No. 25-1343, 25-1344, 25-1345
IN THE UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

COMMONWEALTH OF MASSACHUSETTS; DANA NESSEL, on behalf of the people of the State of Michigan; STATE OF ILLINOIS; STATE OF ARIZONA; STATE OF CALIFORNIA; STATE OF CONNECTICUT; STATE OF COLORADO; STATE OF HAWAII; STATE OF MAINE; STATE OF MARYLAND; STATE OF MINNESOTA; STATE OF NEVADA; STATE OF NEW JERSEY; STATE OF DELAWARE; STATE OF NEW MEXICO; STATE OF NEW YORK; STATE OF NORTH CAROLINA; STATE OF OREGON; STATE OF RHODE ISLAND; STATE OF VERMONT; STATE OF WASHINGTON; STATE OF WISCONSIN,

Plaintiffs-Appellees,

v.

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

Defendants-Appellants.

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

Plaintiffs-Appellees,

v.

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

Defendants-Appellants.

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

Plaintiffs-Appellees,

v.

DEPARTMENT OF HEALTH AND HUMAN SERVICES; NATIONAL INSTITUTES OF HEALTH; ROBERT F. KENNEDY, JR., in their official capacity as Secretary of the U.S. Department of Health and Human Services; JAY BHATTACHARYA, M.D., Ph.D. in their 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 OF SCHOLARS OF ECONOMICS AND INNOVATION AS *AMICI CURIAE* IN SUPPORT OF PLAINTIFFS-APPELLEES AND AFFIRMANCE

(Counsel listed on next page)

Phillip R. Malone
Bar No. 1067183
Nina K. Srejovic
Bar No. 1217909
JUELSGAARD INTELLECTUAL
PROPERTY AND INNOVATION CLINIC
MILLS LEGAL CLINIC
STANFORD LAW SCHOOL
559 Nathan Abbott Way
Stanford, CA 94350
(650) 725-6369
pmalone@law.stanford.edu

Counsel for Amici Curiae Scholars of Economics and Innovation

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Rules

Regulations

Other Authorities

INTEREST OF *AMICI CURIAE*

Amici curiae are the scholars listed below:[1]

Professor Pierre Azoulay
International Programs Professor of Management, MIT Sloan School of Management

Professor Daniel P. Gross
Associate Professor, Duke University Fuqua School of Business

Professor Lisa Larrimore Ouellette
Deane F. Johnson Professor of Law, Stanford Law School

Professor Bhaven N. Sampat
Johns Hopkins University School of Government and Policy and Carey Business School

Amici are academics who study, teach, and write on issues in economics and innovation.[2] Their scholarship includes analyses on the efficacy of National Institutes of Health (NIH) policy. *See, e.g.*, *Building a Better NIH*, BROOKINGS (2023), https://perma.cc/B9PB-2W2P. Like most academics studying the economics of NIH grants, *amici* are employed by research universities that could be affected by

[1] Affiliation is provided for identification purposes only. All signatories are participating in their individual capacity, not on behalf of their institutions.

[2] Neither the parties nor their counsel have authored this brief in whole or in part, and neither they nor any other person or entity other than *amici curiae* and their counsel contributed money that was intended to fund preparing or submitting this brief. Pursuant to Fed. R. App. P. 29(a)(2), all plaintiffs-appellees have consented to the filing of this brief; counsel for defendants-appellants has advised that they consent to any timely filed *amicus* brief that comports with the Court's rules.

changes to federal indirect cost recovery policy.[3] *Amici* have a shared interest in clarifying the economics of indirect cost recovery for the court and avoiding disruption to longstanding funding policies that enable important scientific innovation without careful evaluation of pertinent evidence.[4]

SUMMARY OF ARGUMENT

The United States innovation system is one of the greatest success stories of our nation. The scientific research that helps support this innovation is expensive, but it produces societal benefits substantially greater than its cost. For over eighty years, the National Institutes of Health (NIH) has awarded grants to support and enable medical research by covering certain of its costs, including "direct costs"—which are assignable to a particular project—and "indirect costs"—which are required for research but not easily assigned to a single project. For nearly sixty years, indirect research costs have been funded through the application of institution-

[3] Some *amici* have previously received financial support from NIH and from the U.S. National Science Foundation (NSF). NSF is an independent agency of the federal government that supports fundamental research in non-medical fields. NSF recently announced a new 15% rate on indirect cost recovery that is similar to the policy at issue in this case. A challenge is pending in the District of Massachusetts. Complaint, *Ass'n of Am. Univs. v. Nat'l Sci. Found.*, No. 1:25-cv-11231 (D. Mass. May 5, 2025).

[4] *Amici* wish to thank Stanford Law School Juelsgaard Intellectual Property and Innovation Clinic Certified Law Students Justin Walthier and Hana Ryan for their substantial assistance in drafting this brief.

specific indirect cost reimbursement (ICR) rates negotiated between the government and each federally funded research institution.

As of 2024, NIH grantee institutions' negotiated ICR rates averaged 58%. The NIH's February 2025 notice of supplemental guidance at issue in this case (Notice) abruptly abandoned its longstanding policy and practice of negotiated ICR rates and imposed an ICR rate of 15% on all grants to all institutions.

The NIH Notice violates the Administrative Procedure Act and relevant regulations by arbitrarily, capriciously, and without reasoned decision making or documented justification imposing the 15% indirect cost rate on all grants. The Notice failed to acknowledge the necessity of indirect costs such as infrastructure and facilities to high-value medical research. It also failed to make the required reasoned evaluation of the factors relevant to its action by mischaracterizing indirect costs, including by conflating negotiated and effective reimbursement rates and overattributing indirect costs to administrative overhead. Finally, by purporting to use ICR rates in private foundation funding as a benchmark, the Notice relied on a flawed comparison that disregards fundamental differences between private foundation and government funding structures.

The District Court's order enjoining implementation, application, or enforcement of the NIH's Notice is correct and should be affirmed.

BACKGROUND

The public return on government investments in innovation for U.S. taxpayers is substantial. Benjamin F. Jones & Lawrence H. Summers, *A Calculation of the Social Returns to Innovation*, *in* INNOVATION AND PUBLIC POLICY 13, 36 (Austan Goolsbee & Benjamin F. Jones eds., 2021). The U.S. innovation system is an "engine of technological progress, driving improvements in standards of living and economic growth." Pierre Azoulay et al., *Indirect Cost Recovery in U.S. Innovation Policy* 1 (Nat'l Bureau of Econ. Rsch., Working Paper No. 33627, March 2025, rev'd June 2025) (hereinafter Azoulay et al., *Indirect Cost Recovery*). Even under conservative assumptions, "the average social gain is about $5 in benefit per $1 invested [in innovation]." Jones & Summers, *supra*, at 36. When "[c]onsidering reasonable amounts of inflation bias or health benefits," that gain is closer "to $10 or even $20 per $1 invested." *Id.*

However, scientific research and innovation are costly. For over eighty years, the National Institutes of Health (NIH) has provided grants to research institutions to cover their indirect as well as direct research costs. Azoulay et al., *Indirect Cost Recovery*, at 4. Direct costs are project-specific and include items such as salaries and consumable supplies. Indirect costs are costs not easily assigned to a specific project and include expenditures such as lab space, enforcement of biosafety and security protocols, data and computing resources, and utility costs.

For nearly sixty years, indirect research costs have been funded using institution-specific negotiated rates. *Id*. at 7. These rates are known as indirect cost reimbursement (ICR) rates. ICR rates are negotiated between the federal government and federally funded research institutions every two to four years and are specified as a fixed percentage increment over the direct costs of federally sponsored research, typically supported by "several-hundred-page[s]" of evidence. *Id.* at 9. In 2024, negotiated rates averaged 58%. *Id.* at 16.

In February 2025, Defendant-Appellant NIH issued a Notice reversing sixty years of federal policy. Notice No. NOT-OD-25-068, *Supplemental Guidance to the 2024 NIH Grants Policy Statement: Indirect Cost Rates* (Feb. 7, 2025) (hereinafter "Notice"), J.A. 88-90. The Notice imposed a standard ICR rate of 15% on all grants to all institutions. *Id.*

The Notice was notably sparse, containing only 1,172 words. *Id.* The Notice cited insufficient evidence to support the NIH's dramatic policy reversal. Instead, the Notice made only three summary assertions. *Massachusetts v. Nat'l Insts. of Health*, No. 25-CV-10338, 2025 WL 702163, at *17 (D. Mass. Mar. 5, 2025) (Memorandum and Order on Motion for Preliminary Injunction) (Appellants' Br. Addendum ("Add") at 32), *judgment entered*, No. 1:25-CV-10338, 2025 WL 1063760 (D. Mass. Apr. 4, 2025). First, "in a single line," the NIH noted "'[i]t is . . . vital to ensure that as many funds as possible go towards direct scientific research

costs rather than administrative overhead.'" *Id.*, Add. 32 (quoting Notice, J.A. 89). Second, "again in a single line," the NIH asserted that "[i]ndirect costs are, by their very nature, 'not readily assignable to the cost objectives specifically benefitted' and are therefore difficult for NIH to oversee." *Id.* (quoting Notice, J.A. 89). And third, the NIH relied on irrelevant and misleading evidence that some universities accept grants at 15% or lower ICRs from what the District Court deemed a "random collection" of private charitable foundations to justify a 15% federal ICR rate. *Id.* (citing Notice, J.A. 89).

The District Court correctly found these purported justifications insufficient and properly concluded that the Notice was arbitrary and capricious. *Nat'l Insts. of Health*, No. 25-CV-10338, 2025 WL 702163, at *16-21, Add. 30-43. The Court separately and correctly found that the Notice ignored regulatory requirements dictating that the NIH must provide a "documented justification" for deviations from its longstanding indirect cost policy. *Id.* at *9-11, Add. 18-22.

ARGUMENT

I. The NIH must engage in reasoned decision making.

As the District Court noted, "[a]lthough empowered to make impactful policy decisions," a new administration may not ignore the law. *Nat'l Insts. of Health*, at *21, Add. 43. The District Court correctly found that the NIH violated the Administrative Procedure Act (APA), 5 U.S.C. §§ 551-706, and existing U.S.

Department of Health and Human Services (HHS) regulation, 45 C.F.R. § 75.414(c), by failing to engage in the required reasoned decision making and failing to provide documented justification for the agency's sudden and severe policy deviation.

A. The APA requires consideration of pertinent evidence and adequate reasoning.

The APA "sets forth the procedures by which federal agencies are accountable to the public . . . ." *Franklin v. Massachusetts*, 505 U.S. 788, 796 (1992). The APA provides that courts must "hold unlawful and set aside agency action[s]" that are "arbitrary" or "capricious." 5 U.S.C. § 706(2)(A).

"The task of a court reviewing agency action under the APA's 'arbitrary and capricious' standard is to determine whether the agency has examined the pertinent evidence, considered the relevant factors, and 'articulate[d] a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *Penobscot Air Servs., Ltd. v. FAA*, 164 F.3d 713, 719 (1st Cir. 1999) (citations omitted). "[A] court may uphold agency action only on the grounds that the agency invoked when it took the action." *Michigan v. EPA*, 576 U.S. 743, 758 (2015).

In other words, agency decisions must be "founded on a reasoned evaluation of the relevant factors." *Marsh v. Or. Nat. Res. Council*, 490 U.S. 360, 378 (1989); *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009) (agencies must show there are "good reasons for new policy"); *Michigan*, 576 U.S. at 750 (agencies must

engage in "reasoned decisionmaking"); *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021) (agency action must be "reasonable and reasonably explained").

As the District Court noted, the requirement that federal agencies engage in reasoned decision-making is heightened when an agency "changes course[.]" *Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 591 U.S. 1, 30 (2020). The APA requires an agency to "provide more substantial justification" when the agency's policy has "'engendered serious reliance interests.'" *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 106 (2015) (citation omitted). "In such cases . . . a *reasoned explanation* is needed for disregarding facts and circumstances that underlay or were engendered by the prior policy." *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 222 (2016) (citation omitted) (emphasis added).

The District Court found that the Notice implicated serious reliance interests, a conclusion that the NIH does not rebut. *Nat'l Insts. of Health*, at *19-21, Add. 37-43. As such, the NIH needed to provide a reasoned explanation in announcing its new policy, not only examining the pertinent evidence but also adequately justifying and explaining its decision. The NIH did not do so.

B. Existing HHS regulations require documented justification.

In addition to the NIH's statutory requirements under the APA, the agency also has regulatory obligations. As the District Court noted, 45 C.F.R. § 75.414(c) prescribes the process by which HHS, and by extension the NIH, can "deviate" from

negotiated ICR rates. *Id*. at *9-10, Add. 18-19. The regulation explicitly states that the agency "must" provide "documented justification" for deviations 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." 45 C.F.R. § 75.414(c)(1), (3). Again, the NIH did not do so.

II. The NIH failed to examine pertinent evidence and did not engage in reasoned decision making.

The NIH failed to comply with the APA and regulatory requirements in issuing its Notice capping ICR rates. It did not sufficiently grapple with the relevant evidence or establish a rational connection between the facts cited. The NIH's reasoning was critically lacking in at least three respects: (1) in attempting to justify its ICR rate cut as an effort "to ensure taxpayer dollars are used in ways that benefit the American people and improve their quality of life," Notice, J.A. 89, the NIH neglected the importance of indirect cost funding in supporting scientific research; (2) the NIH failed to engage in a reasoned evaluation of the relevant factors by mischaracterizing indirect costs and understating their contribution to scientific research, Notice, J.A. 88-89; and (3) in benchmarking its new 15% ICR rate to those used by private foundations, the NIH attempted to justify the rate based on a misleading and irrelevant benchmark. Notice, J.A. 88-90.

A. The NIH ignored the necessity of indirect cost recovery to support high-value research.

NIH funding for scientific research produces significant and consistent benefits for the public. *See, e.g.*, Pierre Azoulay et al., *Public R&D Investments and Private-sector Patenting: Evidence from NIH Funding Rules*, 86 REV. ECON. STUD. 117 (2018); Andrew Fieldhouse & Karel Mertens, *The Returns to Government R&D: Evidence from U.S. Appropriations Shocks* (Fed. Rsrv. Bank of Dall., Working Paper No. 2305, 2024); Jones & Summers, *supra*.

To be sure, details about the most efficient design and operation of the existing NIH grant process are the subject of ongoing academic discourse. *See, e.g.*, *Building a Better NIH*, *supra*. ICR policy itself has been a subject of debate for decades. *See* Azoulay et al., *Indirect Cost Recovery*, at 2. But instead of grappling with that discourse and articulating an evidence-based explanation for its drastic 15% ICR rate cap, the NIH simply asserted that cuts to indirect costs are necessary "to ensure taxpayer dollars are used in ways that benefit the American people." Notice, J.A. 89. This unsupported assertion disregards the fact that indirect costs are a necessary component of research, and that indirect cost recovery is thus critical to benefit the American people through socially valuable scientific and medical research. *See* Azoulay et al., *Indirect Cost Recovery*, at 1-2.

Within the context of the American research ecosystem, adequate reimbursement of indirect costs is necessary to serve the NIH's stated goal of

ensuring that "taxpayer dollars are used in ways that benefit the American people and improve their quality of life." Notice, J.A. 89. For one, "unlike other countries, the U.S. lacks a centrally-funded national university system" to support research infrastructure. Azoulay et al., *Indirect Cost Recovery*, at 1. Second, unlike some other countries, the U.S. federal government primarily funds *research projects* rather than directly financing *institutions or infrastructure* necessary for research. *Id.* However, institutions and infrastructure are not operated, built, or maintained free of cost. These present fixed costs of research that are shared across multiple research projects.

"Because shared costs are difficult (and in some cases, potentially impossible) to budget into grants as a direct cost of the work, absent federal indirect cost support, institutions would lack the means to cover their fixed costs." *Id.* As a result, the current system of negotiated ICR rates developed to ensure that institutions had the proper financial means to engage in critical research on behalf of the federal government. Indeed, this form of indirect cost recovery has been in place "since World War II." *Id.*

The proposed decrease in indirect cost reimbursement would thus reduce high-value research. The flat 15% ICR rate "would reduce funding for research infrastructure" and "discourage investment in equipment and facilities or discourage high-potential but high fixed-cost research." *Id.* at 23. The reduction in indirect cost

reimbursement is estimated to be an average of 17% of each institution's recent NIH funding—a total of $7 billion per year across institutions—if the rate is recovered on total direct costs, or significantly more if recovered on a "modified" direct cost base, which is the basis for setting and applying indirect cost recovery under existing policy. Azoulay et al., *Indirect Cost Recovery*, at 3, 16. The Notice did not specify to which cost base the 15% rate would be applied. Notice, J.A. 88-90.

This funding loss would likely be even more severe for institutions at the cutting edge of science, as measured by links to commercial patents and new drug development. Those institutions that are "associated with 30% more commercial patents—and nearly 50% greater commercial patent value"—would experience a "10 percentage point larger decline in NIH funding under the proposed ICR rate." *Id.* at 21. In addition, the NIH's severe 15% rate cap would likely result in "substantial funding cuts for the institutions that contributed the most to new drug development over the past 20 years." *Id.* By at least one relevant measure, the institutions "facing the largest potential funding reductions" have the strongest "links to private sector innovation." *Id.*

The result of these cuts could be a wholesale reduction in innovative scientific research in the United States. And "[e]ven if some of the savings were redirected to direct costs, the fundamental problem of paying for the fixed cost of modern

biomedical research would remain unresolved." *Id.* at 23. The NIH failed to articulate or document any consideration of this problem.

B. The NIH mischaracterized indirect costs and their importance for scientific research.

In issuing the Notice, the NIH did not engage in a reasoned evaluation of indirect costs and failed to grapple with its own data and historical practices. First, the Notice repeatedly referenced irrelevant metrics for indirect costs that misrepresent trends in ICR rates. Second, it overattributed indirect costs to administrative overhead. And third, it inaccurately portrayed the negotiation process for ICR rates between research institutions and the government. In combination, these factual errors disregard the agency's mandate to "'articulate[] a satisfactory explanation for its action including a rational connection between the facts found and the choice made.'" *Penobscot Air Servs.*, 164 F.3d at 719 (citations omitted).

i. The NIH conflated negotiated and effective rates and obfuscated the underlying facts.

The NIH consistently mischaracterized indirect cost data in the Notice—and in its belated attempt in its brief to support its actions[5]—rather than engaging in a reasoned evaluation of the evidence. The Notice stated that "the average indirect cost

[5] The government may not rely on "*post hoc* rationalization" for its decision-making, and courts generally confine their analysis under the APA to the "agency's original reasons." *Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 591 U.S. 1, 21-23 (2020).

rate reported by NIH has averaged between 27% and 28% over time," but that some organizations are "charging indirect rates of over 50% and in some cases over 60%." Notice, J.A. 89. This is an inaccurate description that indicates a misunderstanding of the definition and calculation of ICR rates. The first figure of 27-28% refers to the indirect cost *share* of total funding—not the indirect cost *rate*. *See* NAT'L INSTS. OF HEALTH, FISCAL YEAR 2021 OVERVIEW 87 (2020), https://perma.cc/HU39-SKE5. The indirect cost *rate* is calculated as indirect costs divided by direct costs (in other words, the additional funding the government provides on top of the direct costs of federally funded research to cover indirect costs associated with federally funded research). Calculating ICR rates from the table cited by the Notice, the true average ICR rate ranges from 38% to 39%.

More concerningly, however, the NIH compared apples to oranges. The first citation to ICR rates—albeit incorrectly calculated—describes *effective* rates, and represents an NIH-wide average. Effective rates are based on the ratio of total indirect cost funding to total direct cost (TDC) funding, and represent the ICR that NIH actually pays. But the latter figure of "50% or even higher" refers to *negotiated* rates, which are determined from the ratio of total indirect costs to *modified* total direct costs (MTDC) and are institution-specific.

Comparisons between the two rates are problematic for two reasons. The first is the comparison of an NIH-wide average rate to institution-specific rates, which

can reflect structural differences in institutions' overhead costs. The second, more fundamental reason is that MTDC (the cost basis for negotiated rates) excludes specific categories of direct costs from the calculation and application of ICR rates and is thus lower than TDC (the cost basis for effective rates). Because their denominator is lower, negotiated rates are mechanically higher than effective rates, and not comparable. This fundamental misunderstanding pervades the Notice. By confusing the two rates, the government failed to appropriately grapple with the pertinent evidence and conduct a reasoned evaluation of the issue.

This confusion between effective and negotiated ICR rates undermines an important claim the NIH makes to try to support its rate cut. The NIH claims that the Notice "explains that NIH's funding of indirect costs has grown markedly" over time, without acknowledging that effective ICR rates have been steady for decades. Appellants' Br. 11. While research institutions' negotiated rates have "increased from a median of roughly 43% to 56% over the past 40 years, [their] effective indirect cost reimbursement has essentially held steady for decades, at around 35-45% of direct costs." Azoulay et al., *Indirect Cost Recovery*, at 3. By focusing on negotiated rates rather than effective rates, the NIH uses the specter of administrative bloat to cut potentially indispensable funding for scientific and medical research, failing to engage in a reasoned evaluation of pertinent evidence and the relevant factors. The negotiated rate is misleading as an indicator of actual indirect costs paid,

and due to the mechanics of rate calculations, may not even necessarily indicate an increase in administrative expenses at research institutions.[6]

ii. The NIH overattributed indirect costs to administrative overhead and ignored the core, research-enabling functions of indirect costs.

The Notice trivialized the importance of indirect costs, failing to consider pertinent evidence of the fundamental contribution of indirect costs to high-impact scientific research. In reducing ICR rates, the NIH claimed that it is "helping . . . ensure that grant funds are, to the maximum extent possible, spent on furthering its mission," which is to "seek fundamental knowledge about the nature and behavior of living systems." Notice, J.A. 89-90. But in characterizing indirect costs as peripheral to the core mission of scientific research, the NIH ignored that indirect costs are intrinsic to all enterprises, research or otherwise, in the academic or commercial sector.

[6] The calculation of negotiated ICR rates, which is based on modified total direct costs (MTDC, as described above), excludes certain categories of costs from the direct cost base, such as "equipment above certain limits, patient care costs, subcontract accounts over a specific amount, and other exceptions." Azoulay et al., *Indirect Cost Recovery*, at 8. As a result, the negotiated ICR rate can increase without an increase in overhead expenses (the numerator), for instance, if MTDC (the denominator) decreases. To illustrate these mechanics, imagine that in Scenario A, a university spends $10 on direct research costs with $2 of overhead. Its ICR rate would be 2/10, or 20%. Now imagine that in Scenario B, the university spends $10 on direct research, but $3 of that expenditure is allocated to equipment that is not included in Modified Total Direct Costs (MTDC), and overhead remains unchanged at $2. The ICR rate would then be 2/(10-3), or 2/7, or ~28.5%, even though the overhead costs are identical to those in Scenario A.

In its conclusory statements in the Notice, the NIH neglected that the indirect costs of universities and other research institutions encompass many mission-critical cost categories. Instead, it equated cutting the ICR rate with reducing "administrative overhead." Notice, J.A. 89. Indirect costs are split into "either Facilities or Administration (F&A), where the cost pools for the 'F' include (i) building depreciation, (ii) interest, (iii) equipment and capital improvements, and (iv) operations and maintenance." Azoulay et al., *Indirect Cost Recovery*, at 8. The Notice emphasizes the "Administration" side of F&A. In doing so, it does not acknowledge that some administrative functions at research institutions which incur indirect costs are activities which the NIH requires, such as biosecurity training and research integrity. NAT'L INSTS. OF HEALTH, NIH GRANTS POLICY STATEMENT § 4.1 (2024), https://perma.cc/45YW-F667. Moreover, "since 1991, the Administration component [of ICR rates] for universities . . . has been capped at 26%" of direct costs. Azoulay et al., *Indirect Cost Recovery*, at 8.

Additionally, indirect cost reimbursement covers cost categories *other than* administrative costs: for many research universities, a majority of indirect costs are associated with the "Facilities" side of F&A, which includes core, research-enabling expenditures. Princeton, for example, has a negotiated ICR rate of 64% for Organized Research, with 38% generated exclusively by Facilities costs, and the remaining 26% representing the capped Administrative costs. *Facilities and*

Administrative (F&A) Rate, PRINCETON UNIV. OFF. OF FINANCE & TREASURY, https://perma.cc/DFH9-F8L9. Those facilities expenditures include "Building Depreciation," "Equipment Depreciation," "Plant operation and maintenance," "Interest Expense," and "Library," all of which directly facilitate Princeton's research activities. *Id.* The University of Michigan similarly has a 56% negotiated ICR rate, with 30% generated by Facilities costs. *Colleges and Universities Rate Agreement*, UNIV. OF MICH. (May 2025), https://perma.cc/FCK5-BJTS. The consequence of the ICR rate cut is that universities like Princeton and Michigan would recover a much smaller share of not only their administrative costs but also their facilities costs, deterring investment in infrastructure that is essential to groundbreaking scientific research.

C. The NIH drew a misleading comparison between ICR rates for foundation and government funding.

The Notice failed to demonstrate a rational connection between private foundation funding and federal grants. NIH implied, without reasoned analysis or consideration of the relevant factors, that it had elected to impose a flat 15% cost rate to better comport with private foundation funding. Notice, J.A. 89. Yet research, economic theory, and common sense demonstrate that funding from these two sectors differs in fundamental ways, as do their indirect cost rates.

i. Foundation funding differs in scale, objectives, cost-calculation bases, and allowable cost recovery.

First, research institutions receive relatively little funding from private foundations. According to the National Center for Science and Engineering Statistics, foundations comprise only 6% of university research funding. NAT'L CTR. FOR SCI. & ENG'G STATS., HIGHER EDUCATION RESEARCH AND DEVELOPMENT: FISCAL YEAR 2023, at 13 tbl.2 (2024), https://perma.cc/42VV-CF97. By contrast, the federal government makes up 55% of funding, and institutional resources 25%. *Id*. One natural conclusion from this funding disparity is that the federal government is the key provider of research financing, whereas private foundations are merely incidental funding sources. Given these foundations' small scale and heterogeneous goals, universities cannot count on private foundations to support the facilities, computing, and biosecurity and biosafety infrastructure needed to safely and effectively conduct modern biomedical research.

Second, private foundations calculate indirect costs differently than the federal government, muddying comparisons between the two rates. Many foundations provide more flexibility to budget common F&A expenses into direct costs than the government. *See* Sherry A. Glied, *Aligning NIH's Indirect Cost Recovery Rates with Foundation Rates Is Bad Policy*, 6 JAMA HEALTH F. e251700 (2025). For example, the Gates Foundation notes that "[f]oundations have flexibility in accounting for . . . 'indirect costs' as 'direct costs,' unlike the federal

government." *How We Work*, GATES FOUND., https://perma.cc/J7GG-Y5G2. The Foundation highlights that "project management, lab charges, and data/IT charges that are related to a specific project are allowable as direct costs in a Gates Foundation grant," whereas they would not be allowable as direct costs in a federal grant. *See* Glied, *supra.*

Mathematically, some foundations also use different ICR formulas than the federal government. Foundations often calculate ICR rates based on calculated total direct costs (TDC) rather than *modified* total direct costs (MTDC), which the NIH uses. *See* ASS'N AM. UNIVS., COMPARING FOUNDATION AND FEDERAL GOVERNMENT RESEARCH SUPPORT 2 n.3 (2024), https://perma.cc/RN2R-EKPK. Because TDC is larger than MTDC, foundations' ICR rates are unavoidably and inherently lower than negotiated federal ICR rates. *Id.*

Third, research institutions often do not recover all of their indirect costs assignable to foundation-funded research from their foundation grants. Institutions such as Boston University and Yale explicitly note that "many non-federal sponsors do not fully reimburse the University" for its indirect costs. *Charging F&A Type Expenses to Non-Federal Sponsored Projects*, BOS. UNIV. (May 2017), https://perma.cc/4PFU-84MZ; *Charging of Facilities and Administrative ("F&A") Type Expenses to Non-Federal Sponsored Projects*, YALE UNIV. (Dec. 19, 2024), https://perma.cc/9QX2-Q3RD. The Gates Foundation notes that its applicants might

need to "conduct other fundraising to cover operations costs." *Indirect-Cost Guidelines*, GATES FOUND. (2020), https://perma.cc/B3Z6-UU9N.

ii. By ignoring these distinctions, the NIH provided no reasoned basis for importing foundation overhead limits into federal policy.

The Notice did not engage in a reasoned analysis of the relevance of private foundation indirect costs to NIH costs, nor did it articulate a reasoned explanation for its attempt to rely on private funding rates. Instead, the Notice's unstated logic regarding private foundations may be that (a) the foundation rate is the true rate to cover full costs of research or (b) regardless of the real costs of research, universities would also be "willing to accept" government grants with lower rates with no serious harms to the performance of the research enterprise. Notice, J.A. 89.

But the foundation rate is not the true rate, given differences in funding size, objectives, and formulas. See *supra* II.C.i. And any implied notion that universities would be "willing to accept" less federal funding fundamentally misunderstands the economics of research funding. Because foundations provide a small share of funding, universities can afford to absorb foundation grants that cover not much more than marginal costs *as long as the indirect costs are otherwise supported*.

The Notice's wholesale move to limit the NIH to paying only marginal costs and a low (foundation-level) ICR rate could result in there being no funders in the system adequately supporting the overhead costs of socially valuable scientific and biomedical research. Universities would be forced to significantly scale back their

research enterprise, with deleterious consequences for medical research, clinical trials, drug development, jobs, and global competitiveness.

The NIH did not grapple with these complications and evidence. It ignored the many differences between federal funding and private funding. As a result, its comparison of NIH funding to private foundation funding is not a "satisfactory explanation for its action." *Penobscot Air Servs.*, 164 F.3d at 719. The NIH failed to meet its obligation under the APA and 45 C.F.R. § 75.414(c) to consider the salient differences between private and public funding, engage in reasoned decision-making, and provide documented justifications for a 15% ICR rate.

CONCLUSION

For the foregoing reasons, the District Court's order enjoining implementation, application or enforcement of the NIH's Notice is correct and should be affirmed.

Dated: June 16, 2025

Respectfully submitted,

/s/ Phillip R. Malone

Phillip R. Malone
Nina K. Srejovic
JUELSGAARD INTELLECTUAL PROPERTY AND INNOVATION CLINIC
MILLS LEGAL CLINIC
STANFORD LAW SCHOOL
559 Nathan Abbott Way
Stanford, CA 94350
(650) 725-6369
pmalone@law.stanford.edu

Counsel for Amici Curiae
Scholars of Economics and Innovation

CERTIFICATE OF COMPLIANCE

This document complies with the type-volume limitation set forth in Federal Rules of Appellate Procedure 32(a)(7)(B) and 29(a)(5) because it contains 5,033 words.

This document complies with the type-face requirements of Federal Rule of Appellate Procedure 32(a)(5)(A) and the type-style requirements of Rule 32(a)(6) because it has been prepared in a proportionally spaced type-face using 14-point font.

Respectfully submitted,

/s/ Phillip R. Malone

Phillip R. Malone
JUELSGAARD INTELLECTUAL PROPERTY AND INNOVATION CLINIC
MILLS LEGAL CLINIC
STANFORD LAW SCHOOL
559 Nathan Abbott Way
Stanford, CA 94350
(650) 725-6369
pmalone@law.stanford.edu

Counsel for Amici Curiae
Scholars of Economics and Innovation

CERTIFICATE OF SERVICE

I hereby certify that on June 16, 2025, I caused the foregoing Brief of Scholars of Economics and Innovation as *Amici Curiae* in Support of Plaintiffs-Appellees for Affirmance to be electronically filed with the Clerk of the Court for U.S. Court of Appeals for the First Circuit using CM/ECF, which will automatically send email notification of such filing to all counsel of record.

Dated: June 16, 2025

Respectfully submitted,

/s/ Phillip R. Malone

Phillip R. Malone
JUELSGAARD INTELLECTUAL PROPERTY AND INNOVATION CLINIC
MILLS LEGAL CLINIC
STANFORD LAW SCHOOL
559 Nathan Abbott Way
Stanford, CA 94350
(650) 725-6369
pmalone@law.stanford.edu

Counsel for Amici Curiae
Scholars of Economics and Innovation