

Nos. 25-1343, 25-1344, 25-1345

IN THE
United States Court of Appeals for the First Circuit

COMMONWEALTH OF MASSACHUSETTS; 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 HAWAII; STATE OF MAINE; STATE OF MARYLAND; STATE OF MINNESOTA; STATE OF NEVADA; STATE OF NEW JERSEY; STATE OF DELAWARE; STATE OF NEW MEXICO; STATE OF NEW YORK; STATE OF NORTH CAROLINA; STATE OF OREGON; STATE OF RHODE ISLAND; STATE OF VERMONT; STATE OF WASHINGTON; STATE OF WISCONSIN,

Plaintiffs - Appellees,

v.

NATIONAL INSTITUTES OF HEALTH; JAY BHATTACHARYA, M.D., Ph.D. in their official capacity as Director of the National Institutes of Health; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS); ROBERT F. KENNEDY, JR., in their official capacity as Secretary of the U.S. Department of Health and Human Services,

Defendants - Appellants.

ASSOCIATION OF AMERICAN MEDICAL COLLEGES; THE AMERICAN ASSOCIATION OF COLLEGES OF PHARMACY; THE ASSOCIATION OF SCHOOLS AND PROGRAMS OF PUBLIC HEALTH; THE CONFERENCE OF BOSTON TEACHING HOSPITALS, INC.; GREATER NEW YORK HOSPITAL ASSOCIATION,

Plaintiffs - Appellees,

v.

NATIONAL INSTITUTES OF HEALTH; JAY BHATTACHARYA, M.D., Ph.D. in their official capacity as Director of the National Institutes of Health; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS); ROBERT F. KENNEDY, JR., in their official capacity as Secretary of the U.S. Department of Health and Human Services,

Defendants - Appellants.

BRIEF OF AMICI CURIAE THE NATIONAL ASSOCIATION OF COLLEGE AND UNIVERSITY BUSINESS OFFICERS AND SEVENTEEN OTHER HIGHER EDUCATION ASSOCIATIONS IN SUPPORT OF PLAINTIFFS-APPELLEES AND AFFIRMANCE

On Appeal from the United States District Court for the District of Massachusetts
Case No. 1:25-cv-10338-AK

(Caption continues and counsel listed on inside cover.)

ASSOCIATION OF AMERICAN UNIVERSITIES; AMERICAN COUNCIL ON
EDUCATION; ASSOCIATION OF PUBLIC AND LAND-GRANT UNIVERSITIES;
BRANDEIS UNIVERSITY; BROWN UNIVERSITY; CARNEGIE MELLON UNIVERSITY;
THE REGENTS OF THE UNIVERSITY OF CALIFORNIA; 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;
TRUSTEES OF TUFTS COLLEGE; THE CALIFORNIA INSTITUTE OF TECHNOLOGY,

Plaintiffs - Appellees,

v.

DEPARTMENT OF HEALTH AND HUMAN SERVICES; NATIONAL INSTITUTES OF
HEALTH; ROBERT F. KENNEDY, JR., in their official capacity as Secretary of the U.S.
Department of Health and Human Services; JAY BHATTACHARYA, M.D., Ph.D. in their
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RULE 26.1 DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, *amici curiae* the National Association of College and University Business Officers, American Association of State Colleges and Universities, American Speech-Language-Hearing Association, APPA – Leadership in Educational Facilities, Association of American Law Schools, Association of Independent Research Institutes, Association of Research Libraries, Association of University Technology Managers, Campus Safety Health and Environmental Management Association, Council on Governmental Relations, Council on Social Work Education, EDUCAUSE, NASPA – Student Affairs Administrators in Higher Education, National Association of Independent Colleges and Universities, National Council of University Research Administrators, Society for College and University Planning, Society of Research Administrators International, and University Risk Management and Insurance Association each state that it is a nonprofit association, with no parent corporation, and that no publicly held corporation owns 10 percent or more of its stock.

/s/ Jessica L. Ellsworth
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STATEMENT OF INTEREST OF *AMICI CURIAE*¹

Amicus curiae the National Association of College and University Business Officers (NACUBO) is a nonprofit professional organization representing chief administrative and financial officers from over 1,700 nonprofit and public colleges and universities nationwide. Over 200 of NACUBO's members are research universities, and they reflect the extraordinary breadth and innovative contributions of degree-granting colleges and universities in the United States. Founded in 1962, NACUBO seeks to advance the economic vitality and business practices of higher education institutions in pursuit of their missions. It provides a bold voice, collaboration, and resources to tackle higher education's evolving challenges.

NACUBO is joined in this brief by the following organizations:

- American Association of State Colleges and Universities,
<https://aascu.org/our-organization>;
- American Speech-Language-Hearing Association,
<https://www.asha.org/about>;
- APPA – Leadership in Educational Facilities,
<https://www.appa.org/about/our-story>;
- Association of American Law Schools,
<https://www.aals.org/about>;

¹ All parties have consented to the filing of this brief. No party's counsel authored this brief in whole or in part; no party or party's counsel contributed money intended to fund the brief's preparation or submission; and no person other than *amici* contributed money intended to fund the brief's preparation or submission.

- Association of Independent Research Institutions,
https://airi.org/about_AIRI;
- Association of Research Libraries,
<https://www.arl.org/who-we-are>;
- Association of University Technology Managers,
<https://autm.net/about-autm/who-we-are>;
- Campus Safety Health and Environmental Management Association,
<https://www.cshema.org/about-us/who-we-are>;
- Council on Governmental Relations,
<https://www.cogr.edu/mission-statement>;
- Council on Social Work Education,
<https://www.cswe.org/about-cswe>;
- EDUCAUSE,
<https://www.educause.edu/about>;
- NASPA – Student Affairs Administrators in Higher Education,
<https://www.naspa.org/about/about-naspa>;
- National Association of Independent Colleges and Universities,
<https://www.naicu.edu/about-naicu>;
- National Council of University Research Administrators,
<https://www.ncura.edu/AboutUs.aspx>;
- Society for College and University Planning,
<https://www.scup.org/about>;
- Society of Research Administrators International,
<https://www.srainternational.org/about/who-we-are>; and
- University Risk Management & Insurance Association,
<https://www.urmia.org/about/abouturmia>.

Amici submit this brief to provide the Court with important context for the issues on appeal—including the history and purpose of indirect costs in higher education research funding, the differences between private grants and federal grants, and the harm that would flow from the challenged action. Negotiated indirect cost rates are essential to the research objectives of academic research institutions. For decades, each institution has worked collaboratively with the federal government to determine the appropriate rate that will advance its own particular research missions. The research produced by *amici*'s member universities has been critical to the development of American science and medicine. Because the challenged action upends the long-settled framework governing indirect costs and threatens vital research, *amici* urge this Court to affirm the District Court.

ARGUMENT

Federal funding for university research has made the United States a global leader in medical and technological innovation. Conducting this research rests, in large part, on universities being able to recover a fair portion of their “indirect costs.” Those costs run the gamut of “facilit[y] and administrati[ve]” expenses that academic research institutions incur when operating world-class laboratories—which require everything from high-speed data-processing systems, to radiation safety and hazardous waste disposal systems, to specialized personnel who maintain these complex systems and ensure regulatory compliance. 45 C.F.R. § 75.414(a).

What makes these costs “indirect” is simply the fact that they support multiple projects, and cannot be attributed to any one particular grant. *See* 2 C.F.R. § 200.1.

The government’s current framework for compensating those costs reflects the culmination of a multi-decade, interbranch effort to work out the appropriate way to incentivize and finance research at universities. Under this framework—mandated by statute and codified in regulations—academic research institutions negotiate individual “indirect cost rates” with the government, which is then “binding on every federal agency” across all of the institution’s grants. ADD.5. Congress has repeatedly affirmed this individual-rate model over the past 60 years in the face of Executive Branch challenge. And this model, in turn, has allowed research institutions to budget for and effectuate the specific research projects they undertake.

Disregarding this history, express directives from Congress, and universities’ serious reliance interests, the National Institutes of Health (NIH) upended this well-established framework in one fell swoop. Late on a Friday evening, NIH issued a cursory supplemental guidance document that turned the research world in this country upside down by “slashing and capping previously negotiated indirect cost rates on all existing and future grant awards for biomedical research” to a new maximum of 15%. ADD.2. NIH announced this new cap applied immediately to all institutions and all new and existing NIH grants—regardless of a university’s

negotiated rate, regardless of the impact on in-progress studies, and regardless of any university's particular circumstances that were the basis for a higher negotiated rate in the first place.

This "Rate Change Notice" is unlawful. The District Court properly enjoined it, preliminarily and then permanently. *Amici* submit this brief to provide additional context about the history of the current individual-rate model, the substantive differences between private and federal funding, and the on-the-ground impacts that NIH's action would have had absent the permanent injunction. This history and context underscores the illegality of NIH's actions, which would cause extensive irreparable harm.

I. NIH IGNORED THE HISTORY OF INDIRECT COST RATES FOR FEDERALLY FUNDED RESEARCH.

Universities are the beating heart of American innovation. Cutting-edge medical, technological, and scientific advances from academic research institutions have made the United States the envy of the scientific world and contributed to our nation's strength and prosperity. Those advances have depended, in no small part, on the federal government's funding structure for indirect costs associated with this research. NIH's abrupt imposition of a Procrustean 15% indirect-rate cap is unlawful for many reasons—but key among them is the agency's blatant disregard of the "longstanding polic[y]," enshrined in statutes and regulations, that Executive Branch agencies negotiate individualized rates to account for each institution's

circumstances. *DHS v. Regents of the Univ. of Cal.*, 591 U.S. 1, 30 (2020); *see* AAMC & AAU Plaintiffs-Appellees’ Br. 45-47; State Plaintiffs-Appellees’ Br. 33-37. Parsing the derivation and history of this policy reveals the depth of Congress’s commitment to the individual-rate model. And it highlights how consistently the one-size-fit-all approach that NIH took here has been rejected.

A. The Individual-Rate Model Is A Product Of Executive Practice And Legislation.

1. Universities in the United States were not always the world leaders in research they are today. Prior to World War II, academic research institutions conducted much smaller research operations, which primarily depended on funding from philanthropy or private foundations. *See* Daniel P. Gross & Bhaven N. Sampat, *America, Jump-Started: World War II R&D and the Takeoff of the US Innovation System*, 113 *Am. Econ. Rev.* 3323, 3327 (2023); Written Testimony of Dr. Kelvin K. Droegemeier 7 (Oct. 24, 2017) (Droegemeier Testimony).² That changed in the run-up to the war. *See, e.g.*, Gross & Sampat, *supra*, at 3327-28. In an effort to build up the country’s industrial base, the federal government began funding research at institutions of higher education through the Office of Scientific Research and Development (OSRD). *See id.* OSRD funded research that culminated in, among other things, mass-produced penicillin. *See id.* at 3328.

² <https://perma.cc/G32H-3MAA>.

From the outset, OSRD recognized the necessity of funding the indirect costs of this world-shaping research to attract participation by top-tier institutions. Specifically, OSRD aimed to ensure that institutions neither profited from nor lost money on government-funded research—a principle described as “no-profit, no-loss.” Pierre Azoulay et al., *Indirect Cost Recovery in U.S. Innovation Policy: History, Evidence, and Avenues for Reform* 4 (NBER Working Papers, No. 33627, 2025).³ To that end, OSRD applied a fixed-rate policy: Universities received overhead payments equal to 50% of direct salaries on contracts, while private firms received 100%, partly to offset corporate taxes. Droegemeier Testimony, *supra*, at 8; *see also* Genevieve J. Knezo, Cong. Rsch. Serv., *Indirect Costs for R&D at Higher Education Institutions: Annotated Chronology of Major Federal Policies* 2 (1994).

This standardized approach led to inconsistencies and concerns about fairness, as it potentially overcompensated some institutions while undercompensating others. *See* Azoulay et al., *supra*, at 4. So, OSRD began auditing its largest contractors and informally negotiating institution-specific indirect cost rates. *See* Carol Gruber, *The Overhead System in Government-Sponsored Academic Science: Origins and Early Development*, 25 *Hist. Stud. in Physical & Biological Scis.* 241, 244-245 (1995). These early agreements were precursors to today’s individual-rate model.

³ <https://perma.cc/U3VC-LWJ3>.

2. As the federal government's role in funding research at U.S. universities matured in the post-war era, so too did its approach to the funding of indirect costs. During this time, the government gradually embraced reimbursing academic research institutions for their indirect costs based on an *individualized* rate that aimed to ensure that the federal government paid its fair share.

The Office of Naval Research (ONR)—the leading funder of research in the Department of Defense in the years immediately following World War II—initiated what became the modern approach. In 1947, ONR introduced the first set of principles to determine indirect cost rates for research conducted by universities. *See* Knezo, *supra*, at 4. In doing so, ONR recognized that “universities were significantly different both organizationally and programmatically from commercial firms and required different cost principles to cover unique accounting practices.” *Id.* Under this framework, ONR used a single, individualized indirect cost rate for each particular university based on a “campuswide average rate to be applied in proportion to the size of the project.” *Id.* at 4-5. ONR's principles likewise contemplated that universities would receive a lower indirect cost rate for projects they “were likely to undertake on their own,” and a higher rate for those that the university “pursu[ed] at government request.” Gruber, *supra*, at 263.

In 1958, the forerunner to the Office of Management and Budget (OMB) adopted these principles for the federal government writ large. Knezo, *supra*, at 6.

In Circular A-21, titled “Cost Principles for Educational Institutions,” OMB provided guidance for determining indirect costs in research grants and contracts with educational institutions. Among other things, this circular defined indirect costs and required the “use of accounting principles to develop indirect costs rates and methods to distribute costs among the various R&D functions performed by an academic institution.” *Id.* Circular A-21—whose principles were codified as the “Uniform Guidance” in current OMB regulations at 2 C.F.R. Part 200, *see* Federal Acquisition Regulation; OMB Circular Citation Update, 81 Fed. Reg. 45,852 (July 14, 2016)—thus contemplates that agencies would cooperate with individual research institutions in developing institution-specific indirect cost rates based on actual costs.

Even so, universities continued to under-recover their indirect costs because those costs were capped at artificially low rates. For example, although NIH was “the largest patron of university research” during this era, the indirect cost rate for its grants was capped at 15% in 1958 and only rose to 20% in 1963. Robert M. Rosenzweig, *The Politics of Indirect Costs* 3 (1998);⁴ *see* Knezo, *supra*, at 4, 9-11. Notably, those 15% and 20% caps were the result of budget amendments enacted into law by Congress. *See* Departments of Labor, and Health, Education, and Welfare Appropriation Act, Pub. L. No. 85-67, § 208, 71 Stat. 210 (1957);

⁴ <https://perma.cc/XJ3N-N8Z7>.

Departments of Labor, and Health, Education, and Welfare Appropriation Act, Pub. L. No. 87-582, § 203, 76 Stat. 361 (1962). And universities struggled under these caps to keep up with research demands. *See Azoulay et al., supra*, at 6 (1954 internal NIH memo warning that the 8% cap was a “hindrance to the full development of research activities in this country” (citation omitted)). Indeed, universities argued that such low rates resulted in them “subsidizing government.” *Knezo, supra*, at 4.

3. Ultimately, Congress stepped in to solve the problem. First, in 1962, Congress passed a law authorizing agencies to reimburse “indirect costs on the basis of predetermined fixed-percentage rates applied to the total, or an element thereof, of the reimbursable direct costs incurred.” Pub. L. No. 87-638, 76 Stat. 437 (1962). Second, Congress lifted the cap on indirect costs in 1965 “and replace[d] it with a requirement for negotiation of rates based on actual costs.” *Knezo, supra* at 12; *see also* Departments of Labor, and Health, Education, and Welfare Appropriations Act, 1966, Pub. L. No. 89-156, § 203, 79 Stat. 589 (1965). Taken together, these laws enshrined the individual-rate model.

B. Congress Has Consistently Committed To The Individual-Rate Model, Rejecting Efforts To Broadly Reduce Indirect Costs.

In the decades after uncapping indirect costs and cementing into law the individual-rate model, Congress consistently fought back efforts to categorically limit the recovery of indirect costs for NIH-funded research. Instead, Congress kept the core principle of individualized negotiations intact by endorsing only targeted

modifications to the default model, which were all enacted through statute or notice-and-comment rulemaking.

Two of the failed efforts to limit recovery of indirect costs were led by NIH's parent agency, the Department of Health and Human Services (HHS). In 1983, HHS proposed that Congress limit indirect costs on all grants to universities to 90% of the negotiated rate. *See Knezo, supra*, at 18. Congress rejected this proposal. *See id.* Then, in 1985, HHS proposed that Congress institute “a one-year freeze on all indirect costs.” *Id.* Congress rejected this proposal, too. *Id.*

A year later, Congress rejected a proposal by OMB to cap the administrative portion of indirect costs at 26%. In 1986, OMB proposed—through notice-and-comment procedures—a rule amending Circular A-21 to include such a cap. *See id.* at 20; Proposed Revision of Circular A-21, “Cost Principles for Educational Institutions,” 51 Fed. Reg. 5,286 (Feb. 12, 1986). Even though OMB's final rule omitted that 26% cap, Congress passed a rider *prohibiting* OMB from spending any money to implement any changes to Circular A-21 made after February 11, 1986. *See Knezo, supra*, at 21-22. This rider “focused specifically on the proposal to cap administrative costs at 26 percent.” *Id.*

By the end of the 1980s, OMB had succeeded in modifying the individual-rate model in only one limited way: by “set[ting] a fixed overhead allowance for the administration of federally sponsored grants and contracts by department heads and

faculty.” Revision of OMB Circular A-21, “Cost Principles for Educational Institutions,” 51 Fed. Reg. 20,908, 20,908 (June 9, 1986). This cap, which was implemented after going through notice-and-comment, did not limit the expense rate for university facilities; it merely capped the expenses that the university could recoup related to “salaries of department heads and faculty in departmental administration.” *Id.* at 20,910; *see* Revision of OMB Circular A-21, “Cost Principles for Educational Institutions,” 51 Fed. Reg. 43,487, 43,488 (Dec. 2, 1986) (setting this rate at 3.6%); *see also* Knezo, *supra*, at 22.

The public debate concerning indirect cost rates continued through the 1990s. In 1991, the House of Representatives exhibited renewed interest in capping the administrative portion of indirect costs of some grants awarded to academic research institutions to 26%. *See* Knezo, *supra*, at 25. That year, the House passed two different bills including such a cap on grants awarded by NIH and the National Science Foundation. *See id.* Neither proposal cleared the Senate. *See id.*

The Executive likewise sought to impose such caps. In October 1991, following notice-and-comment rulemaking, OMB issued a final rule revising Circular A-21 to impose a 26% cap applicable only to the administrative-costs portion of indirect costs. Revisions to Circular A-21, “Cost Principles for Educational Institutions,” 56 Fed. Reg. 50,224, 50,228 (Oct. 3, 1991) (codified at 2 C.F.R. pt. 200, app. III § C(8)(a)). Until NIH’s action in this case, this was “the most

important” change to the indirect-cost model since Congress codified the pursuit of negotiated individualized rates. Droegemeier Testimony, *supra*, at 11. And, even then, this cap did not apply to all indirect costs—and did not supplant the individual-rate model.

OMB’s partial cap ultimately proved to be the high point for efforts to limit indirect expenses. In 1994, President Clinton proposed capping indirect costs rates, but OMB withdrew the plan after “significant opposition by universities.” Knezo, *supra*, at 29. The next year, President Clinton’s budget proposed a one-year pause on indirect costs, but it died in the Senate. Marcy E. Gallo & Laurie Harris, Cong. Rsch. Serv., R48540.2, *Universities and Indirect Costs for Federally Funded Research* 11 (2025). The House and Senate at times also proposed caps or pauses of the indirect cost rate in the early 1990s. *See* Knezo, *supra*, at 31-32; Gallo & Harris, *supra*, at 9. None of these efforts proved successful. And by 1996 Congress started including language in appropriations acts prohibiting the use of appropriated funds “to implement any cap on reimbursements to grantees for indirect costs, except as published in OMB Circular A-21.” Gallo & Harris, *supra*, at 11. Congress included similar prohibitions into the mid-2000s. *See id.*

C. The Individual-Rate Model Reflects A Fair-Share Principle That Congress Has Repeatedly Endorsed.

The model that existed until NIH’s action in this case reflected decades of public, interbranch negotiation between Congress and the Executive. That model,

codified in large part as the “Uniform Guidance” in current OMB regulations at 2 C.F.R. Part 200, is built around the repeatedly reaffirmed principle that individualized rate-setting through negotiation is the appropriate way to ensure that “the Federal Government bear[s] its fair share of total costs” of research. Circular A-21, at 1 (Revised 5/10/04).⁵

The Uniform Guidance devotes an entire Appendix and over 10,000 words to how academic research institutions must compute their indirect cost rates. *See generally* 2 C.F.R. pt. 200, app. III. An institution’s indirect cost rate proposal reflects a detailed and extensive internal costing analysis, often the product of painstaking accounting and financial evaluations over several months. The costs must be necessary and reasonable, allowable under the cost principles, appropriately allocated, and adequately documented. Following submission of an indirect cost rate proposal, the government and the university negotiate over many months or even years to reach a meeting of the minds on the rate.

As the Uniform Guidance lays out, an institution’s indirect cost rate should be based on (1) a methodology tied to “generally accepted accounting principles” and (2) a meaningful back-and-forth between the government and institutions. 2 C.F.R. § 200.1; *see also id.* § 200.414(c)(1) (“Negotiated indirect cost rates must be accepted by all Federal agencies.”). Successfully applying these principles, the

⁵ <https://perma.cc/2STC-RL9H>.

Guidance cautions, requires that there “be an advance understanding in each case between the institution and the cognizant agency for indirect costs.” *Id.* pt. 200, app. III § C(5). To that end, the Guidance repeatedly states that rates must be “negotiated.” *See generally id.* pt. 200, app. III. The Guidance observes that “[e]ach institution’s indirect (F&A) cost rate process must be appropriately designed” based on its own individualized considerations. *Id.* pt. 200, app. III § C(1)(a)(3). And the Guidance endorses as “the norm” using “predetermined rates”—that is, the rate agreed to between the institution and the government—during a particular accounting period. *Id.* pt. 200, app. III § C(4).⁶ In all these ways, the Guidance makes clear that an indirect cost rate should be both individualized and the product of good-faith negotiation.

Over the last decade, Congress has again shown its commitment to this individual-rate model. As Plaintiffs and the District Court below detailed, in 2017, the Trump Administration issued a budget proposal capping the indirect-cost rate to a uniform rate of 10%. *See* Department of Health and Human Services, *Fiscal Year 2018: Justification of Estimates for Appropriations Committees* 3;⁷ *see also* ADD.7.

⁶ At the same time, in keeping with the compromise nature of the current model, the Uniform Guidance maintains the 26% cap on *administrative* costs, first adopted in 1991 after years of public debate and through notice-and-comment rulemaking. *See id.* pt. 200, app. III § C(8)(a); *see also supra* pp. 11-13.

⁷ <https://perma.cc/S766-99XP>.

Congress unequivocally rejected that proposal with a bipartisan appropriations rider freezing in place the regulatory provisions related to indirect costs as they existed the year prior. *See Consolidated Appropriations Act, 2018, Pub. L. No. 115-141, § 226, 132 Stat 348, 740 (2018); see also ADD.7.*

The House and Senate Appropriations Committees spotlighted in their reports that this rider was a direct response to the Administration’s proposal. The House Appropriations Committee observed that “the Administration’s proposal to drastically reduce and cap reimbursement of facilities and administrative (F&A) costs to research institutions is misguided and would have a devastating impact on biomedical research across the country.” H.R. Rep. No. 115-244, at 50 (2017). The Senate Appropriations Committee, too, stressed that “[t]he Administration’s proposal would radically change the nature of the Federal Government’s relationship with the research community, abandoning the Government’s long-established responsibility for underwriting much of the Nation’s research infrastructure, and jeopardizing biomedical research nationwide.” S. Rep. No. 115-150, at 109 (2017).

Congress has repeatedly reenacted that rider in the appropriations laws governing HHS, including the now-operative statute. *See Further Consolidated Appropriations Act, 2024, Pub. L. No. 118-47, § 224, 138 Stat. 460, 677 (2024); see also ADD.7.*

* * *

In sum, both Congress and the Executive have embraced—for more than six decades—a general framework where institutions are reimbursed for the indirect costs associated with research grants according to an individualized negotiated rate. And when either Congress or the Executive seeks to change that default, it does so only after years of public debate and through appropriate procedures: an Act passed by Congress and signed into law by the President, or notice-and-comment rulemaking. The resulting system is the epitome of a long-standing policy. No wonder, then, that this model has engendered serious reliance interests: Academic research institutions have, for over half a century, negotiated individualized indirect cost rates with the federal government, and have been assured that such rates will continue to govern in all research projects they undertake until the next round of negotiation.

In its rush to wind the clock back to the early 1960s, NIH wholly failed to consider, much less explain, why it is appropriate to alter the longstanding government policy for funding research—including in multi-year research projects that are currently midstream. Indeed, NIH did not even gesture at the history and rationale underlying the current funding model. “It [was] arbitrary and capricious to ignore such matters.” *Regents*, 591 U.S. at 30 (citation omitted).

II. NIH FAILED TO ACCOUNT FOR THE SUBSTANTIVE DIFFERENCES BETWEEN FEDERAL AND PRIVATE FUNDING.

Rather than engage with the extensive history of the current individual-rate model, NIH attempted to justify its sea-change in federal funding by stating that the Rate Change Notice brings the indirect cost rates paid by the federal government in line with the indirect cost rates paid by some private foundations. *See* JA 89. NIH repeats this purported rationale before this Court too. *E.g.*, U.S. Br. 39. As the District Court rightly held, however, the mere fact that private foundations impose caps on indirect costs does not make the Rate Change Notice a product of reasoned decision-making. *See* ADD.34-35. That is because the statutory and regulatory framework mandating the government's reimbursement of indirect costs diverges substantially from the funding models used by private foundations. NIH entirely failed to consider these fundamental differences, rendering the Rate Change Notice arbitrary and capricious on this basis as well.

First, the federal government and private foundations calculate indirect costs in different ways. Private foundations typically allow for the recovery of indirect costs as a percentage of the grantee's *Total Direct Costs*. *See Comparing Foundation and Federal Government Research Support*, Council on Governmental Rels. 2 n.2 (Dec. 2024).⁸ But the federal indirect cost rate is a percentage of *Modified*

⁸ <https://perma.cc/M2UA-K6QP>.

Total Direct Costs—a smaller category that excludes certain costs. *See id.* For example, Modified Total Direct Costs exclude from an institution’s indirect cost recovery any expenditures for “equipment, capital expenditures, charges for patient care, rental costs, tuition remission, scholarships and fellowships, [and] participant support costs,” among other costs. 2 C.F.R. § 200.1. The result of these differing accounting techniques can be that a private grant covers a comparable percentage of “indirect” and similar costs as the federal government does. *See Comparing Foundation and Federal Government Research Support, supra*, at 2. The Rate Change thus would not bring the federal government in line with the private sector; it would result in the federal government reimbursing institutions for *less* of their indirect costs than the private sector does.

Second, the rate formalized in an institution’s indirect-rate agreement reflects the significant administrative burden the institution must undertake to comply with a federal grant. Federal grants are subject to a host of regulatory requirements that do not attach to private grants. Among other things, NIH awards are subject to effort-certification requirements, *see* 2 C.F.R. § 200.430; prior-approval, salary-cap, data-sharing, and subrecipient-monitoring requirements, *see id.* §§ 200.308, 331-333; and invention-reporting, financial-reporting, and audit requirements, *see id.* §§ 200.328, 500-521. Private grants, in contrast, typically require only simple financial reporting and are rarely subject to federally mandated standards. *See, e.g.,*

Reports from Grantees, Internal Revenue Serv.;⁹ *Private Foundation Expenditure Responsibility Requirements*, Gates Found. 2 (June 2022).¹⁰

These vastly different compliance requirements make the administrative burden for conducting federally funded research substantially higher than for conducting privately funded research. Put simply, academic research institutions bear more overhead costs to perform research under a federal grant than under a private grant. Those increased administrative expenses are offset in part by the higher federal indirect cost rates that institutions negotiate with agencies. NIH thus cannot simply look to grants offered by the private sector—which do not come along with a web of expensive regulations—to justify cutting the federal rate.

NIH would have recognized these fundamental differences between private foundation and federal grants if it had conducted a proper analysis. It would have also acknowledged that, unlike some private grants, federal grants generally allow institutions to retain title to inventions, promoting broad dissemination and societal use.¹¹ But NIH conducted no such analysis. Instead, it offered an apples-to-oranges comparison to justify what appears to have been a predetermined conclusion. This falls far short of the “‘reasoned decisionmaking’ required by the APA.” ADD.35

⁹ <https://perma.cc/3RG9-CJH5>.

¹⁰ <https://perma.cc/VJ4Z-QBXJ>.

¹¹ See 35 U.S.C. § 200 (Bayh-Dole Act’s purpose is “to promote the commercialization and public availability of inventions made in the United States”).

(quoting *Regents*, 591 U.S. at 16); see AAMC & AAU Plaintiffs-Appellees’ Br. 47-48; State Plaintiffs-Appellees’ Br. 40.

III. THE RATE CHANGE WILL CAUSE IMMEDIATE AND IRREPARABLE HARM TO UNIVERSITIES AND THE NATION AS A WHOLE.

In addition to correctly finding NIH’s rate cap substantively unlawful, the District Court also correctly concluded that an injunction against its enforcement was necessary to forestall irreparable harm. ADD.56-68. Plaintiffs have amply demonstrated this harm in their papers. See AAMC & AAU Plaintiffs-Appellees’ Br. 53-54; State Plaintiffs-Appellees’ Br. 29-30. *Amici* write separately to underscore the scope of this harm.

A. The Rate Change Will Irreparably Harm Universities And The Scientific Enterprise.

Like the dozens of institutions that submitted declarations testifying to the harm they would suffer absent injunctive relief, *amici*’s own members credibly fear the enormous negative consequences that will flow from the Rate Change.

1. A permanent injunction is necessary to avoid upending groundbreaking research that benefits the nation as a whole. The Rate Change Notice threatens a wide range of critical biomedical and basic research and development performed by *amici*’s members that rely on specialized facilities and infrastructure. This infrastructure is made possible by predictable and adequate federal indirect-cost funding to support their long-term operation.

Examples of actual projects affected by the rate cut include **cardiovascular-disease research** defining risk factors for heart attacks and strokes to determine which interventions are effective; **cancer-related research** improving treatment outcomes for breast and prostate cancer, studying the impact of certain proteins in metastasis of melanoma, and understanding rural mortality disparities in cancer; research into the **prevention of Alzheimer’s Disease and related dementias**; the development of **lab-grown heart tissue** that can be used for drug cardiotoxicity screening; the development of imitation learning systems that can **improve the reliability and safety of generative artificial intelligence algorithms** using mathematically precise frameworks; **pulmonary-disease research** with the potential to transform how we treat pneumonia and other respiratory diseases; research to understand the **effects of repetitive head injury** in contact sports; and brain-inspired algorithms to **improve hearing aids and speech recognition** for individuals with autism and Attention-Deficit/Hyperactivity Disorder.

That only begins to scratch the surface. These projects, and many others underway at *amici*’s member universities, require specialized facilities and infrastructure, which in turn require a predictable and adequate federal indirect cost rate that accounts for an institution’s specific circumstances. *Cf.* Azoulay et al., *supra*, at 21 (concluding that “a flat 15% rate would have resulted in substantial

funding cuts for the institutions that contributed the most to new drug development over the past 20 years”).

Academic research institutions operate cutting-edge facilities such as **cancer centers** that foster innovative approaches to suppressing disease at its earliest stage and that conduct immunotherapy research into accessible natural killer cell therapies for blood cancers; **metabolomics centers** that enable early, non-invasive cancer detection and microbiome research for conditions like *C. difficile* infection; **science-imaging centers** offering Magnetic Resonance Imaging (MRI), ultra-high-field MRI instrumentation, electrophysiology, and other neuroimaging capabilities essential for research on Alzheimer’s Disease and other neurodegenerative diseases, brain function in psychiatric disorders, and brain plasticity; **clinical research centers** supporting studies on maternal nutrition, cardiovascular health among cancer survivors, and endometriosis; and **high-containment biosafety labs, nano-fabrication cleanrooms, and high-performance computing facilities** addressing national priorities in health, energy, environment, and security. If the indirect cost rate cap took effect, there is a very real probability that these critical facilities would languish in the short term and ultimately be shuttered, depriving Americans of breakthroughs in lifesaving medicine and treatment options.

Specialized research programs that cannot be easily reconstituted would be hit especially hard. Consider centers for the study of child maltreatment, which support

science to change health and developmental trajectories for victims of child abuse. Given the sensitive nature of this research, these studies take place in specialized secure facilities with strict compliance standards. Without fair reimbursement of the indirect costs necessary to run these facilities, investigators would not be able to provide victims and their families with the safety and security necessary to track the child's mental, behavioral, and physical health outcomes across development, imperiling the development of novel interventions to promote resilience.

Clinical-trial programs would likewise face immediate jeopardy absent an injunction. The Institutional Review Boards that oversee ethical review and compliance of all clinical trials would be forced to reduce staff, delaying protocol reviews and hindering the timely initiation of critical studies, including early-phase trials for cancer therapies and precision medicine. Patient-navigator programs supporting rural and underserved populations in accessing clinical trials would lose funding, reducing trial diversity and generalizability of results. In rare-disease and pediatric trials requiring long-term follow-ups and multisite collaborations, academic research institutions would be forced to cut coordination staff and specialized research nurses, reducing the viability of participation in multisite trials and jeopardizing advancements for these vulnerable patient populations.

2. Universities cannot simply pivot to other funds to sustain these research programs and facilities if a blanket 15% indirect cost rate immediately took effect.

Amici's member universities rely on sources of revenue that are often highly restricted for specific purposes: from endowments with donor-specific restrictions to state funding that is often designated for specific undergraduate education purposes, to charitable contributions that are often restricted to student aid or athletics, and so on. Simply put, a 15% cap would require institutions to either: (1) subsidize the federal government even more than they already do by diverting funds from students and certain academic programs, *contra* 2 C.F.R. § 200.306(a); (2) narrow the scope of their research endeavors or perform less research on behalf of the federal government; and/or (3) exit the research enterprise altogether. There is no good option: Either students or the scientific community will have to pick up the tab for the government breaching its longstanding promise to pay its fair share of the research it purports to fund.

Indeed, *amici*'s members anticipate that, if the rate cap takes effect, they will have to furlough many non-tenured researchers—starting immediately. *Amici*'s member universities report that although researchers do not want to leave their institutions, the likely outcome is that top talent will relocate to or begin collaboration with other countries, or shift to conducting research for private gain rather than the public good. Academic research institutions would be hard-pressed to replace lost faculty, particularly after projects have been halted mid-cycle and research momentum has been lost. This brain drain will have significant ripple

effects. The next generation of researchers will not be able to learn from the best, causing the country to fall further behind in scientific advancements and discovery.

Should institutions attempt to continue engaging in federal research, they could not make up the shortfall by reducing their own facility and administrative costs. As explained above, the administrative infrastructure that indirect costs support is not optional overhead but essential compliance machinery. Indirect costs fund the administration of awards, including staff who ensure compliance with the vast number of regulatory mandates from agencies such as NIH. *See supra* pp. 19-20, 23-24. These mandates serve critical functions for *amici*'s members: ensuring research integrity; protecting the safety of participants and researchers; properly managing, securing, and disposing of chemical and biological agents; managing funds in accordance with federal regulations; providing the high level of cybersecurity mandated for regulated data; ensuring compliance with specialized security protocols and safety standards; maintaining facility accreditation and equipment calibration; and reviewing and managing potential financial conflicts of interest to prevent bias in research. These staff often must have specialized education and training as well as federal approvals needed to work on NIH projects—expertise that cannot be readily replaced. *See, e.g., Grants Compliance & Oversight*, NIH (last updated Sept. 23, 2024);¹² *see also* 2 C.F.R. §§ 200.308, 328,

¹² <https://perma.cc/KNM8-5698>.

331-333, 430, 500-521 (detailing the many research-related compliance requirements).

3. The long-term effects of dramatically cutting indirect cost reimbursement would be both cumulative and cascading. By kneecapping research at academic research institutions, the rate cap will undermine the local economies surrounding and supporting this research. *See NIH'S Role in Sustaining the U.S. Economy, United for Med. Rsch. 2* (Mar. 2025).¹³ After all, research is not self-sustaining: Materials must be purchased, labs must be cleaned, and facilities must be kept secure. Capping indirect costs at 15% will immediately hamstring institutions' ability to pay for these subsidiary services. This rapid shift in funding will thus harm localities surrounding research institutions, many of which are in rural areas.

In this way, the Rate Change Notice will have economic impacts extending far beyond individual institutions. *See id.* at 5. Universities employ tens of thousands of people and collaborate with state and local partners to help solve regional challenges through joint research and innovation. Research fuels spending in the regional economy, driving discoveries that launch new ventures, attract private investment, and make positive social impact. *See id.* at 4. A massive reduction in universities' research budgets would immediately and seriously jeopardize these

¹³ <https://perma.cc/NW9F-SHZM>.

contributions to local regions, creating ripple effects throughout entire state economies.

B. These Harms Cannot Be Remedied Through Retrospective Financial Damages.

The nature of these harms makes clear why the District Court was right to reject NIH’s contention that this suit should have been brought under the Tucker Act. The sole type of relief authorized by the Tucker Act—money damages—is wholly insufficient to address the structural and irreversible harms that will flow from imposition of an immediate rate cut and cap. *See, e.g., Bowen v. Massachusetts*, 487 U.S. 879, 893-894 (1988) (explaining that the Tucker Act only authorizes damages that provide “compensation” for injury, not reimbursement for “costs that Congress intended” be paid).

Academic research institutions have for decades relied on the individual-rate model to build and maintain sophisticated research infrastructure. The well-established process for negotiating indirect cost rates with the government has informed institutional budgeting and planning, with operating budgets relying on estimates of both direct- and indirect-sponsored funding to plan for annual staffing needs, infrastructure support, and facility and equipment purchases.

Money damages cannot remedy the myriad ways this planning and investment would be disrupted—in no small part because there is no meaningful way to measure or reverse the cascading harms from that disruption after the fact. As explained

above, should the rate cap go into effect, life-saving research will halt or be upended. *See supra* pp. 21-28. This research slowdown, in turn, will likely cause institutions to cease investing in their research infrastructure. The specialized facilities that support cutting-edge research require continuous maintenance, upgrades, and compliance with evolving safety and security standards. *Amici*'s members maintain that once this infrastructure degrades or is shuttered, the cost of bringing it back to operational status far exceeds the original investment—and any judgment an institution can expect to receive in the Court of Federal Claims.

The cascading effects extend beyond physical infrastructure to operational systems. The immediate loss of researchers and administrative staff precipitated by the rate cap would be followed by a degradation of workflow and research administration and operations, leading to inefficiencies and vulnerabilities that would compound over time. The regulatory compliance systems, data-management protocols, and safety procedures that enable complex research cannot be quickly reconstituted once dismantled—and their loss is hard to even quantify.

And then there is the devastating loss of human capital that drives American scientific leadership. *See supra* pp. 25-26. No dollar figure can adequately compensate for the scientific talent that flee American universities and their commitment to research for the benefit of the American public.

The long-term scientific, national-security, and economic implications of NIH's action cannot be understated, and cannot be remedied by money damages. The shuttering of core research infrastructure and the loss of talent will not only undermine the scientific enterprise—with devastating consequences for those whose health relies on the cutting-edge research conducted at universities—it will undermine national security and hinder the nation's long-term economic growth. Slowdowns or halts in domestic research will allow competitor nations that are maintaining their investments in research to beat the United States to scientific breakthroughs. Indeed, *amici*'s members report that several foreign countries have already started increasing recruitment of top-tier faculty, recognizing the opportunity to capture American scientific talent and expertise. And slashing the indirect cost rate for the basic research that underpins so much innovation in the American economy will slow growth across industries.

Money damages are fundamentally inadequate because they assume that financial compensation can restore what has been lost. *See generally Bowen*, 487 U.S. at 895 (explaining that “[d]amages are given to the plaintiff to *substitute* for a suffered loss” (emphasis in original) (citation omitted)). But the damage that would follow from the Rate Change is not merely a question of money owed but of scientific capacity destroyed, human capital dispersed, and national competitive advantage surrendered. Once research ecosystems are dismantled, faculty have

departed, students have been denied training opportunities, and infrastructure has degraded, no amount of retrospective financial compensation can restore America's position as the global leader in scientific research and innovation.

CONCLUSION

For these reasons and those in Plaintiffs-Appellees' Briefs, this Court should affirm the District Court's judgment.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

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I certify that on June 16, 2025, the foregoing was electronically filed through this Court's CM/ECF system, which will send a notice of filing to all registered users.

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