Ostendorf Decl. ¶ 3; Declaration of Ezemanari M. Obasi, Ph.D ("Obasi Decl."), ¶ 4; Dr. Joseph T. Walsh, Jr. ("Walsh Decl."), ¶ 5.

the development of new therapies and clinical tries for a range of diseases, including cancer, Amytrophic Lateral Sclerosis ("ALS"); genetic diseases like Tay-Sachs, cystic fibrosis, and sickle cell; emerging infectious disease; cardiovascular disease; kidney disease, muscular dystrophy; Diabetes; Parkinson's Disease; and Alzheimer's.[12]

ARGUMENT

The same legal standard applies to assessing requests for temporary restraining orders and preliminary injunctions. *Goldstein v. Batista Contracting LLC*, 671 F. Supp. 3d 68, 72 (D. Mass. 2023). Under that standard, "[t]he district court must consider the movant's likelihood of success on the merits; whether and to what extent the movant will suffer irreparable harm in the absence of preliminary injunctive relief; the balance of relative hardships [and equities]; and the effect, if any, that either a preliminary injunction or the absence of one will have on the public interest." *U.S. Ghost Adventures, LLC v. Miss Lizzie's Coffee LLC*, 121 F.4th 339, 347 (1st Cir. 2024) (cleaned up). The final two factors—the balance of equities and the public interest—"merge when the Government is the opposing party." *Nken v. Holder*, 556 U.S. 418, 435 (2009). "While all four factors are relevant, likelihood of success is the 'main bearing wall' of the preliminary injunction framework." *Goldstein*, 671 F. Supp. 3d at 72 (quoting *Corp. Techs., Inc. v. Harnett*, 731 F.3d 6, 10 (1st Cir. 2013).

[12] Barr-Gillespie-Decl. ¶¶ 9, 11-12; Barton Decl. ¶ 24; Declaration of Ken Dill, ¶ 6; Declaration of Ben Friedman ¶ 16; Moseley Dec. ¶ 4; Obasi Decl. ¶ 4; Ostendorf Decl. ¶ 15; Walsh Decl. ¶ 5.

I. Plaintiff States Have Standing to Challenge the Rate Change Notice.

If the Rate Change Notice stands, Plaintiff States' IHEs collectively stand to lose hundreds of millions of dollars in indirect research costs. For this reason, Plaintiff States easily meet the Article III standard for standing.

"To ensure the proper adversarial presentation, . . . a litigant must demonstrate that it has suffered a concrete and particularized injury that is either actual or imminent, that the injury is fairly traceable to the defendant, and that it is likely that a favorable decision will redress that injury." *Mass. v. EPA*, 549 U.S. 497, 517 (2007). "[M]onetary harms are obviously concrete" for standing purposes. *Webb v. Injured Workers Pharm., LLC*, 72 F.4th 365, 372 (1st Cir. 2023) (cleaned up). And Plaintiff States' IHEs are instrumentalities of the Plaintiff States, which have standing to bring suit on their behalf. *See Biden v. Nebraska*, 143 S. Ct. 2355, 2365-68 (2023); *Peters v. Bd. of Trs. of S. Ill. Univ.*, 816 N.E.2d 1, 3 (Ill. App. Ct. 2004) ("There are numerous decisions finding that a state university and its board of trustees are arms of the State."). Thus, Plaintiff State IHEs "los[ing] out on federal funds . . . is a sufficiently concrete and imminent injury to satisfy Article III." *Dep't of Com. v. New York*, 588 U.S. 752, 767 (2019).

NIH reimburses Plaintiff States' IHEs for indirect costs at a negotiated rate. These reimbursements amount to hundreds of millions of dollars that Plaintiff States' Institutions rely on to keep their research programs, including lifesaving clinical trials, operational. UMass, for example, receives well approximately $200 million annually from NIH, of which up to $80 million is for indirect costs. Barton Decl. ¶ 14. This is based on a general ICR of 67.5%, agreed upon with HHS, *id.*; and that agreed upon rate is already less than UMass' actual indirect costs. *Id.* By cutting the ICR to 15%, the Rate Change Notice would eliminate—in a single weekend—between $40 and $50 million annually to UMass alone. *Id.* ¶ 15. The impact of this cut will be

immediately felt. UMass draws NIH funds biweekly, and anticipates a loss of $4 million per month, starting now. Barton Decl. ¶ 18. Similar effects will be felt across all of Plaintiff States, which stand to lose millions of dollars, effective immediately.[13] OHSU anticipates a loss of $1.6 million in NIH funding *per week*, beginning today (February 10) when OHSU is due to draw funds. Barr-Gillespie Decl. ¶ 18. The State University of New York anticipates a loss of $21.2 million in the next five months, including an imminent loss of $600,000 for costs incurred in the next two weeks, which it anticipates drawing on or around February 14. Friedman Decl. ¶ 17. Washington State University estimates a monthly loss of more than $400,000 for the remainder of the Federal fiscal year. Brunelli Dec; ¶ 11. Other Plaintiff States' IHEs similarly anticipate drawing funds this week, and thus will experience the immediate harm of the Rate Change Notice. *See* Brunelli Decl. ¶ 24; Moseley Decl. ¶ 8; Gupchup Decl. ¶ 10; Obasi Decl. ¶ 8.

Plaintiff States' IHEs do not have ready access to other sources of funds that could replace the millions in lost federal funding. *See, e.g.*, Brunelli Decl. ¶ 13. Given the absence of notice from NIH, and NIH's total disregard of existing NICRAs—which are supposed to guarantee financial stability for IHE research programs—Plaintiff States have had no ability to plan for this drastic reduction in funding. Barton Decl. ¶ 17; Maldonado Decl. ¶¶ 9-20. They have had no ability to ensure continued operation of existing research programs, which require expensive and specialized laboratory facilities and equipment. *Id.* And the IHEs have undertaken existing financial obligations including payroll, mortgages, and credit agreements, on the basis of the existing NICRAs; their ability to meet these obligations is now in jeopardy. *See, e.g.*, Barton Decl. ¶¶ 18-19. The Rate Change Notice purports to affect an immediate sea change in the operation of research institutions, undermining their ability to continue to engage in life-saving

[13] Allen Decl. ¶ 6; Barr-Gillespie Decl. ¶ 15; Barton Decl. ¶ 15; Brunelli Decl. ¶ 12; Friedman Decl. ¶ 6; Gupchup Decl. ¶¶ 7-10; Obasi Decl. ¶ 7; Moseley Decl. ¶ 7; Ostendorf Decl. ¶ 7.

research. And it will cost people their livelihoods, jeopardize the viability of cell specimens and lab animals, risk closures of labs, and significantly impact the operation of clinic trials, which could harm individual patients, up to and including death.[14]

As to traceability and redressability, Defendants are the sole cause of this fiscal fiasco—there is no other party to whom these injuries can be traced, and the sought after relief will prevent Defendants from financially gutting Plaintiff States' premier research institutions. *See In re Evenflo Co., Marketing, Sales Practices and Prods. Liab. Litig.*, 54 F.4th 28, 34 (1st Cir. 2022) ("Traceability 'requires the plaintiff to show a sufficiently direct causal connection between the challenged action and the identified harm.' And redressability requires the plaintiff to 'show that a favorable resolution of her claim would likely redress the professed injury.'" (quoting *Katz v. Pershing, LLC*, 672 F.3d 64, 71-72 (1st Cir. 2012) (internal citations omitted)).

II. Plaintiff States Are Likely to Succeed on the Merits.

Plaintiff States are likely to succeed on the merits for several reasons, each independently sufficient to invalidate the Rate Change Notice.

First, the Notice is arbitrary and capricious, and therefore violates the Administrative Procedure Act ("APA"), *see* 5 U.S.C. § 706(2)(A), because it completely "fail[s] to consider . . . important aspect[s] of the problem," *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). [15] In particular, the Rate Change Notice does not identify

[14] Barton Decl. ¶¶ 20, 29; Barr-Gillespie Dec. ¶¶ 15-17; Brunelli Decl. ¶¶ 13-24; Friedman Decl. ¶¶ 7-9; Obasi Decl. ¶¶ 7-8; Ostendorf Decl. ¶¶ 8-9, 18-20.

[15] The Rate Change Notice constitutes final agency action subject to the APA. Final agency actions "mark the consummation of the agency's decisionmaking process" and are those "by which rights or obligations have been determined, or from which legal consequences will flow." *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997) (cleaned up). The Rate Change Notice "marks the consummation" of NIH's decisionmaking process because it announces the agency's decision to immediately implement a policy that will dramatically change the awarding and disbursement of funds for all current and future grants.

a basis for setting a categorical, across-the-board rate reduction to 15%, at all. Nor does the Rate Change Notice explain why that categorical ICR limit compares favorably to existing institution-by-institution ICRs, which are calculated according to a detailed and well-established process that involves consideration of an IHE's *actual* incidental costs. *See* 2 C.F.R. Pt. 200, Appx. III, §§ B-C. The Notice also fails to account for the substantial reliance interests that grant recipients, including Plaintiff States' IHEs, have in their existing negotiated rates; and ignores the practical and significant harm that an across-the-board rate cut will cause, most notably in undercutting the very research that NIH has determined to advance the public health.

Second, the Rate Change Notice is contrary to law, in excess of statutory authority, and *ultra vires.* Statutory language in existing HHS appropriations (through which NIH is funded) plainly prohibits the type of across-the-board reduction in ICRs attempted by the Rate Change Notice. Further Consolidated Appropriations Act, 2024, Pub. L. No. 118-47, § 224. The Rate Change Notice also violates NIH's own regulations governing indirect costs. These regulations require federal agencies to accept negotiated ICRs unless an exception applies, which is not the case here. 45 C.F.R. § 75.414(c)(1), (3). Controlling regulations also set forth a process NIH must follow in order to deviate from a negotiated ICR—a process that NIH ignored. 2 C.F.R. § 200.414(c), 2 C.F.R. Pt. 200, Appx. III, § C.7(a). In addition, by imposing new duties and liabilities on existing grants, the Rate Change Notice is a "retroactive action" for which NIH has no authority. *See Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208-09 (1988).

Third, the Defendants have violated the APA by failing to observe notice-and-comment requirements before imposing a binding new, categorical obligation on existing grant agreements. 5 U.S.C. § 706(2)(D); *N.H. Hosp. Ass'n v. Azar*, 887 F.3d 62, 70 (1st Cir. 2018).

A. The Rate Change Policy Is Arbitrary and Capricious.

Plaintiff States' claim that the Rate Change Notice is arbitrary and capricious will likely succeed on the merits because NIH "entirely fail[ed] to consider . . . important aspect[s] of the problem," *State Farm*, 463 U.S. at 43.

First, the Rate Change Notice is arbitrary and capricious because it does not articulate any plausible basis for setting a 15% rate for indirect costs. It is "a fundamental requirement of administrative law . . . that an agency set forth its reasons for decision; an agency's failure to do so constitutes arbitrary and capricious agency action." *Amerijet Int'l, Inc. v. Pistole*, 753 F.3d 1343, 1350 (D.C. Cir. 2014) (cleaned up). "[C]onclusory statements will not do; an agency's statement must be one of *reasoning*." *Id.* (emphasis in original) (cleaned up); *see also Dep't of Com. v. New York*, 588 U.S. 752, 773 (2019) (an agency must "articulate[] a satisfactory explanation for [its] decision").

Here, federal regulations are clear that ICRs must be negotiated and agreed upon against the backdrop of audited and substantiated actual indirect costs. 2 C.F.R. § 200.509; 2 C.F.R. § 510(b)(6); 2 C.F.R. 51; Subpart F of 2 C.F.R. § 200. NIH did not conduct any such audit to support its unilateral, 15% ICR cap. Instead, the Rate Change Notice offers conclusory reference to the practice of a handful of private foundations, never addressing how those entities' reimbursement of incidental costs is relevant; nor why their practices are more instructive than research institutions' actual incidental costs, which each institution documents (and which the federal government routinely audits). *See* 2 C.F.R. Pt. 200, Appx. III, § B-C; 2 C.F.R. § 200.504. The Notice's references to private foundations do not address how those foundations define direct or indirect costs; the extent to which those entities intend for their private grants to *supplement* government-funded research programs (and therefore build on the established NIH

funding model, which the Notice has attempted to disrupt in a single weekend);[16] nor do they evaluate the foundations' approach to biomedical research, where higher incidental costs are most common, or the importance of federal funding as compared to other sources. This is precisely the type of "inscrutable reasoning" that, "given the information available to the agency, [is] facially irrational." *Marasco & Nesselbush, LLP v. Collins*, 6 F.4th 150, 173 (1st Cir. 2021).

Second, the Rate Change Notice is arbitrary and capricious because it does not reflect any consideration of the "serious reliance interests" that Plaintiff States and their IHEs have in NIH grant awards, all of which include specifically negotiated ICRs expressly accepted by the government at the beginning of every grant-funded project. *See DHS v. Regents of the Univ. of Cal.*, 591 U.S. 1, 30, 33 (2020) ("[B]ecause DHS was "not writing on a blank slate, it was required to assess whether there were reliance interests, determine whether they were significant, and weigh any such interests against competing policy concerns.") (cleaned up). Changing political considerations do not alone justify significant changes in policy, especially where, as here, parties have come to rely on express and longstanding federal practice. Instead, "[w]hen an agency changes course," as NIH did here, "it must be cognizant that longstanding policies may have engendered serious reliance interests that must be taken into account." *Id.* (cleaned up).

It is axiomatic that grant recipients rely on the terms of their negotiated grant awards to support their work. Here, IHEs relied on their NIH grant awards, inclusive of negotiated indirect costs, for budget planning. IHEs have made decisions about personnel, facilities, equipment, and

[16] The University of Utah, for example, explains that "most foundations view their grants as supporting an activity or a scientist currently doing research in an area of science that falls within the mission of the foundation, therefore *supplementing* existing support the research or university has from other sources. . . . [M]ost universities decide to accept such [private] grants, knowing that the university (not the federal government) will be subsidizing the research conducted under such grant." Univ. of Utah, *FAQ about the Indirect Costs of Federally Sponsored Research* (2013), https://osp.utah.edu/_pdf/FAQs%20on%20costs%20of%20research.pdf.

maintenance based on their NICRAs to the tune of millions of dollars. There is no indication that NIH considered these substantial reliance interests, much less that NIH meaningfully weighed these interests against the threadbare policy concerns laid out in the Rate Change Notice. *See Nat'l Council of Nonprofits v. OMB*, — F. Supp. 3d —, 2025 WL 368852, at *11 (D.D.C. Feb. 3, 2025) (a freeze on federal funds implicates reliance interests that "are all too real").

Third, the Rate Change Notice is arbitrary and capricious because it fails to recognize the practical consequences and profound harms imposed on the States and their IHEs by an immediate across-the-board cap, let alone justify why such consequences are warranted. It is a basic rule of administrative law that an agency must "pay[] attention to the advantages and the disadvantages of [its] decisions." *Michigan v. EPA*, 576 U.S. 743, 753 (2015) (emphasis omitted). NIH expends billions of dollars on grants annually for the purpose of "enhanc[ing] health, lengthen[ing] life, and reduc[ing] illness and disability," as the Rate Change Notice recognizes.[17] But the Rate Change Notice reflects no consideration of the extraordinary harm it will have on those goals by interfering with ongoing research. Nor does the Notice reflect any consideration of the impact its precipitous cuts will have on the Plaintiff States and their IHEs. By reducing the ICR to 15%, Plaintiff States' IHEs will lose hundreds of millions of dollars currently supporting life-saving and life-extending biomedical research. Allen Decl. ¶ 6; Barr-Gillespie Decl. ¶ 15; Barton Decl. ¶ 15; Brunelli Decl. ¶¶ 12, 18; Friedman Decl. ¶ 6; Gupchup Decl. ¶¶ 7-10; Obasi Decl. ¶ 7; Moseley Decl. ¶ 7; Ostendorf Decl. ¶ 7; Walsh Decl. ¶¶ 7-10. NIH offers no explanation as to why immediate implementation should be imposed upon activity conducted under current awards, notwithstanding the disruption that will cause. The Notice thus

[17] *Mission and Goals*, Nat'l Insts. of Health, https://www.nih.gov/about-nih/what-we-do/mission-goals (last visited Feb. 9, 2025).

threatens the ability of Plaintiff States' IHEs to continue to reliably facilitate research—and does so without any evidence that it considered the enormity of its abrupt policy change.

Lastly, the Rate Change Notice is arbitrary and capricious because it reverses fact-findings by grantmaking agencies as to actual indirect costs, memorialized in NICRAs. To explain such a drastic change of course, NIH must provide an even more substantial justification than is required to reverse long-standing policy. *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 106 (2015) ("[T]he APA requires an agency to provide more substantial justification when 'its new policy rests upon factual findings that contradict those which underlay its prior policy.'") (quoting *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009)). Existing ICRs are the result of extensive, data-driven negotiation and engagement between IHEs, on the one hand, and accounting experts representing the interests of the federal government, on the other hand. *See* 2 C.F.R. Pt. 200, Appx. III § C.11. These rates reflect the true indirect costs incurred by IHEs to deliver their obligations under federal grant awards. 2 C.F.R. § 200.414; 2 C.F.R. Pt. 200, Appx. II, § C. By lowering the ICR across the board, NIH asserts without evidence or support that the indirect costs incurred by research institutions are different from the rates it had previously identified through actual examination of the institutions' accounting systems and operating costs. That falls well short of the "substantial justification" that is required. *See Fox*, 556 U.S. at 515; *see also id.* at 537 (Kennedy, J., concurring) ("An agency cannot simply disregard contrary or inconvenient factual determinations that it made in the past, any more than it can ignore inconvenient facts when it writes on a blank slate.").

Because Defendants "should have considered th[ese] matters but did not," their "failure was arbitrary and capricious in violation of the APA." *Regents*, 591 U.S. at 33.

B. The Rate Change Notice Is in Excess of Statutory Authority, Ultra Vires, and Contrary to Law.

For at least three separate and independently sufficient reasons, the Rate Change Notice is contrary to law under 5 U.S.C. § 706(2)(A) and is otherwise in excess of statutory authority and *ultra vires* under § 706(2)(B).

1. Statutory Limitations on NIH Prohibit the Rate Change Notice.

Congress has expressly prohibited NIH from reducing or modifying negotiated ICRs. *See* Further CAA, 2024, Pub. L. No. 118-47, § 224 ("Section 224"). When the first Trump Administration proposed in its very first budget to significantly cuts ICRs to NIH grant recipients, Congress not only rejected the proposal but adopted statutory language to bar administrative action that would impose such a cut.[18] That language, repeatedly readopted, remains in effect today. *See* Section 224.

Section 224 provides that "the provisions relating to indirect costs in part 75 of title 45, Code of Federal Regulations, including with respect to the approval of deviations from negotiated rates, *shall continue to apply to the National Institutes of Health to the same extent and in the same manner* as such provisions were applied in the third quarter of fiscal year 2017." *Id*. (emphasis added). That is, the regulatory structure at the time the first Trump Administration tried—and failed—to drastically and categorically reduce ICRs was to—and does—remain in place. *Id.* Congress went further still. No dollar "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." *Id.* But, of course, that is exactly what the Rate Change Notice purports to do. In addition, HHS and NIH are directed not to "intentionally or

[18] The first Trump Administration proposed its first budget in May 2017, during the third quarter of the 2017 fiscal year. *See* OMB, *Major Savings and Reforms: Budget of the U.S. Government Fiscal Year 2018*" (Dirks Decl. Ex. 2), at 43.

substantially expand the fiscal effect" of any "deviations from negotiated rates" beyond the existing practice at the time of the 2018 budget proposal. *Id.* Disregarding that instruction, by the proposed Rate Change Notice, NIH now purports to affect more than $4 billion in reimbursement for indirect costs. *See* NIH Statement (Dirks Decl. Ex. 5).

NIH may not "decline to follow a statutory mandate or prohibition simply because of policy objections." *In re Aiken Cnty*., 725 F.3d 255, 259 (D.C. Cir. 2013) (Kavanaugh, J.); a*ccord City & Cnty. of S.F. v. Trump*, 897 F.3d 1225, 1232 (9th Cir. 2018). By the Rate Change Notice, however, NIH violates Section 224's procedural and substantive mandates. The Notice is a dramatic departure from how ICRs historically have been determined and applied; it therefore undertakes the type of "modified approach" to "provisions relating to indirect costs" that Section 224 prohibits. The substance of the Rate Change Notice violates Section 224, too. In the face of a statutory prohibition, the Notice plainly would "intentionally or substantially expand the fiscal effect of the approval of" deviations from negotiated ICRs, as the Notice purports to cut off billions of dollars in grant funds *today*.

The first Trump Administration, at least, openly acknowledged and abided the statutory prohibition against categorically altering ICRs. *E.g*., OMB, *Major Savings and Reforms, Budget of the United States Government, Fiscal Year 2020* (Dirks Decl. Ex. 4), at 43 (recognizing that "for the past two years, NIH has been prohibited by law" from categorically reducing ICRs and asking for relief from that prohibition, which Congress did not grant). This administration is not now free to disregard the very same statutory language, which remains in place.

2. NIH's Regulations Bar a Precipitous, Across-the-Board Rate Change.

The Rate Change Notice also violates NIH's own regulations, which govern how NIH must approach ICRs and potential deviations therefrom. 75 C.F.R. § 75.414(c). The Notice cites

45 C.F.R. § 75.414(c)(1) and (c)(3) in an attempt to support categorical ICR reductions, including for existing grants. Both provisions instead make clear that NIH's actions are unlawful.

Subsection (c)(1) requires negotiated ICRs to "be accepted by all Federal awarding agencies." 45 C.F.R. § 75.414(c)(1). Exceptions are permitted "only when required by Federal statute or regulation, or when approved by the awarding Federal agency . . . based on documented justification as described in paragraph (c)(3) of this section." *Id*. As set forth in Paragraph (c)(3), an HHS awarding agency must "implement, and make publicly available, the policies, procedures and general decision making criteria that their programs will follow to seek and justify deviations from negotiated rates." Neither (c)(1) or (c)(3) contemplate or allow a categorical ICR cap. No federal statute or regulation requires an across-the-board deviation from negotiated indirect rates. Instead, Section 224 *prohibits* such an action. NIH's use of subsection (c)(3) to implement a universal ICR change cannot be squared with the plain text of the regulation. *See Textron Inc. v. Comm'r of Internal Revenue*, 336 F.3d 26, 31 (1st Cir. 2003) ("[I]f the language of a statute or regulation has a plain and ordinary meaning, courts need look no further and should apply the regulation as it is written.") (cleaned up). Defendants have not implemented or made publicly available any "policies, procedures [or] general decision making criteria" to effectuate deviations from negotiated rates. 45 C.F.R. 75.414(c)(3). Even were Defendants to do so, the regulation plainly envisions additional steps—"seek[ing] and justify[ing]" deviations on a case-by-case basis, for a particular reason and with a substantiated justification. *Id.* That is not what occurred here.

Instead, in a single two-page Rate Change Notice, NIH purported to adopt new decision-making criterion and apply them to thousands of research institutions over a single weekend, with no serious justification (let alone particularized justification). The regulations allow no such

thing. 45 C.F.R. § 75.414(c)(1), (3). What is more, because all factors pertinent to a research institution's ability to "make an informed decision" about whether to seek NIH funding must be disclosed *before* a grant is made available for competition, any new policies about ICR deviations were required to have been included in the notice of funding opportunity. *See* 45 C.F.R. §§ 75.203(c)(2), 75.414(c)(4). That did not occur, either.

3. NIH May Not Impose a Retroactive Rate Change.

By depriving Plaintiff States' IHEs of many millions in indirect costs that NIH had agreed to pay, the Rate Change Notice also unquestionably "impair[s] rights a party possessed when [it] acted, increase[s] a party's liability for past conduct, [and] impose[s] new duties with respect to transactions already completed." *Landgraf v. USI Film Prods.*, 511 U.S. 244, 280 (1994). The Notice is therefore a "retroactive action" and the APA, "as a general matter, forbids retroactive rulemaking." *Bowen*, 488 U.S. at 208. Agencies cannot "promulgate retroactive rules unless that power is conveyed by Congress in express terms." *Id.* (citations omitted). No such power was conveyed by Congress here; as noted above, Congress has expressly precluded what NIH now purports to do. NIH's action was therefore in excess of its statutory authority and *ultra vires*; its very own regulations expressly so recognize. *E.g.*, 45 C.F.R. Pt. 75, Appx. III, § C.7.

C. The Rate Change Policy Was Adopted Without Observance of Procedure Required by Law.

Because the rights of research institutions throughout Plaintiff States cannot be impaired by a threadbare Notice, purporting to be effective within 72 hours, Plaintiffs are also likely to succeed on their procedural APA claim.

Generally, the APA requires "that before a federal agency adopts a rule it must first publish the proposed rule in the Federal Register and provide interested parties with an opportunity to submit comments and information concerning the proposal. Failure to abide by

these requirements renders a rule procedurally invalid." *N.H. Hosp. Ass'n v. Azar*, 887 F.3d 62, 70 (1st Cir. 2018) (cleaned up). Substantive rules that, like the Notice, "create[] rights, assign[] duties, or impose[] obligations, the basic tenor of which is not already outlined in the law itself," must go through the notice-and-comment process. *Id.* (cleaned up).

The Notice purports to impose "a standard indirect cost rate on *all grants* of 15% pursuant to its 45 C.F.R. § 75.414(c) authority," and thus imposes a new obligation on recipient organizations that did not exist before Friday.[19] As the face of the Notice recognizes, that standard affects the existing rights and obligations of thousands of research institutions nationwide. *Id.* Notice and comment was required. There was no good cause to skip the notice and comment process, nor has NIH claimed otherwise.

This should be no surprise to NIH, as past changes to ICR policies have been effected through the rulemaking process.[20] *See, e.g.,* 56 Fed. Reg. 29530 (June 17, 1991); 56 Fed. Reg. 50224 (Oct. 3, 1991).[21] Defendants' issuance of the Rate Change Notice without notice and comment rulemaking, and without good cause to proceed otherwise, violates the APA.

[19] By definition, the Rate Change Notice is a substantive rule because it is an "agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy." 5 U.S.C. § 551(4).

[20] HHS has voluntarily agreed to abide by the APA's notice and comment requirements for provisions governing grants and contracts because it "believes that its decision-making ought to be as transparent as appropriate to better enable the citizenry to comment on its proposed rules and demonstration projects," 45 C.F.R. Subpart A, furthering the objective of the "Richardson Waiver," *see id*., 36 Fed. Reg. 2,532 (Feb. 5, 1971) (requiring all agencies within HHS to abide by APA public participation requirements in the formulation of rules related to grants).

[21] Where changes were adopted, they were prospective only, underscoring the anomaly of NIH's attempted retroactive action here. *See* 56 Fed. Reg. 50224 (Oct. 3, 1991).

III. Plaintiff States Will Be Irreparably Harmed Absent a Temporary Restraining Order.

Application of the Rate Change Notice to NIH grant awards will irreparably harm Plaintiff States. Plaintiff States' IHEs rely on their budgeted NIH indirect cost reimbursement to pay for critical infrastructure and personnel that are the backbone of their research programs. Without proper funding for indirect costs, Plaintiff States' IHEs will not have sufficient funding to maintain critical laboratory and clinical research capabilities, compromising their ability to continue to safely operate their world class research programs.

The impact on clinical trials will be profound. The loss of many millions of dollars in indirect cost funding immediately threatens the ability of IHEs to continue to engage in groundbreaking, lifesaving clinical research, many addressing diseases for which the current therapy is inadequate. Barr-Gillespie Decl. ¶ 15; Barton Decl. ¶¶ 6, 29; Brunelli Decl. ¶¶ 18-20; Gupchup Decl. ¶ 7; Declaration of Rafael Jaime ("Jaime Decl.") ¶ 4; Maldonado ¶ 19; Moseley Decl. ¶ 8; Walsh Dec. ¶ 10. If indirect cost budgets are dramatically reduced, this workforce, which has highly specialized and technical expertise, will have to be laid off or furloughed, which also harm local economies. Barton Decl. ¶¶ 11, 17-19; Brunelli Decl. ¶ 20: Ostendorf Decl. ¶ 9; *see also* Maldonado Decl. ¶¶ 7, 20-22 (also noting that the UC system is California's third largest employer, generating $80 billion in economic activity statewide). By definition, the Rate Change Notice is a substantive rule because it is an "agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy." 5 U.S.C. § 551(4). Likewise, without adequate funding for indirect costs, IHEs will be at risk of delaying debt payments, failing to meet other obligations, or not being able to properly maintain facilities and equipment used in clinical research. Barton Decl. ¶¶ 11, 18, 35 ("At the time of the next draw, if the funds are diminished in accord with the [Rate Change Notice],

[UMass] will need to reduce expenditures associated with ongoing medical and scientific research and clinical trials by approximately $4 million *per month*"]). These risks are immediate: unless emergency relief is granted, some IHEs will lose critical funds as soon as this week, and even as soon as today, which will have an immediate, destructive impact on clinical research and trials. *See* Barr-Gillespie Decl. ¶ 18; Friedman Decl. ¶ 17; Brunelli Dec; ¶ 11; Maldonado Decl. ¶¶ 19-20; Moseley Decl. ¶ 8; Gupchup Decl. ¶ 10; Obasi Decl. ¶ 8.

Without adequate staff and appropriate facilities, IHEs would have to discontinue clinical trials. Barton Decl. ¶¶ 20, 29 ("The implementation of the [Rate Change Notice] will likely result in the suspension and/or cancellation of ongoing clinical trials for potentially life-saving investigational therapies"); Maldonado Decl. ¶¶ 16, 21. According to NIH itself, clinical trials are "at the heart of all medical advances." Dirks Decl. Ex. 6. In just the past few years, NIH-funded clinical research is responsible for the development of mRNA vaccines for pancreatic cancer; advancements in COVID-19 vaccine research, including boosters; research on skin grafts to match complex body parts, improving the quality of life for burn victims; developments of new treatments for obesity and Type II Diabetes, such as subcutaneous semaglutide; and the development of biomarkers to better (and more quickly) identify diseases like Alzheimer's.[22]

Plaintiff States' IHEs have been at the forefront of this groundbreaking clinical research. UMass Chan Medical School, for example, has over 500 active clinical trials, with thousands of enrolled study participants ranging in age from newborns to those over 65 years of age. Barton

[22] *See, e.g.*, *Breakthrough Research: A Showcase of Discoveries from NIH Intramural Labs and Clinics*, Nat'l Insts. of Health Catalyst, vol. 33 (January-February 2025), https://irp.nih.gov/catalyst/33/1/breakthrough-research; https://www.nih.gov/news-events/nih-research-matters/2023-nih-research-highlights-human-health-advances; *2024 Research Highlights—Human Health Advances*, Nat'l Insts. of Health Research Matters, https://www.nih.gov/sites/default/files/news-events/research-matters/2024/2024-nih-research-highlights.pdf; *2023 Research Highlights—Human Health Advances*, Nat's Insts. of Health Research Matters, https://www.nih.gov/news-events/nih-research-matters/2023-nih-research-highlights-human-health-advances.

Decl. ¶ 27. Of these trials, 65% are therapeutic, meaning that they are investigating and providing access to innovative new treatments for a broad range of diseases, including cancer, lupus, congenital disorders, psychiatric disorders, neurological diseases (Alzheimer's, multiple sclerosis, ALS) and neurodevelopmental disorders (autism). *Id*. ¶ 28. Many of these clinical trials are funded by NIH; their continued operation depends on indirect costs. *Id*. ¶¶ 10-11, 26. These clinical trials have saved lives, and people may die without them. *Id*. ¶ 20 (noting that "the consequences to individual patients could include their death or the advancement of their condition to the point where recovery is no longer possible"). For example:

- UMass Chan Medical School saved the life of a 12-month-old girl who was diagnosed with a rate, fatal genetic disease called Tay-Sachs disease. Researchers at UMass Chan, supported by NIH funded staff and facilities administered a novel experimental gene therapy that was not available from any commercial biopharma company because of the market limitations inherent in the rarity of the condition.

- UMass Center for Clinical Science saved the lives of a mother and son who ingested toxic mushrooms. NIH-funding helped secure an experimental.

- Similarly, a 22-year-old diagnosed with lupus is one of just twelve patients in the country to have received an experimental new therapy for severe or nonresponsive lupus. As a result of these treatments, the patient reports that "this is the best I've ever felt. I feel really good."

Id. ¶ 30. Without long-established funding, patients in Plaintiff States like those described above would not be enrolled in clinical trials, denying them access to care for rare and severe diseases. *Id*. ¶ 29; Ostendorf Decl. ¶ 7. Existing clinical trials would be at risk, too. Absent adequate indirect cost funding, IHEs may need to discontinue ongoing clinical trials and pull patients in Plaintiff States from lifesaving drugs or medicines that substantially improve a patient's quality of life. Barton Decl. ¶¶ 18, 29; Brunelli Decl. ¶¶ 20, 22; Ostendorf Decl. ¶ 7. The loss of access to sufficient indirect cost funding will thus have short- and long-term impacts and potentially dangerous, even fatal, consequences for clinical trial patients. Barton Decl. ¶¶ 6, 29, 36; Brunelli Decl. ¶¶ 22-23; Friedman Decl. ¶¶ 9, 16.

The catastrophic consequences of the Rate Change Notice extend further still. IHEs operate thousands of research facilities that are equipped with myriad state-of-the-art research equipment. Maintaining these facilities and equipment to demanding ethical and safety standards is incredibly costly, and paid through indirect cost budgets. Barton Decl. ¶¶ 10-11; Maldonado Decl. ¶ 15. If these funds are depleted, as the Rate Change Notice envisions, equipment and maintenance needs will go unmet, which would jeopardize the ability to continue research programs and the results of ongoing studies. Barton Decl. ¶¶ 16, 35. Research programs will be forced to shutdown, which could even jeopardize accreditation under some circumstances. *See, e.g.*, Brunelli Decl. ¶¶ 20-21.

The Rate Change Notice also may yield intolerable safety risks. Indirect costs include disposal of hazardous waste and costs of compliance with federal, state, and local regulations, such as the Institutional Review Boards for human subject or animal research. *See* Barton Decl. ¶ 10-11; *see also* Gupchup Decl. ¶¶ 9-10; Maldonado Decl. ¶ 15; Walsh Decl. ¶ 7. An immediate and dramatic reduction in the amount of funds budgeted for these indirect costs will inevitably increase the risk of harm to scientists, their patients, and the public. *See* Barton Decl. ¶¶ 10-11.

IV. The Public Interest and the Balance of Equities Strongly Favor Entry of a Temporary Restraining Order.

When the government is a party, the "balancing of the equities and the analysis of the public interest . . . merge" and may be evaluated "together." *Does 1-6 v. Mills*, 16 F.4th 20, 37 (1st Cir. 2021) (cleaned up). Both factors strongly favor Plaintiff States.

As an initial matter, Plaintiff States have established a strong likelihood of success on the merits and the prospect of irreparable harm to their IHEs and patients that they serve. The "extremely high likelihood of success on the merits" indicates that preliminary relief "would serve the public interest." *League of Women Voters v. Newby*, 838 F.3d 1, 12 (D.C. Cir. 2016).

Moreover, "there is a substantial public interest 'in having governmental agencies abide by the Federal laws that govern their existence and operations.'" *League of Women Voters*, 838 F.3d at 12 (quoting *Washington v. Reno*, 35 F.3d 1093, 1103 (6th Cir. 1994)). Conversely, courts routinely observe that "there is generally no public interest in the perpetuation of unlawful agency action." *Planned Parenthood of N.Y.C. v. HHS*, 337 F. Supp. 3d 308, 343 (S.D.N.Y. 2018). Here, as Plaintiff States have shown, the Rate Change transgresses the APA in multiple ways. There is a strong public interest in curtailing NIH's unlawful conduct and requiring it to comply with basic statutory and procedural requirements. Put simply, the public has a paramount interest in the Federal government playing by the rules.

The public also has strong reliance interests in preserving existing Federal grant funding to support the research activities of Plaintiff States' IHEs. Plaintiff States have detailed the devastating consequences of the Rate Change Notice, and the myriad ways in which it will impair lifesaving medical advancement. Plaintiff States IHEs do not have access to, and are not able to find, the hundreds of millions of dollars necessary to support laboratories, equipment, staff, and students to keep these research programs operational, without incurring significant downstream damage. Barton Decl. ¶ 17; Brunelli Decl. ¶ 3 ("WSU does not have the funds available to cover the immediate loss of millions of dollars in indirects from its research budget."). The funding reduction will put people out of work and further reduce health care access, depriving patients in Plaintiff States of treatments that could save lives or materially improve health outcomes. Barton Decl. ¶¶ 11, 16. 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); *see also Whitman-Walker Clinic, Inc. v. HHS*, 485 F. Supp. 3d 1, 61 (D.D.C. 2020) (describing "a robust public interest in safeguarding prompt access to health care").

For its sake, 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 *Rodriguez v. Robbins*, 715 F.3d 1127, 1145 (9th Cir. 2013)). Because the Rate Change Notice is unlawful, Defendants have no cognizable interest in its enforcement.

The public interest and the equities here point in a single direction. The Rate Change Notice is unlawful and there is no public interest in its enforcement. *See Planned Parenthood of N.Y.C.*, 337 F. Supp. 3d at 343. A temporary restraining order will protect a vital source of funding for essential research and clinical trials.

CONCLUSION

NIH unquestionably overstepped the bounds of its authority in issuing the Rate Change Notice, which will cause imminent and irreparable harm to Plaintiff States. Plaintiff States respectfully request a temporary restraining order; and further request that the Court order Defendants to file a status report within 24 hours, and regularly thereafter, confirming the regular disbursement and obligation of federal financial assistance funds and reporting all steps that Defendants taken to comply with the Court's order.

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Respectfully submitted,

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