Nos. 25-1344, 25-1345

UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

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.

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; 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 Department of Health and Human Services; JAY BHATTACHARYA, M.D., PH.D. in their official capacity as Director of the National Institutes of Health,

Defendants-Appellants.

On Appeal from the United States District Court for the District of Massachusetts

---

BRIEF FOR PLAINTIFFS-APPELLEES

(*Counsel Listed on next page*)

JOHN P. BUEKER
ROPES & GRAY LLP
800 Boylston Street
Boston, MA 02199
(617) 951-7951

DOUGLAS H. HALLWARD-DRIEMEIER
STEPHANIE A. WEBSTER
ROPES & GRAY LLP
2099 Pennsylvania Ave., NW
Washington, DC 20006

Counsel for Plaintiffs-Appellees in Case No. 25-1344

ISHAN K. BHABHA
LINDSAY C. HARRISON
LAUREN J. HARTZ
ELIZABETH HENTHORNE
ZACHARY C. SCHAUF
ADAM G. UNIKOWSKY
JENNER & BLOCK LLP
1099 New York Ave., NW, Suite 900
Washington, DC 20001
(202) 637-6327

Counsel for all Plaintiffs-Appellees in Case No. 25-1345

PAUL D. CLEMENT
Counsel of Record
JAMES Y. XI*
KYLE R. EISWALD*
CLEMENT & MURPHY, PLLC
706 Duke Street
Alexandria, VA 22314
(202) 742-8900
paul.clement@clementmurphy.com

* Supervised by principals of the firm who are members of the Virginia Bar

Counsel for Association of American Universities, Association of Public Land-grant Universities, and American Council on Education in Case No. 25-1345

SHOBA PILLAY
JENNER & BLOCK LLP
353 N Clark Street
Chicago, IL 60654

June 9, 2025

CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1(a), the Association of American Medical Colleges, the American Association of Colleges of Pharmacy, the Association for Schools and Programs of Public Health, the Conference of Boston Teaching Hospitals, Inc., and Greater New York Hospital Association certify that they do not have parent corporations and that no publicly held corporations own more than ten percent of any of their stock.

Pursuant to Federal Rule of Appellate Procedure 26.1(a), the Association of American Universities, the American Council on Education, and the Association of Public and Land-grant Universities, Brandeis University, Brown University, California Institute of Technology, Carnegie Mellon University, 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 Regents of the University of California, and University of Chicago certify that they do not have parent corporations and that no publicly held corporations own more than ten percent of any of their stock.

TABLE OF CONTENTS

CORPORATE DISCLOSURE STATEMENT i

TABLE OF AUTHORITIES iv

INTRODUCTION 1

STATEMENT OF THE CASE 4

A. Statutory and Regulatory Background 4

1. Federal Reimbursement of Indirect Research Costs 4

2. Prior Attempts to Cap Indirect Cost Rates for NIH Grants 10

3. The Challenged Guidance 12

B. Procedural Background 13

SUMMARY OF ARGUMENT 17

ARGUMENT 20

I. The District Court Had Jurisdiction 20

II. NIH's Decision To Cap Indirect Cost Rates Is Unlawful 26

A. Congress Prohibited NIH From Capping Indirect Costs 26

B. The Supplemental Guidance Runs Afoul of NIH's Own Regulations 36

C. NIH's Decision to Cap Indirect Cost Rates Is Arbitrary and Capricious 43

D. The Supplemental Guidance Should Have Gone Through Notice and Comment 49

E. The Supplemental Guidance Is Impermissibly Retroactive 51

III. The Dramatic Effect On Plaintiffs And Their Members Fully Justifies Permanent Injunctive Relief 53

CONCLUSION 55

CERTIFICATE OF COMPLIANCE WITH RULE 32(a)

CERTIFICATE OF SERVICE

TABLE OF AUTHORITIES

Cases

Am. Sci. & Eng'g v. Califano,
571 F.2d 58 (1st Cir. 1978) 21

Ass'n of Am. Univs. v. DOE,
2025 WL 1414135 (D. Mass. May 15, 2025) ..... *passim*

Atterbury v. U.S. Marshals Serv.,
805 F.3d 398 (2d Cir. 2015) 23

Biden v. Nebraska,
600 U.S. 477 (2023) 35, 38

Bowen v. Georgetown Univ. Hosp.,
488 U.S. 204 (1988) 51

Bowen v. Massachusetts,
487 U.S. 879 (1988) 22

California v. U.S. Dep't of Educ.,
2025 WL 760825 (D. Mass. Mar. 10, 2025) 24

Clarian Health W. v. Hargan,
878 F.3d 346 (D.C. Cir. 2017) 49

Cmty. Legal Servs. in E. Palo Alto v. HHS,
2025 WL 1393876 (9th Cir. May 14, 2025) 21, 25

Comm'r v. Clark,
489 U.S. 726 (1989) 38

Crowley Gov't Servs. v. GSA,
38 F.4th 1099 (D.C. Cir. 2022) 20, 21, 23

Dep't of Com. v. New York,
588 U.S. 752 (2019) 34

Dep't of Educ. v. California,
145 S.Ct. 966 (2025) 18, 20, 24, 25

DHS v. Regents of the Univ. of Cal.,
591 U.S. 1 (2020) 43, 45, 47

FCC v. Fox Television Stations,
556 U.S. 502 (2009) 46, 47, 50

FDA v. Wages & White Lion Invs.,
145 S.Ct. 898 (2025) 50

Landgraf v. USI Film Prods.,
511 U.S. 244 (1994) 51

Lomax v. Ortiz-Marquez,
140 S.Ct. 1721 (2020) 32

Martin v. Hadix,
527 U.S. 343 (1998) 52

MCI Telecomms. Corp. v. AT&T,
512 U.S. 218 (1994) 38

Me. Cmty. Health Options v. United States,
590 U.S. 296 (2020) 22, 25

Megapulse v. Lewis,
672 F.2d 959 (D.C. Cir. 1982) 21, 22, 23

N.H. Lottery Comm'n v. Rosen,
986 F.3d 38 (1st Cir. 2021) 29

Niz-Chavez v. Garland,
593 U.S. 155 (2021) 42

OPM v. Richmond,
496 U.S. 414 (1990) 35

Perez v. Mortg. Bankers Ass'n,
575 U.S. 92 (2015) 47, 49

Plaut v. Spendthrift Farm,
514 U.S. 211 (1995) 33, 34

Ratzlaf v. United States,
510 U.S. 135 (1994).....33

Rotinsulu v. Mukasey,
515 F.3d 68 (1st Cir. 2008).....50

Service v. Dulles,
354 U.S. 363 (1957).....50

Stern v. Marshall,
564 U.S. 462 (2011).....26

Util. Solid Waste Activities Grp. v. EPA,
236 F.3d 749 (D.C. Cir. 2001).....50

Constitutional Provision

U.S. Const. art. I, §9, cl. 7.....35

Statutes

2 U.S.C. §683(b).....32

5 U.S.C. §553(a)(2).....49

5 U.S.C. §706(2)(A).....43

28 U.S.C. §1331.....20

28 U.S.C. §1491.....13

42 U.S.C. §241(a)(3).....5

Act of June 29, 1957,
Pub. L. No. 85-67, 71 Stat. 210 (1957).....6

Act of Aug. 14, 1962,
Pub. L. No. 87-582, 76 Stat. 361 (1962).....6

Act of Aug. 31, 1965,
Pub. L. No. 89-156, 79 Stat. 589 (1965).....7

Act of Dec. 12, 1985,
Pub. L. No. 99-178, 99 Stat. 1102 (1985).....8

Consolidated Appropriations Act, 2018,
Pub. L. No. 115-141, 132 Stat 348 (2018) 2, 11

Full-Year Continuing Appropriations and Extensions Act, 2025,
Pub. L. No. 119-4, 139 Stat. 9 (2025).....11

Further Consolidated Appropriations Act, 2024,
Pub. L. No. 118-47, 138 Stat. 460 (2024).....11, 27, 35

Public Health Service Act,
Pub. L. No. 78-410, 58 Stat. 682 (1944) 5

Rural Development, Agriculture, and Related Agencies Appropriations Act, 1990,
Pub. L. No. 101-161, 103 Stat. 951 (1989) 10

Regulations

45 C.F.R. §75.2 ..... 8, 9, 37

45 C.F.R. §75.100(c).....8

45 C.F.R. §75.404 8

45 C.F.R. §75.405 8

45 C.F.R. §75.414(c).....8

45 C.F.R. §75.414(c)(1) ..... *passim*

45 C.F.R. §75.414(c)(3)..... *passim*

45 C.F.R. §75.414(c)(4) 9, 37, 40, 46

45 C.F.R. §75.415(a).....31

45 C.F.R. §75.501(b).....9

45 C.F.R. §75.504 9

45 C.F.R. §75.514 9

45 C.F.R. pt. 75, App. III.....8

45 C.F.R. pt. 75, App. III §C.1.a 48

45 C.F.R. pt. 75, App. III §C.4 8

45 C.F.R. pt. 75, App. III §C.5 9

45 C.F.R. pt. 75, App. III §C.7 8

45 C.F.R. pt. 75, App. III §C.7.a 9, 46

45 C.F.R. pt. 75, App. III §C.7.b 45

45 C.F.R. pt. 75, App. III §C.11.a 8

45 C.F.R. pt. 75, App. III §C.11.f 8

45 C.F.R. pt. 75, App. III §F.1 31

45 C.F.R. pt. 75, App. IV §C.1.a 8

Health and Human Services Grants Regulation,
81 Fed. Reg. 45,270 (July 13, 2016) 50

Public Participation in Rule Making,
36 Fed. Reg. 2,532 (Feb. 5, 1971) 49

Other Authorities

Application, *Dep't of Educ. v. California*,
145 S.Ct. 966 (2025) (No. 24A910) 24

R. Geiger, Research & Relevant Knowledge:
American Research Universities Since World War II (1993) 4, 5

H.R. 3958, 103rd Cong. (1994) 10

H.R. Rep. No. 89-272 (1965) 7

H.R. Rep. No. 99-402 (1985) 8

H.R. Rep. No. 115-244 (2017) 11, 31, 33, 46

Jocelyn Kaiser, *NIH Plan to Reduce Overhead Payments Draws Fire*,
Science (June 2, 2017), https://tinyurl.com/ykeafy4d 48

Limitation on Indirect Costs in Research Grants: Hearing Before the H.
Comm. on Sci. & Astronautics, 87th Cong. (1962) 6, 7

NIH Study Comm., Biomedical Science and Its Administration: A Study of the National Institutes of Health (1965) 7

Off. of Mgmt. & Budget, A Budget for a Better America (2019) 2, 11

F. Roosevelt, Letter on Plans for Postwar Scientific Research and Development (Nov. 20, 1944) 4

S. 1184, 103rd Cong. (1993) 10

S. Rep. No. 115-150 (2017) ..... *passim*

The American Heritage Dictionary (5th ed. 2016) 38

U.S. Dep't of Health & Hum. Servs. & Nat'l Insts. of Health, NIH Grants Policy Statement (rev. Apr. 2024) 9, 10

Webster's Third New International Dictionary (1966) 40

INTRODUCTION

The United States' world-leading position in medical research reflects in large part how it has funded research for the last six decades. For over sixty years, the National Institutes of Health has followed an institution-specific approach to reimbursing "indirect costs," i.e., costs that are necessary for research to occur but are shared between multiple projects. Under that process, research institutions negotiate an institution-specific "indirect cost rate" with the government through a carefully regulated process, based on each institution's unique needs and cost structure. That negotiation yields a rate that is intended to reflect the actual, verified indirect costs incurred by the institution. The wide variety of institution-specific circumstances means rates can vary greatly depending on the kind of research and the types of facilities a particular institution employs in its research. After having gone to the trouble of negotiating a bespoke rate, the regulations allow agencies to deviate from that negotiated rate only in narrow circumstances, and only via procedures that provide ample notice and protection to the institution to ensure the basic terms of engagement are not changed precipitously and without warning. The regulatory framework recognizes that there is no one-size-fits-all approach and that participating institutions have profound reliance interests in their negotiated rates.

Over the years, policymakers in Washington have toyed with capping indirect cost rates for medical research. But Congress has repeatedly and decisively rejected

such an approach. Most recently, in 2017, the Administration proposed displacing NIH's longstanding regime of institution-specific negotiated rates with an across-the-board 10% cap on indirect costs. Congress' reaction was swift and unmistakable. Citing the extensive reliance interests of research institutions on negotiated rates, Congress enacted an appropriations rider nixing the 10% cap and providing that the regulatory "provisions relat[ed] to indirect costs . . . 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." Pub. L. No. 115-141, §226, 132 Stat 348, 740 (2018). The rider further prohibits NIH from spending appropriated funds "to develop or implement a modified approach to such provisions or to intentionally or substantially expand the fiscal effect of the approval of such deviations from negotiated rates beyond the proportional effect of such approvals in such quarter." *Id.* The Administration acknowledged in 2019 that, under the rider, "NIH has been prohibited by law from reducing grantee administrative costs and shifting these resources to support direct research." Off. of Mgmt. & Budget, A Budget for a Better America 43 (2019). While the Administration called on Congress to "eliminate the current prohibition," *id.*, Congress declined to do so and has re-enacted the rider in every Department of Health and Human Services appropriation bill since.

In defiance of the riders and the broader regulatory regime they embrace, NIH issued "Supplemental Guidance" in early February that purported to overturn its decades-long approach. Without any notice, NIH announced on a Friday evening in a terse, three-page document that, starting the next business day, it would no longer reimburse grantees for indirect costs based on institution-specific rates, but would instead cap indirect-cost reimbursements at 15% for all NIH grants, including existing ones.

As the district court correctly recognized, NIH's attempt to discard carefully negotiated institution-specific rates in favor of a one-size-fits-all rate of 15% is the definition of arbitrary and capricious agency action and is unlawful for a host of reasons. The Guidance defies the appropriations rider Congress specifically (and repeatedly) enacted to prohibit NIH from adopting such a cap. It contravenes NIH's own regulations which allow NIH to deviate from pre-negotiated, institution-specific rates only for a subset of its grants and only after publicly announcing the "policies, procedures and general decision making criteria" NIH "will follow to seek and justify deviations from negotiated rates." 45 C.F.R. §75.414(c)(3). And it violates the Administrative Procedure Act both substantively and procedurally, as it is arbitrary and capricious in the extreme, was promulgated without notice and comment, and is impermissibly retroactive. The district court correctly vacated the Guidance and enjoined the government from enforcing it. This Court should affirm.

STATEMENT OF THE CASE

A. Statutory and Regulatory Background

1. Federal Reimbursement of Indirect Research Costs

Federal funding for research was born out of necessity during World War II. Concerned that its own labs could not keep up with scientific advances in Germany, the federal government partnered with American universities and other research institutions to churn out research necessary to develop tools for war. *See* R. Geiger, Research & Relevant Knowledge: American Research Universities Since World War II 5-7 (1993). While much of that research focused on developing weapons and improving aviation, radar, and communications technology, "war-related medical research" was important too. *Id.* at 12. Federally funded medical research led to numerous discoveries critical to the war effort, including new methods of mass-producing penicillin and improvements in blood-transfusion technology. *Id.*

President Roosevelt saw "no reason" why the "information, the techniques, and the research experience developed" by the federal government and "the thousands of scientists in the universities" during the war could not "be profitably employed in times of peace" for "the improvement of the national health." F. Roosevelt, Letter on Plans for Postwar Scientific Research and Development (Nov. 20, 1944). Thus, in 1944, Congress passed and President Roosevelt signed the Public Health Service Act, which authorized the Surgeon General to "[m]ake grants in aid to universities" to conduct medical research. Pub. L. No. 78-410, §301(d), 58

Stat. 682, 692 (1944) (codified as amended at 42 U.S.C. §241(a)(3)). By 1951, NIH was "providing approximately half of the funds in the medical grants economy." Geiger, *supra*, at 27. Today, NIH is the primary source of federal funding for medical research in the United States. In Fiscal Year 2023, for instance, NIH spent over $35 billion on almost 60,000 competitive grants to more than 300,000 researchers. ADD.3. Those grants have generated pathbreaking discoveries—ranging from breakthroughs in genomic sequencing, to MRI technology, to cancer treatments.

Ever since the federal government began funding medical research in the 1940s, debates have raged about how the government should account for the "indirect costs" of that research, "from administration and facilities to the cost of equipment shared across multiple researchers." S. Rep. No. 115-150, at 109 (2017). Unlike "direct costs" that can be attributed to a specific research project, "indirect costs" (also known as "facilities and administrative costs," or "F&A costs") are spread out across multiple projects. "[A]t research facilities focused on making the next breakthrough in cancer treatment," for example, "indirect costs supply the air handlers that provide the precise conditions needed to generate therapeutic T cells for immunotherapy trials, complex data systems to analyze and protect patients' genomic data, and support for the next generation of scientific leaders." *Id.* Indirect costs are no less critical for medical research than direct costs and may simply reflect

that some institutions have received multiple grants and are efficiently employing facilities across several projects.

Congress initially capped reimbursement for "indirect expenses" of NIH-funded research at "15 per centum of the direct costs." Pub. L. No. 85-67, §208, 71 Stat. 210, 224 (1957); *see also* Pub. L. No. 87-582, §203, 76 Stat. 361, 379 (1962) (increasing cap to 20 percent). But that approach proved controversial—and short lived. President Kennedy "urge[d] the Congress to remove" the "current limitation on payment of indirect costs by the National Institutes of Health in connection with research grants to universities and other institutions," explaining that the "statutory limitation for indirect costs [that] is now in effect for research grants made by the National Institutes of Health … has imposed serious financial difficulties particularly for many of our medical schools." Limitation on Indirect Costs in Research Grants: Hearing Before the H. Comm. on Sci. & Astronautics, 87th Cong. 6-7 (1962). He explained that such costs "are just as much a part of the cost of research as the salary of the scientist or technician." *Id.* at 6. And he noted that a "flat rate does not recognize that research projects differ greatly in character and in the nature of their indirect costs." *Id.* at 7. Research "involving substantial physical facilities such as animal quarters for biological research or particle accelerators," for example, "requires considerable space or electrical power with consequent high indirect costs," while "theoretical studies may require little supporting assistance

beyond administrative help." *Id.* "Clearly," President Kennedy explained, "a single inflexible rate for indirect costs would treat unfairly those institutions whose research work is such as to need substantial indirect services." *Id.*

A study commissioned by the President likewise concluded that "the establishment of an arbitrary indirect percentage limit has some unfortunate consequences." NIH Study Comm., Biomedical Science and Its Administration: A Study of the National Institutes of Health 28-29 (1965). It recommended that Congress "abandon[]" "[r]eliance upon an arbitrary indirect cost percentage" and replace it with an approach where "each institution" "present[s] a complete accounting of all of the costs of 'doing business' that it can support as chargeable or allocable to the project in question, with a minimum of emphasis on formal direct/indirect distinctions." *Id.*

Congress agreed and removed the cap on indirect costs, replacing it with language specifying that federal funds may not exceed "the entire cost of such project." Pub. L. No. 89-156, §203, 79 Stat. 589, 608 (1965). Thus, while Congress required that "part of the cost of research and demonstration projects should be met by the sponsoring institution" via a cost-sharing requirement, it eliminated the cap on indirect cost payments to permit an "institution[]" or "project" specific approach to indirect costs. H.R. Rep. No. 89-272, at 52-53 (1965). Congress later eliminated the explicit cost-sharing requirement on the understanding that NIH would "take

steps to contain both indirect and direct costs" through "careful management" rather than "[a]rbitrary percentage reductions in indirect and direct costs." H.R. Rep. No. 99-402, at 28 (1985) (Conf. Rep.); *see also* Pub. L. No. 99-178, 99 Stat. 1102 (1985).

The current "methodology for negotiating indirect costs" has thus "been in place since 1965." S. Rep. No. 115-150, at 109 (2017). Under that methodology, research institutions use cost-based accounting systems to recover their actual, documented costs for conducting research. Typically, a single agency, such as HHS, negotiates an indirect cost rate with an institution. 45 C.F.R. pt. 75, App. III §C.11.a.1, f. That rate then applies to all that institution's grants across the federal government. *Id.* §75.414(c); *id.* pt. 75, App. III §C.11.f(1); *id.* pt. 75, App. IV §C.1.a. As part of those negotiations, federal regulations require institutions to conduct comprehensive cost analyses that follow detailed federal guidelines governing reasonable and allowable indirect costs. *Id.* §§75.2, 75.100(c), 75.404, 75.405; *id.* pt. 75, App. III. The process entails extensive back-and-forth negotiations ultimately yielding an agreement between the institution and the agency on an indirect cost rate. This rate reflects the actual, verified indirect costs incurred by the institution.

Once the institution and the agency agree on a cost rate, that rate binds the federal government for a specified period (typically at least one year, but sometimes up to four). *Id.* pt. 75, App. III §C.4, 7; *see id.* §75.414(c)(1). After payments are made, federal agencies conduct audits to ensure that the negotiated indirect cost rate

conforms to actual indirect costs incurred. *Id.* §§75.2, 75.501(b), 75.504, 75.514. The indirect cost rate for the next period is then adjusted if the audit establishes that the institution has recovered excess costs. *See id.* pt. 75, App. III §C.5.

NIH's regulations require it to use the institution-specific negotiated indirect cost rate in effect at the time of an initial grant award for the life of such award, *id.* §C.7.a, unless a deviation "for a class of Federal awards or a single Federal award" is "required by Federal statute or regulation" or is "approved by a Federal awarding agency head or delegate based on documented justification as described in paragraph (c)(3) of this section." *Id.* §75.414(c)(1). Paragraph (c)(3), in turn, 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." *Id.* §75.414(c)(3). The regulations also require the agency to include its policies relating to indirect cost rate reimbursement in notices of funding opportunities so prospective grantees can make an informed decision about whether to apply for a grant. *See id.* §75.414(c)(4). The NIH Grants Policy Statement sets out for NIH grant recipients "the policy requirements that serve as the terms and conditions of NIH grant awards." U.S. Dep't of Health & Hum. Servs. & Nat'l Insts. of Health, NIH Grants Policy Statement ii (rev. Apr. 2024). As to the reimbursement of indirect costs, the Policy Statement confirms that these rates are to be negotiated with one of several

"agenc[ies] with cognizance for F&A/indirect cost rate (and other special rate) negotiation.," *id.* at IIA-68, and 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.

2. Prior Attempts to Cap Indirect Cost Rates for NIH Grants

NIH's Supplemental Guidance is not the first attempt to supplant institution-specific negotiated rates with a one-size-fits-all approach. But while Congress has sometimes capped indirect cost rates for research funded by *other* agencies, *see, e.g.*, Pub. L. No. 101-161, §639, 103 Stat. 951, 986 (1989) (capping indirect costs on research grants awarded by the Cooperative State Research Service at "25 per centum of total direct costs"), efforts to cap indirect cost rates for *NIH-funded research* have repeatedly failed. In the 1990s, for example, Congress considered multiple bills that would have capped indirect costs at 50% of direct costs. *See* S. 1184, 103rd Cong. §1 (1993); H.R. 3958, 103rd Cong. §702 (1994). Congress did not enact any of those bills.

In 2017, as part of his annual budget submission to Congress, President Trump proposed slashing the indirect cost rate for NIH-funded research to 10% across the board. JA94. That proposal, like the less drastic ones before it, spurred immediate criticism and swift action. In response, Congress enacted an appropriations rider "directing NIH to continue reimbursing institutions for F&A costs according to the

rules and procedures described in 45 CFR 75" and "prohibit[ing] funds … from being used to implement any further caps on F&A cost reimbursements." H.R. Rep. No. 115-244, at 50 (2017); *see also* S. Rep. No. 115-150, at 109 (2017). The provision states:

> 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 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.

Pub. L. No. 115-141, §226, 132 Stat. 348, 740 (2018).

The Administration acknowledged in 2019 that the rider "prohibit[s]" NIH "by law from reducing grantee administrative costs and shifting these resources to support direct research." Off. of Mgmt. & Budget, *supra*, at 43. While the Administration called on Congress "to eliminate the current prohibition," *id.*, Congress declined to do so and has instead enacted identical riders in each subsequent appropriations cycle. The rider remains in effect today. *See* Pub. L. No. 118-47, §224, 138 Stat. 460, 677 (2024); Pub. L. No. 119-4, §§1101(8), 1105-06, 139 Stat. 9, 11-12 (2025).

3. The Challenged Guidance

The Supplemental Guidance attempts to effectuate via administrative action what Congress has expressly forbidden by statute, using funds that Congress has prohibited NIH from spending for that purpose. On February 7, 2025, NIH issued a document titled "Supplemental Guidance to the 2024 NIH Grants Policy Statement: Indirect Cost Rates." ADD.82-84. The Guidance sets a 15% cap on indirect costs for every single NIH grant. ADD.82. It also established that "[f]or any new grant issued, and for all existing grants to [institutions of higher education] retroactive to the date of issuance of this Supplemental Guidance, award recipients are subject to a 15 percent indirect cost rate." ADD.84.

If allowed to go into effect, the Guidance would create cataclysmic and irreparable harms for the country's medical-research apparatus. NIH's actions would wreak havoc at research institutions across the country, as applying an across-the-board 15% indirect cost rate will cause institutions to lose tens of millions of dollars in funding, in turn causing them to have to lay off critical personnel, halt important infrastructure projects, and shut down research projects altogether. *See, e.g.*, JA 938, 995-96, 1042-43. NIH's decision will also cause widespread harm to the public health, as ongoing research into cancer, dementia, heart disease, and more will be derailed. *See, e.g.*, JA983, 985, 1163. Research institutions will be forced to shut down clinical trials, which "must generally be continuous to be effective."

ADD.60. "Even a temporary interruption of work would threaten clinical trials that supply lifesaving medicine and risk derailing years of careful progress and efforts directed toward major health challenges." ADD.58.

B. Procedural Background

Plaintiffs in No. 23-1344 are several associations of medical schools and academic medical centers. Plaintiffs in No. 23-1345 are several associations of universities and individual universities. On February 10, Plaintiffs sued in federal court seeking injunctive and declaratory relief, alleging that the Guidance is unlawful on multiple grounds. JA725-34; JA884-903.

The district court granted Plaintiffs' requests for a preliminary injunction. ADD.2. The court first concluded that it had subject-matter jurisdiction over Plaintiffs' cases, rejecting NIH's argument that Plaintiffs' claims were breach-of-contract claims subject to the Court of Federal Claims' exclusive jurisdiction under the Tucker Act, 28 U.S.C. §1491. ADD.8-16. The court found that "the gravamen of Plaintiffs' Complaints d[id] not turn on terms of a contract between the parties" but rather were based on a "federal statute and regulations put in place by Congress and NIH." ADD.12. The court noted that its conclusion was underscored by the Guidance's impact on future grants (as Plaintiffs could not sue for breaches of contracts that do not yet exist), ADD.12-13, and by the fact that Plaintiffs did not ask the court to examine any contract or agreement between the parties but only to

"review and interpret the governing federal statute and regulations." ADD.13. The court concluded that Plaintiffs were seeking equitable relief in the form of injunctions and declaratory judgments—not monetary damages for sums not paid. ADD.13-16. The court emphasized that just "because 'a judicial remedy may require one party to pay money to another' does not necessarily 'characterize the relief as "money damages."'" ADD.14. And because Plaintiffs' claims were brought to preserve ongoing and prospective agreements with NIH rather than fixing past pecuniary harms, the court found that Plaintiffs' "primary purpose in bringing their claims [wa]s to seek equitable, not monetary, relief." ADD.15.

On the merits, the court held that the Guidance likely transgresses the appropriations rider in three respects. First, the court held that the rider requires NIH to abide by its existing regulations pertaining to negotiated rates, which NIH violated. ADD.25. Second, the court held that the rider's prohibition on using appropriated funds "to develop or implement a modified approach" to the provisions governing indirect rates forbade NIH from adopting an across-the-board cap, as such a move would "certainly [be] a different approach than negotiating [rates] institution by institution with deviations allowed in limited, justified circumstances." ADD.25-26. Third, the court held that NIH violated the prohibition that "[n]one of the funds appropriated … may be used" to create a disproportional fiscal effect compared to the effect of approved deviations in 2017. ADD.26-28.

The district court also found the Guidance inconsistent with NIH's own regulations, specifically 45 C.F.R. §75.414. ADD.18-22. The court noted that the regulations generally require NIH to apply negotiated rates. And while the regulations allow for deviations from negotiated rates in limited, justified circumstances, none of those circumstances apply here. The court concluded that NIH's actions transgressed §75.414(c) in multiple ways: NIH did not publicize the requisite procedures and decision making criteria its programs would follow to seek and justify deviations, ADD.20; it "did not comply with the step-by-step process mandated by" the regulatory language, ADD.20; and it ignored that the regulation authorizes only deviations from a "class of Federal awards" by seeking to apply an across-the-board 15% rate to *all* NIH grants. ADD.21.

The district court also concluded that the Guidance likely violates the APA because it is arbitrary and capricious, was promulgated without notice and comment, and is impermissibly retroactive. ADD.29-55. The court held that the Guidance was inadequately reasoned because (among other things) its purported justifications were conclusory and unexplained, ADD.32-33; it failed to explain how money would be directed to fund more research, ADD.33-36; it did not explain why the existing audit system did not adequately alleviate NIH's concern that indirect costs are difficult to oversee, ADD.34; nor did it adequately explain why it compared indirect cost rates for NIH-funded research to indirect cost rates for privately funded research given

the obvious differences between the two. ADD.34-35. On top of all that, the court held that the Guidance "fail[ed] in its entirety to recognize or consider the substantial reliance interests at issue." ADD.37. The court noted that "[t]he reliance interests at play are many and acknowledged by all parties," as grantees relied on negotiated rates to plan their budgets and infrastructure-improvement projects, make researcher- and graduate-student-hiring decisions, and more. ADD.38-39. In the face of these real and weighty interests, the court found that NIH's "fleeting reference to reliance interests" was "plainly insufficient." ADD.41.

The Guidance further violates the APA, according to the court, because NIH failed to follow notice-and-comment procedures. The court acknowledged that the APA provides an exception to its notice-and-comment requirements for legislative rules in matters relating to grants. ADD.45. The court nevertheless held that the exception did not apply in this case because HHS's predecessor agency waived the grant exception for HHS actions in 1971. ADD.45. This waiver bound HHS, and NIH by extension, such that NIH needed to use notice and comment for legislative rulemakings. *See* ADD.46-50. And the court found that the Guidance was a legislative rule because it "changes the entire field of play, as legislative rules often do." ADD.50-52. The court also held that the Guidance is likely impermissibly retroactive because it impairs grantee institutions' rights to have their negotiated rates respected in connection with their existing grants. ADD.53-55.

The district court then held that the equities favored granting preliminary injunctive relief. ADD.56-71. The court enjoined NIH from enforcing the Guidance. ADD.71-75. The parties subsequently agreed to convert the preliminary injunction into a permanent injunction and final judgment. ADD.77-81.

SUMMARY OF ARGUMENT

For 60 years, NIH has reimbursed indirect costs pursuant to institution-specific rates negotiated via a process that accounts for the institution's actual, documented costs of conducting research. That approach has helped make the United States a world leader in medical research and has spurred numerous discoveries that have improved public health. The Guidance would eradicate that longstanding approach by replacing carefully negotiated institution-specific rates with an arbitrary across-the-board 15% cap. The district court correctly concluded that the Guidance is unlawful multiple times over: It defies the rider Congress enacted to prohibit NIH from adopting such a cap, contravenes NIH's own regulations, and violates the APA substantively and procedurally.

NIH begins by questioning the district court's jurisdiction, insisting that this lawsuit is in essence a breach of contract action that belongs in the Court of Federal Claims. But as the district court correctly recognized, this is not a dispute about a contract—it is a dispute about whether agency action violates federal statutes, NIH regulations, and the Constitution. Plaintiffs contend that the Guidance is illegal in

toto, including as applied to future grants for which no contract exists. Plaintiffs do not seek damages or an order directing NIH to pay past due sums; they seek prospective declaratory and injunctive relief prohibiting NIH from enforcing the Guidance—relief that the Court of Federal Claims lacks authority to grant. While a ruling in Plaintiffs' favor may ultimately lead Plaintiffs to recover indirect costs at rates higher than 15%, the Supreme Court has long held—and recently reaffirmed—that "a district court's jurisdiction 'is not barred by the possibility' that an order setting aside an agency's action may result in the disbursement of funds." *Dep't of Educ. v. California*, 145 S.Ct. 966, 968 (2025) (per curiam).

On the merits, this is a straightforward case. There are numerous problems with the Guidance, chief among them is that Congress specifically prohibited NIH from taking the action it took here. The Administration floated replacing negotiated rates with a uniform rate cap in 2017, and Congress enacted an appropriations rider prohibiting NIH from taking that approach or even spending a single cent taking any action with that effect. The Administration's attempt to impose by fiat what it proposed in 2017 plainly violates the rider multiple times over (and violates the Appropriations Clause in the process). The Guidance does what Congress expressly forbade, and NIH impermissibly expended funds to formulate the Guidance. Statutory violations do not come more cut and dried than that.

The Guidance also contravenes NIH's own regulations. Those regulations mandate the use of negotiated rates subject only to narrow exceptions and careful procedures. In recognition of the reliance interests generated by negotiated rates, the regulations permit deviating from those rates for only a subset of awards and only if NIH publishes ahead of time "the policies, procedures and general decision making criteria" it "will follow to seek and justify deviations from negotiated rates." 45 C.F.R. §75.414(c)(3). Nothing in the regulations permits NIH to deviate from negotiated rates for all awards, and especially not when NIH has concededly failed to announce the procedures and criteria it will follow when seeking deviations.

The Guidance also violates the APA. Discarding exhaustively negotiated institution-specific rates in favor of a one-size-fits-all approach is the very definition of arbitrary and capricious agency action. The Guidance ignores all the obvious reasons why NIH has stuck with negotiated rates for six decades; does not acknowledge the reliance interests it subverts; and rests on a facile comparison between NIH grants and those from private foundations. And to make matters worse, the Guidance failed to go through the required notice-and-comment process and is impermissibly retroactive to boot.

The district court correctly enjoined NIH from enforcing the Guidance. This Court should affirm.

ARGUMENT

I. The District Court Had Jurisdiction.

The district court correctly rejected NIH's jurisdictional objection. District courts have jurisdiction over "all civil actions arising under the Constitution, laws, or treaties of the United States." 28 U.S.C. §1331. This case involves a classic challenge to government action as forbidden by statutes, regulations, and the Constitution and was properly filed in federal district court.

NIH nevertheless insists that the district court lacked jurisdiction because Plaintiffs' claims "are in essence contractual," and the Tucker Act grants the Court of Federal Claims exclusive jurisdiction over such claims. U.S.Br.28-29. That implicit exception to the express grant of district court jurisdiction in §1331 and the APA is narrow. Courts routinely reject the "'broad' notion 'that any case requiring some reference to or incorporation of a contract is necessarily on the contract and therefore directly within the Tucker Act.'" *Crowley Gov't Servs. v. GSA*, 38 F.4th 1099, 1107 (D.C. Cir. 2022). While NIH seizes on the Supreme Court's recent decision in *Department of Education v. California*, that decision expressly reaffirmed that principle, emphasizing that "a district court's jurisdiction 'is not barred by the possibility' that an order setting aside an agency's action may result in the disbursement of funds." 145 S.Ct. at 968. Where "the source of the rights upon which the plaintiff bases its claims" is not contractual, and the "type of relief sought"

is not a "prototypical contract remedy," there is no basis "to deny a court jurisdiction to consider a claim." *Megapulse v. Lewis*, 672 F.2d 959, 967-68 (D.C. Cir. 1982); *Crowley*, 38 F.4th at 1107.

This lawsuit is plainly not "a contract dispute," in "essence" or otherwise. *See Am. Sci. & Eng'g v. Califano*, 571 F.2d 58, 62-63 (1st Cir. 1978). Plaintiffs "seek to enforce compliance with statutes and regulations" and the Constitution, "not any government contract." *Cmty. Legal Servs. in E. Palo Alto v. HHS*, 2025 WL 1393876, at *2 (9th Cir. May 14, 2025). Their lead claim is that NIH violated the appropriations rider (and thus the Appropriations Clause) because it expended funds to "develop or implement a modified approach to" the provisions addressing indirect costs and deviations from negotiated rates, and because the "fiscal effect" of a drastic across-the-board deviation to a 15% rate is plainly not "proportional" to the "fiscal effect" of deviations NIH approved in 2017. *Infra* at Part II.A. Likewise, Plaintiffs argue that the Guidance contravenes NIH's own regulations, which require NIH to use negotiated rates unless NIH approves a deviation through processes that NIH disregarded here. *Infra* at Part II.B. Moreover, the agency's promulgation of the Guidance violated the APA in multiple respects. *Infra* at Parts II.C-E. This case is not a dispute about the terms of any contract. Indeed, Plaintiffs contend that the Guidance is illegal as applied to *all* NIH grants, *including future grants for which no contract exists*. This lawsuit challenges agency overreach through and through and

falls within the heartland of the APA. *See* ADD.8-16; *accord Ass'n of Am. Univs. v. DOE*, 2025 WL 1414135, at *5-7 (D. Mass. May 15, 2025) (rejecting government's jurisdictional argument in APA challenge to the Energy Department's effort to impose a similar 15% cap on indirect costs).

What is more, the "type of relief sought" in this case differs from the relief available from a Tucker Act claim. *Megapulse*, 672 F.2d at 968. Plaintiffs do not "seek specific sums already calculated, past due, and designed to compensate for completed labors." *Me. Cmty. Health Options v. United States*, 590 U.S. 296, 327 (2020). Nor do they seek an injunction directing the government to pay money. Instead, they seek vacatur of the Guidance and declaratory and injunctive relief prohibiting NIH from displacing its longstanding process of negotiating institution-specific rates with a uniform across-the-board cap. The Supreme Court has made clear that this type of suit may proceed in district court, because it "is not a suit seeking money in *compensation* for the damage sustained by the failure of the Federal Government to pay as mandated; rather, it is a suit seeking to enforce the statutory [and regulatory] mandate itself." *Bowen v. Massachusetts*, 487 U.S. 879, 900 (1988). The fact that an injunction may later cause the government to honor its obligation to make payments does not strip the district court of jurisdiction. "[E]ven if the plaintiff filed the complaint with an eye to future monetary awards, a district

court with otherwise appropriate jurisdiction may hear the claim and grant the proper equitable relief." *Crowley*, 38 F.4th at 1108.

NIH points out that the regulations in 45 C.F.R. Part 75 are incorporated by reference into grant agreements, which, according to NIH, means that Plaintiffs' claims based on the regulations are really just breach-of-contract claims. U.S.Br.30. That is no answer to Plaintiffs' *statutory and constitutional claims* or to its challenge to the Guidance's effect on future grants. Regardless, courts routinely reject the notion that the government can exempt itself from APA review by simply incorporating regulatory terms into a contract. "APA jurisdiction does not turn on whether the plaintiff could conceivably have based his claim on a government contract." *Atterbury v. U.S. Marshals Serv.*, 805 F.3d 398, 407 (2d Cir. 2015). And "the mere fact that a court may have to rule on a contract issue does not … automatically transform an action . . . into one on the contract and deprive the court of jurisdiction it might otherwise have." *Megapulse*, 672 F.2d at 968. Here, Plaintiffs contend that the Guidance violated, *inter alia*, the regulations themselves, not the grants in which those regulations are incorporated. Indeed, Plaintiffs would have exactly the same argument even if no grants incorporated the regulations.

NIH insists that the district court's exercise of jurisdiction "cannot be reconciled" with the Supreme Court's recent stay-stage decision in *California*. U.S.Br.33. That claim is ironic given that the government explicitly told the

Supreme Court that this case is "distinguishable" from *California*. Application at 16, *Dep't of Educ. v. California*, 145 S.Ct. 966 (2025) (No. 24A910). The government had it right the first time. *California* involved a challenge to the Department of Education's decision to rescind over 100 specific grants for programs to recruit and train teachers. The district court granted a TRO expressly directing the government to continue paying the plaintiffs money while the case progressed. *See California v. U.S. Dep't of Educ.*, 2025 WL 760825, at *5 (D. Mass. Mar. 10, 2025). The Supreme Court vacated the TRO, reasoning that "the APA's limited waiver of immunity does not extend to orders 'to enforce a contractual obligation to pay money' along the lines of what the District Court ordered here." *California*, 145 S.Ct. at 968. The Supreme Court then remanded the case to this Court without suggesting that the Tucker Act precluded jurisdiction over the entire case, as opposed to just precluding the relief embodied in the TRO. *Id.*

This case is nothing like *California*. In *California*, the challenged agency action was to "individual funding terminations," not "a single agency policy." Application at 16, *California*, 145 S.Ct. 966 (No. 24A910). And the TRO ordered the government to continue paying the plaintiffs money despite the individual funding determinations. In that context, it was fair to conclude that the case—or at least the TRO itself—was in essence an action for breach of contract.

That logic does not even begin to carry over to this case. Here, the challenged agency action is "a single agency policy" that purports to impact existing and future grants via agency action that cannot be squared with the appropriations riders, the agency's own regulations, the APA, and ultimately the Constitution itself. *See Cmty. Legal Servs.*, 2025 WL 1393876, at *3. Plaintiffs are not seeking an order directing NIH to pay "past due sums." *Me. Cmty.*, 590 U.S. at 326-27. They are seeking "prospective declaratory and injunctive relief to clarify the extent of the Government's ongoing obligations" to apply negotiated cost rates in accordance with its regulations—relief that the Court of Federal Claims "does not have the general equitable powers" to grant. *Id.*

Although a ruling in Plaintiffs' favor may ultimately lead Plaintiffs to recover indirect costs at rates higher than 15% (under both existing grants and future grants), *California* was careful to underscore that "a district court's jurisdiction 'is not barred by the possibility' that an order setting aside an agency's action may result in the disbursement of funds." 145 S.Ct. at 968. And while NIH tries to minimize the fact that the "Guidance addresses 'not just … current grants, but future ones as well,'" U.S.Br.35-36, the Supreme Court has repeatedly held that claims seeking "prospective relief … belong[] in district court," and are not impliedly precluded by a statute giving jurisdiction to a court that lacks the power to order such relief. *Me. Cmty.*, 590 U.S. at 326; *accord DOE*, 2025 WL 1414135, at *5-7 (rejecting

government's reliance on *California* and concluding that government's effort to treat that case as fundamentally changing the law was belied by both its procedural posture and its reaffirmation of *Bowen*). Indeed, stripping Article III courts of jurisdiction over cases like this one would raise serious constitutional questions, as there is no other adequate remedy for the unlawful executive-branch actions alleged (especially as to future grants) and enjoining such unlawful executive-branch action is a classic office of equity that Congress cannot generally "withdraw from judicial cognizance." *Stern v. Marshall*, 564 U.S. 462, 484 (2011) (quotation marks omitted).

In short, there is no basis to treat Plaintiffs' claims as if they were breach-of-contract claims. The district court had jurisdiction.

II. NIH's Decision To Cap Indirect Cost Rates Is Unlawful.

A. Congress Prohibited NIH From Capping Indirect Costs.

On the merits, this is a straightforward case. There are no shortage of grounds to invalidate the Guidance, but the most obvious is that it does precisely what Congress told NIH not to do. Section 224 of the Further Consolidated Appropriations Act makes clear that NIH cannot discard negotiated rates and replace them with an across-the-board cap. Indeed, §224 tells NIH not to spend a cent taking any action with that effect. The first sentence states that "[i]n 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." Pub. L. No. 118-47, §224, 138 Stat. 460, 677 (2024). The rider thus reflects Congress' understanding that the existing regulatory regime mandates the use of negotiated rates in all but narrow circumstances and precluded the kind of blunderbuss across-the-board approach proposed in 2017 and embodied in the Guidance. The rider prevents NIH from instituting a cap by, for example, revising or ignoring its regulations "with respect to the approval of deviations from negotiated rates." *Id.*

To remove all doubt, the second sentence prohibits NIH from expending any funds "to develop or implement a modified approach to such provisions." *Id.* In other words, the rider not only requires NIH to maintain the use of negotiated rates mandated by the regulations but forbids the Executive from spending any money to modify that approach. The final clause drives the point home by prohibiting NIH from "intentionally or substantially expand[ing] the fiscal effect of the approval of such deviations from negotiated rates beyond the proportional effect of such approvals in such quarter." *Id.* That provision bars NIH from approving deviations from negotiated rates that have a "fiscal effect" that is not "proportional" to the "fiscal effect" of deviations approved by NIH in 2017. *Id.*

The Guidance contravenes the rider several times over. Most obviously, by issuing the Guidance, NIH impermissibly expended funds to "develop or implement a modified approach to" the provisions addressing indirect costs and deviations from negotiated rates. The Guidance seeks to jettison NIH's longstanding approach of employing meticulously negotiated institution-specific rates and replace those bespoke rates with an across-the-board 15% cap for all research institutions, regardless of whether the government's own negotiation and auditing process yielded a rate of 48.5% or 72.9% and regardless of whether an institution primarily engages in biomedical research requiring specialized facilities and equipment or social sciences research that does not typically require such things. JA766, 785. It is difficult to imagine how that could be described as anything other than implementing a "modified approach" to the provisions addressing deviations from negotiated rates. Indeed, the government does not dispute that NIH has never in its history invoked 45 C.F.R. §75.414(c)(1) to displace institution-specific negotiated rates with an across-the-board cap. Its unprecedented effort to do so now marks a sea change in how NIH "approach[ed]" 45 C.F.R. §75.414(c)(1) in 2017.

By displacing NIH's longstanding approach of using negotiated institution-specific rates with an across-the-board 15% cap, the Guidance also "intentionally or substantially expand[s] the fiscal effect of the approval of such deviations from negotiated rates beyond the proportional effect of such approvals in such quarter."

The "fiscal effect" of a drastic across-the-board deviation to a 15% rate is plainly not "proportional" to the "fiscal effect" of any deviations NIH may have approved in 2017, since negotiated rates have historically averaged about 30%. ADD.26. Indeed, NIH touted that the deviation "will save more than $4B a year." ADD.28. That boldly advertised cost-savings is, in fact, a concession of a brazen statutory violation. And declaration after declaration in this case underscores the cataclysmic fiscal effect of the rate change on institutions of higher education. *See, e.g.*, JA977, 1027, 1041.

NIH's attempts to explain away the rider lack merit. It insists that "[n]othing in the Supplemental Guidance purports to 'develop or implement a modified approach'" to §75.414(c) because the Guidance "invokes the 'approach' for deviation already set forth in the regulations." U.S.Br.43. In other words, so long as NIH "invokes" §75.414(c), it has not developed or implemented a "modified approach" to that provision—regardless of how differently NIH is now applying §75.414(c). For starters, that argument fails for the simple reason that the Guidance brazenly violates the terms of §75.414(c), which mandates the use of negotiated rates subject only to narrow exceptions and careful procedures that are not remotely satisfied by the Supplement Guidance. *See infra* Part II.B.

The argument also fails to consider the statute as a "whole," as this Court demands. *N.H. Lottery Comm'n v. Rosen*, 986 F.3d 38, 55 (1st Cir. 2021). After all,

Congress included three mutually reinforcing sentences to stop the executive from gutting the negotiated-rate regime. In addition to requiring NIH to abide by the existing regulations (in the first sentence), it *also* required NIH (in the second sentence) to take the same "approach" to the regulations that it took in 2017. That "approach" was decidedly not a one-sized-fits-all approach, but an approach that respected and implemented carefully negotiated institution-specific reimbursement rates for all NIH grants. In addition, NIH's position ignores the statutory context that informs the rider. Congress was responding to an executive proposal to abandon the longstanding regulatory mandate to use negotiated rates in favor of a one-size-fits-all approach. Congress thought the surest way to deep six that proposal was to direct the executive to continue following the regulations. NIH's effort to construe that command as an invitation to employ the narrow exceptions in the regulations to impose the precise kind of one-size-fits-all approach Congress forbade blinks reality.

NIH has even less to say about the final clause of the rider. Having touted some $4 billion in projected savings, NIH does not dispute that the Guidance would have devastating "fiscal effects" on research institutions. It just insists (in a single, citation-free sentence) that nothing in the Guidance "purports to 'expand the fiscal effect' of NIH's grants through deviations from negotiated rates," since the "purpose" of the Guidance "is to channel taxpayer funds toward direct research, not

to spend less on medical research activities altogether." U.S.Br.43-44. There are multiple problems with that argument.

First, NIH assumes (incorrectly) that the term "fiscal effect" refers solely to the fiscal effect on government finances rather than grant recipient finances. Nothing in the statute limits the phrase "fiscal effect" in that manner. And the statutory context—in particular, congressional members' concern with the devastating fiscal effect on institutions in their home districts, H.R. Rep. No. 115-244, at 50; S. Rep. No. 115-150, at 109—suggests that Congress was principally concerned with the negative fiscal effect on grant recipients. After all, the 2017 proposal was understood to have both a cost-savings effect for the federal government and an immediate fiscal effect on institutions receiving indirect cost reimbursement at rates well above 10%. When Congress rejected the proposal and blocked the use of appropriated funds to develop future proposals to deviate from negotiated rates in ways with significant "fiscal effect," it appears to have been principally concerned with the potentially devastating fiscal effect on grant recipients rather than the relatively trivial effect on the overall federal fisc.

Moreover, NIH's own regulations repeatedly use the word "fiscal" to refer to the finances of grant recipients. *See, e.g.,* 45 C.F.R. §75.415(a) (setting forth certification requirement for the "annual and final *fiscal* reports" from grant recipients emphasis added)); *id.* pt. 75, App. III §F.1 (similar). NIH does not even

try to offer a textual basis for limiting the phrase "fiscal effect" to government finances. Nor could it, as limiting the phrase in that manner would require "inserting words Congress chose to omit." *Lomax v. Ortiz-Marquez*, 140 S.Ct. 1721, 1725 (2020).

Even if the term "fiscal effects" referred solely to government finances, NIH's argument would still lack merit. Contrary to NIH's suggestion, the question is not whether the Guidance "'expand[s] the fiscal effect' of *NIH's grants*," or whether the government will "spend less on *medical research activities* altogether." U.S.Br.44 (emphases added). The statutory text is laser focused on the fiscal effect *of the deviations from negotiated rates*. That requires comparing the "fiscal effect" of the deviations in 2025 with the "fiscal effect" of the deviations in 2017 and assessing whether those effects are "proportional." Under that inquiry, there is no question that the fiscal effect of an across-the-board deviation to a 15% rate is not "proportional" to the fiscal effect of whatever trivial deviations NIH may have approved in 2017. As NIH itself touted when it issued the Guidance, adopting the 15% cap will save the government $4 billion every year. *See supra* at p.29.

NIH's contrary interpretation would render the final clause of the rider meaningless. NIH is *already required* to spend all its appropriated funds. *See* 2 U.S.C. §683(b). Under NIH's interpretation, no deviation from negotiated rates—no matter how drastic—would ever have an impermissible "fiscal effect," since NIH

will spend the funds that it would save from those deviations anyway. But that runs straight into the rule that Congress does not enact meaningless statutes. *Plaut v. Spendthrift Farm,* 514 U.S. 211, 216 (1995).

Context strongly reinforces the conclusion that the rider prohibits NIH from displacing negotiated rates with an across-the-board cap. As NIH appears to acknowledge (at 8-9), Congress enacted the rider in direct response to a proposal in the President's 2017 annual budget submission to Congress. That proposal would have "capped" the "indirect cost rate for NIH grants" at "10 percent of total research." JA94. Instead of approving the proposal, Congress "direct[ed] NIH to continue reimbursing institutions for F&A costs according to the rules and procedures described in 45 C.F.R. 75" and "prohibit[ed] funds … from being used to implement any further caps on F&A cost reimbursements." H.R. Rep. No. 115-244, at 50; *see also* S. Rep. No. 115-150, at 109.

NIH has little to say about that context. It just criticizes the district court for relying on "legislative history" in interpreting the rider. U.S.Br.44. But this is not the use of committee reports or floor statements "to cloud a statutory text that is clear." *Ratzlaf v. United* States, 510 U.S. 135, 147-48 (1994). Instead, this is simply a recognition that Congress was responding to a specific executive branch proposal and rejected it based on concerns that a deviation from longstanding practices would destroy legitimate reliance interests and have a devastating effect on grant recipients.

Relying on that statutory context to reject NIH's reading of statutory language to allow precisely what Congress acted to forbid is not an impermissible use of legislative history. It is instead an application of established principles that Congress does not enact "a blank sheet of paper," *Plaut*, 514 U.S. at 216, and judges "are 'not required to exhibit a naiveté from which ordinary citizens are free.'" *Dep't of Com. v. New York*, 588 U.S. 752, 785 (2019). After all, even the executive branch previously recognized the obvious import of the appropriations rider, acknowledging that it "prohibit[s]" NIH "by law from reducing grantee administrative costs and shifting these resources to support direct research." *Supra* at pp.2, 11.

While NIH no longer acknowledges the obvious import of the rider, it offers no alternative explanation for what the rider is supposed to accomplish if it does not prohibit NIH from capping indirect costs. At most, NIH suggests that the rider just proves that "Congress did not see fit to mandate such reductions as a statutory matter." U.S.Br.44. That makes no sense. Had Congress wanted to simply decline to "mandate such reductions as a statutory matter," it could have just stayed silent. Instead, it went out of its way to enact an appropriations rider affirmatively constraining what *the agency* could do. While NIH suggests that Congress could have been clearer and more specific if it wanted to prohibit NIH from imposing a cap, it is a bit much to insist that Congress add yet another sentence reinforcing Congress' clear directions to abide by regulations mandating the use of negotiated

rates and to not spend one cent to modify that approach or alter the fiscal effect of the existing approach. While Congress could always be clearer, the import of its belt and suspenders approach is unmistakable. Congress acted to forbid exactly what the Guidance seeks to accomplish.

Finally, it bears emphasis that while the district court did not reach the Appropriations Clause issues, the executive's open disregard of an appropriations rider is no ordinary statutory violation. Congress' "power of the purse" enshrined in the Appropriations Clause is a critical component of the separation of powers. *See Biden v. Nebraska*, 600 U.S. 477, 505 (2023). That clause provides that "[n]o Money shall be drawn from the Treasury, but in Consequence of Appropriations made by Law." U.S. Const. art. I, §9, cl. 7. This "straightforward and explicit command" means "that no money can be paid out of the Treasury unless it has been appropriated by an act of Congress." *OPM v. Richmond*, 496 U.S. 414, 424 (1990). Here, Congress did not appropriate funds to NIH to enact an across-the-board indirect rate cap. In fact, Congress did the opposite by prohibiting NIH from using any "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" to make such a change. Pub. L. No. 118-47, §224, 138 Stat. at 677. There was no way for NIH to promulgate—and no way for it to implement—the Guidance without using appropriated funds. Thus, in defying the rider, NIH violated not only an act of

Congress, but the Appropriations Clause and the bedrock constitutional principles that Clause reflects.

B. The Supplemental Guidance Runs Afoul of NIH's Own Regulations.

In addition to contravening the appropriations rider, the Supplemental Guidance runs afoul of NIH's own regulations. Those regulations provide in no uncertain terms: "The negotiated rates must be accepted by all Federal awarding agencies." 45 C.F.R. §75.414(c)(1). Appendix III to 45 C.F.R. part 75 also makes clear that "Federal agencies must use the negotiated rates … in effect at the time of the initial award throughout the life of the Federal award." The regulations permit NIH to deviate from negotiated rates for a subset of awards, but only in "limited circumstances," ADD.19: "An HHS awarding agency may use a rate different from the negotiated rate for a class of Federal awards or a single Federal award *only* when" (as relevant here) "approved by a Federal awarding agency head or delegate based on documented justification as described in paragraph (c)(3) of this section." 45 C.F.R. §75.414(c)(1). (emphasis added).

The referenced provisions in paragraph (c)(3) emphasize the narrowness of the exception to the general mandate to use the negotiated rate and the procedural protections necessary to protect the significant reliance interests engendered by grant making pursuant to negotiated rates. Paragraph (c)(3) states: "The HHS awarding agency *must* implement, and make publicly available, the policies, procedures *and*

general decision making criteria that their programs will follow to seek and justify deviations from negotiated rates." *Id.* §75.414(c)(3) (emphases added). Additionally, paragraph (c)(4) requires the awarding agency to "include in the notice of funding opportunity the policies relating to indirect cost rate reimbursement." *Id.* §75.414(c)(4). This approach gives grant recipients an opportunity to assess ahead of time whether NIH will deviate from their negotiated rates based on the rules and procedures announced by the agency and subject to challenge for conformity with the applicable statutes and regulations. And it gives recipients an opportunity to decide before they submit a grant application whether to pursue a class of grants governed by a reimbursement rate that differs from their negotiated rate.

The Supplemental Guidance "directly conflicts with the plain language of 45 C.F.R. §75.414(c)" several times over. ADD.21. First, the regulations do not authorize NIH to categorically repudiate negotiated rates for *all awards*. The default command of §75.414(c)(1) is that an agency must use the negotiated rate, with deviations allowed only "for *a class of Federal awards* or a single Federal award." 45 C.F.R. §75.414(c)(1) (emphasis added). A "[c]lass of Federal awards" is defined as "*a group* of Federal awards," *id.* §75.2 (emphasis added)—in other words, "a subset, as opposed to all, federal awards." ADD.21. While NIH seems to think a class of federal awards can be all of them, that ignores both the text and structure of the regulation. The clear import of §75.414(c)(1) is to mandate acceptance of the

negotiated rate for the life of a Federal award subject "only" to narrow exceptions. Interpreting one of the narrow exceptions to swallow the default rule violates first principles of interpretation. *See Comm'r v. Clark*, 489 U.S. 726, 739 (1989). It also ignores the regulation's use of the word "deviation[]." 45 C.F.R. §75.414(c)(3). A "deviation" is a "[d]ivergence from an accepted idea, policy, or norm of behavior," The American Heritage Dictionary 496 (5th ed. 2016), not a wholesale elimination of the default norm. *See Biden*, 600 U.S. at 495; *MCI Telecomms. Corp. v. AT&T*, 512 U.S. 218, 228 (1994).

In apparent recognition that it could not deviate for a class that included all awards, NIH insists that the Guidance *does* apply to a subset of awards—namely, "research grants *made to IHEs*." U.S.Br.42 (emphasis added). That assertion does not survive even a quick reading of the Guidance, which says on the very first page: "Pursuant 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." ADD.82 (emphasis added). The Guidance repeats the same thing on the second page: "NIH is accordingly imposing a standard indirect cost rate on *all grants* of 15% pursuant to its 45 C.F.R. 75.414(c) authority." ADD.83 (emphasis added). While the third page notes that the 15% cap also applies to "existing grants to IHEs retroactive to the date of issuance of this Supplemental Guidance," it makes crystal clear that it applies to "*any* new grant issued"—whether

to an institute of higher education or not. ADD.84 (emphasis added). Regardless, treating institutes of higher education differently from other grant recipients would create problems of its own (since the government's stated preference for reimbursing direct costs logically would apply to all grantees) and still leave NIH with a rule-swallowing exception for a supposed class that includes the vast majority of grant recipients. And it would also leave NIH without a coherent justification for deviating from the default mandate to use the carefully negotiated, institution-specific rates.

One can certainly imagine a narrow class of grants with specific characteristics that make a grant-specific reimbursement rate more reflective of actual indirect costs than the negotiated rate that is specific to the institution but applicable to the full range of grants. But NIH has not even tried to justify the Guidance on those grounds. That not only renders the Guidance arbitrary and capricious, *see infra* at Part II.C, but makes clear that NIH targeted a far broader swath of grants than 75.414(c) allows.

The Guidance violates the regulations in a second way: It declares by fiat at the front end a categorical across-the-board 15% rate rather than announcing procedures and criteria that govern *subsequent* decisions to make *individualized* deviations from the negotiated rate. The regulations do not authorize NIH's approach. Sections 75.414(c)(1) and (3) lay out a multi-step process NIH must abide by to deviate from the default command to use a grantee's negotiated rate. NIH

"must implement, and make publicly available"—in the present tense—"the *policies, procedures and general decision making criteria*" that it "will follow"—in the future tense—"to *seek and justify* deviations from negotiated rates." *Id.* (emphases added); *see also DOE*, 2025 WL 1414135, at *15. The first italicized phrase connotes *a process* that applies *standards*. A "procedure" is "a series of steps followed in a regular orderly definite way." Webster's Third New International Dictionary 1807 (1966). Criteria are "standard[s] on which a decision or judgment may be based." *Id.* at 538. A categorical 15% rate applicable to every grantee is not a "procedure," and it does not set forth "general decision-making criteria." Nor can issuing a blanket diktat be said to "seek and justify" a deviation. That phrase connotes an assessment under NIH's announced "procedures" that weighs a particular negotiated rate against NIH's announced "criteria" to see if a deviation is justified.

Paragraph (c)(4) underscores that §75.414(c) prescribes a sequential process that generally allows NIH to deviate only in subsequent grant determinations. Paragraph (c)(4) requires an awarding agency to "include in the notice of funding opportunity the policies relating to indirect cost rate reimbursement." 45 C.F.R. §75.414(c)(4). It would make no sense to require the agency to include its policies in these notices that allow potential grantees to decide whether to apply for the award if the agency can simply pull the rug out from under the grantee later. *See DOE*,

2025 WL 1414135, at *15-16 (discussing identical paragraph (c)(4) in DOE's regulations and concluding similarly).

NIH insists that "[n]othing in the text of section 75.414(c)(1) and (3) expressly calls for a multi-stage adjudicative process." U.S.Br.40. But it is hard to read the text as doing anything else. The text of (c)(3) expressly requires NIH to implement and make publicly available "the policies, procedures and general decision making criteria" it "will follow to seek and justify deviations from negotiated rates." 45 C.F.R. §75.414(c)(3). NIH just insists that it may announce a "uniform policy" that "does not contemplate any individualized redetermination of indirect-cost rates" because (c)(1) "expressly states that an 'HHS awarding agency' may deviate from negotiated rates … for 'a class of Federal awards.'" U.S.Br.41. But NIH misleadingly omits the rest of (c)(1), which goes on to say: "… *only* when … approved by a Federal awarding agency head or delegate based on documented justification *as described in paragraph (c)(3) of this section*." 45 C.F.R. §75.414(c)(1) (emphasis on misleading omissions). The fact that NIH thinks that it can ignore (c)(3)'s requirements when it announces a "uniform policy" that "does not contemplate any individualized redetermination" just underscores that the regulation does not authorize NIH to adopt anything like the Guidance.

Regardless, NIH's arguments just highlight that it failed to satisfy the "procedural obligations" in (c)(3). U.S.Br.39. NIH barely argues otherwise; in fact,

it appears to concede that "the Supplemental Guidance does not set forth … 'procedures and decision making criteria' for applying its policy." U.S.Br.41. It insists that it nevertheless satisfied its "procedural obligation" to provide the requisite "documented justification" because the Guidance sets forth the agency's policy reasons for adopting an across-the-board 15% cap—i.e., that it "accord[s] with private sector funding practices," "reduce[s] taxpayer spending," etc. U.S.Br.39. But that is not what a "documented justification" is under 45 C.F.R.§75.414(c). The regulations specify that NIH must provide "documented justification *as described in paragraph (c)(3) of this section*." 45 C.F.R. §75.414(c)(1) (emphasis added). And (c)(3) in turn explains that the "HHS awarding agency must implement, and make publicly available, *the policies, procedures and general decision making criteria* that their programs will follow to seek and justify deviations from negotiated rates." *Id.* §75.414(c)(3) (emphasis added). While NIH might find it inconvenient to satisfy those requirements every time it seeks to deviate from negotiated rates, ignoring an express regulatory mandate is not an option. "If men must turn square corners when they deal with the government, it cannot be too much to expect the government to turn square corners when it deals with them." *Niz-Chavez v. Garland*, 593 U.S. 155, 172 (2021).

C. NIH's Decision to Cap Indirect Cost Rates Is Arbitrary and Capricious.

The Guidance is also arbitrary and capricious. 5 U.S.C. §706(2)(A). Indeed, abandoning an institution-specific rate painstakingly negotiated to reflect actual indirect costs in favor of a one-size-fits-all approach that does not even pretend to reflect actual indirect costs or undeniable differences among institutions is the very definition of arbitrary and capricious agency action.

The Guidance is arbitrary and capricious multiple times over as it is "both conclusory and fail[s] to grapple with the necessary factors, facts, and pertinent aspects of the problem demanded by this change from the existing [indirect cost rate] negotiation process." ADD.37. First, NIH failed to consider several "important aspect[s] of the problem." *DHS v. Regents of the Univ. of Cal.*, 591 U.S. 1, 30 (2020). The Guidance wholly fails to consider that its across-the-board 15% rate amounts to a decision to fund only part of the costs of the research NIH supports. As explained above, *see supra* at pp.5-6, both direct and indirect costs are *actual* costs of undertaking research, with the principal difference being that indirect costs are shared between multiple research projects rather than allocated to just one. Indirect costs are no less essential to conducting world-class research than direct costs, and in many cases result in a cost savings for the government as what makes the costs "indirect" is that equipment and facilities are being used for multiple projects. Indirect costs fund everything from equipment like particle accelerators to facilities

like biocontainment laboratories to administrative matters like ethics review boards. Spreading the costs of such things over multiple projects is cost-effective and prudent; it in no way makes those costs less necessary. Simply put, "by cutting indirect funds, NIH is cutting research." ADD.36; *see also DOE*, 2025 WL 1414135, at *12 (concluding similarly in discussing materially similar DOE action). The Guidance fails to consider that important aspect of the problem altogether.

The Guidance also fails to acknowledge the dramatic variations in need and circumstances among different institutions across the country—differences that are the *raison d'etre* for negotiated rates. As discussed above, existing regulations establish extensive procedures for setting institution-specific indirect cost rates because different institutions conduct different kinds of research in different ways that manifest themselves in a considerable range of negotiated rates. Institutions primarily engaged in biomedical research, for example, tend to have higher indirect costs because such research requires specialized facilities like biocontainment laboratories for research involving dangerous pathogens and facilities to house animals on which research is conducted. Institutions that primarily engage in social science research, on the other hand, tend to have lower indirect costs. But there is no easy *a priori* way to predict the incidence of indirect costs, which is why the negotiation process focuses on the specifics of the institution and why the regulations allow for follow-up audits. There is no one-size-fits-all rate. Just among the

institutions that submitted declarations below, the negotiated rate can vary from 48.5% for the University of Alabama at Birmingham to 72.9% for Beth Israel Deaconess Medical Center. JA766, 785. By imposing a one-size-fits-all 15% cap, the Guidance ignores that reality. And while NIH could be excused for using a rough proxy where it lacks institution-specific information, *see, e.g.*, 45 C.F.R. pt. 75, App. III §C.7.b, to discard extant negotiated rates—and vitiate all the agency and institutional resources dedicated to the negotiation process—is the height of arbitrariness.

Not only did NIH fail to consider important aspects of the problem, it also failed to adequately consider the "serious reliance interests" of the research institutions receiving federal funding. *Regents*, 591 U.S. at 30; ADD.37. "The well-established, decades-long relationship between [grantees] and the [NIH] prior to the [Guidance] afforded Plaintiffs several reasonable assumptions about [NIH's] position on indirect costs." *DOE*, 2015 WL 1414135, at *13. As for existing grants, budgets have already been determined, people hired, and research predicated on the funding has already begun. As for new grants, research institutions have structured their affairs on the understanding that federal research grant funding will continue to allow them to recover their indirect costs associated with federal funding. NIH does not appear to dispute that funding recipients have significant reliance interests. Nor could it. These reliance interests were front and center when Congress

responded to a proposed 10% cap with its appropriations rider. *See* S. Rep. No. 115-150, at 109; H.R. Rep. No. 115-244, at 50. Even more telling, NIH's own regulations underscore the substantial reliance interests at stake, as they specify that the negotiated rate must be specified in the notice of grant opportunity, 45 C.F.R. §75.414(c)(4), and that the negotiated rate in effect at the time of the grant governs for the life of the grant even if the negotiated rate changes, *id.* pt. 75, App. III §C.7.a, as well as requiring "the policies, procedures and general decision making criteria that their programs will follow to seek and justify deviations from negotiated rates," *id.* §75.414(c)(3), to be specified in advance. *See supra* at Part II.B.

NIH nevertheless insists that it adequately considered reliance interests because the Guidance "acknowledges that 'grant recipients … use grant funds to cover indirect costs like overhead.'" U.S.Br.50. And it claims that it considered reliance interests when it selected a 15% (instead of a 10%) rate and when it decided against imposing the new rate "retroactively back to the initial date of issuance of current grants." U.S.Br.50-51. But the agency hardly gets credit for not adopting an approach that was even less respectful of reliance interests or, in the case of making the 15% cap relate back to the beginning of the grant, would flatly violate the agency's own regulations. *See FCC v. Fox Television Stations*, 556 U.S. 502, 515 (2009). Moreover, the Guidance indicates that NIH adopted the 15% rate "to reflect … private sector indirect cost rates" and "the de minimis cost rate of 15% in

2 C.F.R. 200.414(f)." ADD.83-84. It says nothing about reliance interests. While the Guidance gestures at reliance interests when it acknowledges that recipients use funds to cover overhead, that "fleeting reference to reliance interests … is plainly insufficient because it is conclusory and fails to address some, or any" of Plaintiffs' reliance interests. ADD.41. NIH must provide a "more detailed justification" of its decision to demonstrate that it truly accounted for the serious reliance interests at stake. *Fox*, 556 U.S. at 515. At the very least, it must explain how it "weigh[ed] [reliance] interests against competing policy concerns" or considered obvious ways of "accommodating [those] reliance interests." *Regents*, 591 U.S. at 33. NIH did neither.

As for the considerations that NIH *did* mention in the Guidance, they only reinforce the arbitrariness of the agency's action. The "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.'" *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 106 (2015). NIH's justifications do not meet that standard here. The Guidance references supposedly lower indirect cost rates provided by private foundations. But that is an apples-to-oranges comparison given that private foundations often define both direct and indirect costs differently from NIH. For example, the Gates Foundation (which the Guidance cited as a funder with a maximum indirect cost rate of 10% for institutions of higher education) "is more

expansive than NIH in defining direct costs, meaning some overhead payments are wrapped in with the grant." Jocelyn Kaiser, *NIH Plan to Reduce Overhead Payments Draws Fire*, Science (June 2, 2017), https://tinyurl.com/ykeafy4d. Similarly, private grants do not come with all the same compliance requirements, auditing obligations, and administrative requirements that increase indirect costs associated with federal grants. Moreover, as detailed at length in the supporting declarations in these cases, federal grant funding—for both direct and indirect costs—supports a wide range of critical research activities for which Plaintiffs' member universities, Plaintiffs, and other institutions would otherwise not be able to obtain private funding. *See* JA1027, 1065. Finally, given all these variables, nothing remotely justifies NIH choice to adopt an inapposite private-foundation benchmark, when extensively negotiated institution-specific rates were at the ready.

The Guidance's remaining justifications are inadequate and if anything less persuasive. The Guidance suggests that a cap is necessary because indirect costs are "'not readily assignable to the cost objectives specifically benefitted' and are therefore difficult for NIH to oversee." ADD.83. But that ignores the exhaustive negotiation process, the possibility of audits to ensure accuracy, and a host of regulations "designed to ensure that Federal sponsors do not in any way subsidize the indirect (F&A) costs of other sponsors." 45 C.F.R. pt. 75, App. III §C.1.a.3. In the final analysis, NIH cannot begin to explain why having gone to the trouble of

engaging in detailed negotiations to pinpoint that institution's particular indirect-cost profile, it is anything but arbitrary and capricious to cast all that aside in favor of a one-size-fits-all approach.

D. The Supplemental Guidance Should Have Gone Through Notice and Comment.

The Supplemental Guidance should have gone through notice and comment. Under the APA, legislative rules—that is, agency actions carrying the "force and effect of law," *Perez*, 575 U.S. at 96—may be promulgated only following notice and comment. *Id.*. The district court concluded that the Guidance is such a legislative rule, ADD.50-52, and NIH does not meaningfully challenge that conclusion.

To be sure, the APA provides an exception to the notice-and-comment requirements for matters "relating to … grants," 5 U.S.C. §553(a)(2). But that exception has no application here because the HHS's predecessor voluntarily waived it in 1971. *See Public Participation in Rule Making*, 36 Fed. Reg. 2,532 (Feb. 5, 1971). In "waiv[ing] the §553(a)(2) exception[, NIH] subjected itself to the [APA's] procedural requirements," *Clarian Health W. v. Hargan*, 878 F.3d 346, 356-57 (D.C. Cir. 2017).

NIH resists that conclusion, insisting that the waiver is unenforceable. U.S.Br.53-54. But as the D.C. Circuit recognized in *Clarian*, the Supreme Court has treated similar waivers as binding. *See Service v. Dulles*, 354 U.S. 363, 388-89

(1957). That makes sense. "An agency has an obligation to abide by its own regulations," *Rotinsulu v. Mukasey*, 515 F.3d 68, 72 (1st Cir. 2008), and "may not … depart from a prior policy *sub silentio*," *Fox*, 556 U.S. at 515. Having chosen to live with notice and comment obligations, HHS cannot disregard that commitment. HHS itself has recognized as much: When HHS has previously changed its grant rules, it has either done so through notice and comment or asserted good cause. *E.g.*, *Health and Human Services Grants Regulation*, 81 Fed. Reg. 45,270, 45,271 (July 13, 2016).

NIH contends that any notice-and-comment error has been rendered harmless by HHS's recent abrogation of the waiver. U.S.Br.54-55. But whatever effect that abrogation has on future agency actions, it is too late to dispense with notice and comment for a legislative rule that pre-dated the abrogation by months. Moreover, harmless error can save an agency action when the mistake clearly "had no bearing on the procedure used or the substance of the decision reached." *FDA v. Wages & White Lion Invs.*, 145 S.Ct. 898, 930 (2025). Here, NIH's error clearly had bearing on the procedures it used in promulgating the Guidance. Moreover, the manifold substantive flaws in the Guidance underscore the value of using notice-and-comment procedures before trying to make such a convulsive shift in longstanding agency policy. *See Util. Solid Waste Activities Grp. v. EPA*, 236 F.3d 749, 755 (D.C. Cir. 2001).

Finally, NIH claims that it did not need to use notice and comment to promulgate the Guidance because "the proper procedures governing a deviation from negotiated rates are those set forth in 45 C.F.R. §75.414(c)," and that regulation was promulgated via notice and comment. U.S.Br.55. That assumes (incorrectly) that the Guidance complies with 45 C.F.R. §75.414. *But see supra* at Part II.B. That aside, a regulation cannot excuse NIH from complying with the APA's statutorily prescribed procedural requirements. Under the APA, the Guidance is a legislative rule. Notice and comment was required.

E. The Supplemental Guidance Is Impermissibly Retroactive.

The Supplemental Guidance is also impermissibly retroactive because it saddles Plaintiffs with paying for critical F&A costs that NIH previously committed to reimburse. Agencies do not, absent express statutory authority, have the power to promulgate retroactive rules. *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988). Here, no statute authorizes NIH to retroactively modify indirect cost rates. Yet that is precisely what NIH purports to do. The Guidance asserts that it has changed the terms of existing grants with already-negotiated rates. The Guidance is retroactive thrice over: It "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 government does not dispute that NIH lacks authority to issue retroactive rules, it just insists that the Guidance is not retroactive because it applies only to "go forward expenses from February 10, 2025 forward." U.S.Br.57. But even for those "go forward expenses," NIH's decision to cap indirect cost rates impairs rights the institution possessed when accepting the Notice of Award—specifically, the negotiated rate at the time of the award. The Guidance imposes a new, lower rate, displacing the institution-specific rate negotiated by the institution and guaranteed by regulation to persist throughout the life of the grant.

NIH relies heavily on *Martin v. Hadix*, 527 U.S. 343 (1998), but that case is readily distinguishable. In *Martin*, the Court addressed how the Prison Litigation Reform Act's cap on attorney's fees awarded in prison-litigation suits applied to attorneys' postjudgment work monitoring defendants' compliance with court orders where monitoring was ongoing when the law was enacted. The Court concluded that the cap could not apply to monitoring work performed before the statute's enactment, but it held that the cap could be applied for post-enactment monitoring. *Id.* at 358-60. The Court reasoned that it was unproblematic to tell an attorney she would receive a lower rate moving forward because "[i]f the attorney d[id] not wish to perform services at this new, lower pay rate, she c[ould] choose not to work." *Id.* at 360. That is very different from this case. Here, the parties accepted grants based on representations by NIH. They are in the midst of performing the work required

by those grants in line with those representations. Unlike in *Martin*, there is no realistic way for institutions to stop work on projects they have already agreed to take on and are in the midst of completing, and no way for them to avoid the indirect costs associated with completing the research they undertook when accepting the grant.

III. The Dramatic Effect On Plaintiffs And Their Members Fully Justifies Permanent Injunctive Relief.

The government's decision to agree to convert the district court's preliminary injunction into a permanent injunction may make the overwhelming evidence of irreparable injury less relevant, but it bears emphasis that the record is replete with evidence of the devastating effect of the about-face reflected in the Guidance. In the few weeks that Plaintiffs had to assemble declarations in support of their request for a preliminary injunction, they amassed a wealth of declarations underscoring the dramatic and immediate effect the Guidance would have on ongoing research, including ongoing clinical trials of new and innovative treatments for major health challenges. JA87-405; JA745-824; JA905-1353; ADD58-60. And the effects are hardly limited to the research institutions themselves or to academic researchers but extend to the surrounding communities and countless support staff who depend on a steady and predictable stream of federal funding for their economic well-being. *See, e.g.*, JA937-39, 1045-46. Worse still, the record underscores that NIH's short-sighted pursuit of a one-size-fits-all and wholly inadequate rate of indirect-cost

reimbursement jeopardizes the United States' position as a world leader in cutting-edge medical research. *See, e.g.*, JA955, 1153. That enviable position depends not only on a predictable flow of research funding, but also on a partnership and relationship of trust between institutional researchers and the NIH. *Id.*

None of this was lost on Congress in 2017, the last time the Administration proposed such an approach. Congress gave voice to all these concerns and acted to ensure that the approach reflected in the Guidance could not take effect and could not even be pursued using appropriated funds. The Guidance defies Congress, flouts the Constitution, and violates both NIH's own regulations and the APA. The district court's permanent injunction should be affirmed.

CONCLUSION

This Court should affirm.

Respectfully submitted,

s/John P. Bueker
JOHN P. BUEKER
ROPES & GRAY LLP
800 Boylston Street
Boston, MA 02199
(617) 951-7951

DOUGLAS H. HALLWARD-DRIEMEIER
STEPHANIE A. WEBSTER
ROPES & GRAY LLP
2099 Pennsylvania Ave., NW
Washington, DC 20006

Counsel for Plaintiffs-Appellees in Case No. 25-1344

ISHAN K. BHABHA
LINDSAY C. HARRISON
LAUREN J. HARTZ
ELIZABETH HENTHORNE
ZACHARY C. SCHAUF
ADAM G. UNIKOWSKY
JENNER & BLOCK LLP
1099 New York Ave., NW
Suite 900
Washington, DC 20001
(202) 637-6327

Counsel for all Plaintiffs-Appellees in Case No. 25-1345

s/Paul D. Clement
PAUL D. CLEMENT
Counsel of Record
JAMES Y. XI*
KYLE R. EISWALD*
CLEMENT & MURPHY, PLLC
706 Duke Street
Alexandria, VA 22314
(202) 742-8900
paul.clement@clementmurphy.com

* Supervised by principals of the firm who are members of the Virginia Bar

Counsel for Association of American Universities, Association of Public Land-grant Universities, and American Council on Education in Case No. 25-1345

SHOBA PILLAY
JENNER & BLOCK LLP
353 N Clark Street
Chicago, IL 60654

June 9, 2025

CERTIFICATE OF COMPLIANCE
WITH RULE 32(a)

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because this brief contains 12,805 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Times New Roman size 14-point font with Microsoft 2016.

Date: June 9, 2025

s/Paul D. Clement
Paul D. Clement

CERTIFICATE OF SERVICE

I hereby certify that on June 9, 2025, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the First Circuit by using the CM/ECF system. I certify that all participants in this case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

s/Paul D. Clement
Paul D. Clement