UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

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

Plaintiffs,

v.

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

Defendants.

Case No. _____

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

1. The Commonwealth of Massachusetts, Attorney General Dana Nessel on behalf of the People of the State of Michigan, State of Illinois, State of Arizona, State of California, State of Connecticut, State of Colorado, State of Delaware, State of Hawai'i, State of Maine, State of Maryland, State of Minnesota, State of Nevada, State of New Jersey, 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 and State of Wisconsin ("Plaintiff States") bring this action to protect their states and residents from unlawful action by the National Institutes of Health ("NIH") that will devastate critical public health research at universities and research institutions in the United States. Without relief from NIH's action, these institutions' cutting-edge work to cure and treat human disease will grind to a halt.

2. This suit concerns the "indirect cost rates" for NIH's research funding. High-level research requires funds not just for the costs that can be directly attributed to the specific work of a particular project, but also the indirect costs that support multiple projects. These costs are broken up into "facilities" and "administration" costs. For example, in order to conduct research, a university needs buildings, and needs to maintain those buildings and supply them with heat and electricity. A university also needs the infrastructure necessary to comply with legal, regulatory, and reporting requirements. These facilities costs cannot be attributed to any particular research project, but are still necessary for any research to occur. And university staff need administrative support, including clerical staff, IT support, cybersecurity and data respositories, as well as staff to administer the university as a whole. Again, these administrative costs support the university as a whole, and help make research possible without being attributable to any specific grant or project.

3. Effectively halting research to cure and treat human disease will directly impact the well-being of the Plaintiff states' citizens, who are the beneficiaries of research creating treatments, such as modern gene editing, vaccines such as flu vaccines, and cures for diseases like cancer, infectious diseases, and addiction. The well-being of the Plaintiff States' citizens also will be adversely affrected by the halting of research involving a better understanding of health conditions. These universities and research institutions are vital economic and social institutions in each state, employing thousands of their citizens, educating and training thousands more, and creating investment and partnering opportunities with the private sector.

4. Research institutions negotiate indirect cost rates with the federal government through a carefully regulated process, governed by regulations promulgated by the Office of Management and Budget ("OMB") and the Department of Health and Human Services ("HHS"). Those indirect cost rates are based on each institution's unique needs and cost structure and derive from documented and actual costs experienced for that institution. Typically, after the research institution's specific indirect cost rate is negotiated, it is memorialized in an executed agreement that applies to all of that institution's federal grants. After that agreement is executed, the federal government audits the research institution's indirect costs to ensure that they fall within the negotiated indirect cost rate and the calculations that supported it.

5. The agency may deviate from the negotiated rate only when required by federal statute or regulation, or when the deviation is individually sought and justified through a decision-making process that identifies the criteria and circumstances justifying that decision in specified instances.

6. In 2017, during his first administration, President Trump made a budget proposal that would have reduced the indirect cost rate for research institutions to an across-the-board, categorical rate of 10%. Congress unequivocally responded to ward off such a change to the calculation of indirect cost rates. In 2018, Congress enacted an appropriations rider prohibiting HHS or NIH from spending appropriated funds "to develop or implement a modified approach to" the reimbursement of "indirect costs" and "deviations from negotiated rates." Consolidated Appropriations Act, 2018, Pub. L. No. 115-141, 132 Stat 348, § 226. That rider has remained in effect through every appropriations law governing HHS to this day. *See* Further Consolidated Appropriations Act, 2024, Pub. L. No. 118-47, § 224.

7. On February 7, 2025, NIH nonetheless issued a guidance document pronouncing that all indirect cost rates for NIH grants would be reduced to 15%, in Notice Number NOT-OD-25-068, *Supplemental Guidance to the 2024 NIH Grants Policy Statement: Indirect Cost Rates* (the "Rate Change Notice"). This reduction applies not only to new grants but to existing grants, and becomes effective on February 10, 2025, just one business day after the Rate Change Notice issued.

8. The effects of the Rate Change Notice will be immediate and devastating. Medical schools, universities, research institutions, and other grant recipients across the country have already budgeted for (and incurred obligations based on) the specific indirect cost rates that had been negotiated and formalized with the federal government through the designated statutory and regulatory legal process. This agency action will result in layoffs, suspension of clinical trials, disruption of ongoing research programs, and laboratory closures. As the Guidance acknowledges, NIH's work and the institutions that NIH supports serve to "enhance health, lengthen life, and reduce illness and disability." NIH's extraordinary attempt to disrupt

all existing and future grants not only poses an immediate threat to the nation's research infrastructure, but will also have a long-lasting impact on its research capabilities and its ability to provide life-saving breakthroughs in scientific research.

9. The Rate Change Notice violates the Administrative Procedure Act ("APA") in multiple ways. The Rate Change Notice is arbitrary and capricious in, among other ways, its failure to articulate the bases for the categorical rate cap of 15%, its failure to consider the grant recipients' reliance on their negotiated rates, and its disregard for the factual findings that formed the bases for the currently operative negotiated indirect cost rates. The Rate Change Notice contravenes Congress's express directives in the appropriation acts governing the NIH, and HHS's own regulations that prohibit NIH from requiring such categorial, indiscriminate changes to indirect cost rates. In issuing the Rate Change Notice, the NIH has also acted beyond its statutory authority, and has failed to promulgate the change using notice and comment rulemaking.

10. The Court should set aside the Rate Change Notice and enjoin any actions taken to implement its directives.

JURISDICTION AND VENUE

11. This action arises under the Administrative Procedure Act, 5 U.S.C. §§ 701-706; the Further Consolidated Appropriations Act, 2024, Pub. L. No. 118-47; and federal regulations in the Code of Federal Regulations governing federal grants. The Court has jurisdiction pursuant to 28 U.S.C. § 1331.

12. Venue is proper in this district pursuant to 28 U.S.C. § 1391(e)(1). Defendants are United States agencies or officers sued in their official capacities. The Commonwealth of Massachusetts is a resident of this judicial district and a substantial part of the events or omissions giving rise to this Complaint occurred within the District of Massachusetts.

PARTIES

A. Plaintiff States

13. The Commonwealth of Massachusetts is a sovereign state of the United States of America. Massachusetts is represented by Attorney General Andrea Joy Campbell, who is the chief law enforcement officer of Massachusetts.

14. Attorney General Dana Nessel is Michigan's chief law enforcement officer and is authorized to act in federal court on behalf of the People of the State of Michigan on matters of public concern. Mich. Comp. Laws § 14.28.

15. The State of Illinois is a sovereign state of the United States of America. Illinois is represented by Attorney General Kwame Raoul, who is the chief law enforcement officer of Illinois.

16. The State of Arizona is a sovereign state in the United States of America. Arizona is represented by Attorney General Kris Mayes, who is the chief law enforcement officer of Arizona.

17. The State of California is a sovereign state in the United States of America. California is represented by Attorney General Rob Bonta, who is the chief law enforcement officer of California.

18. The State of Colorado, represented by and through its Attorney General Phil Weiser, is a sovereign state of the United States. The Attorney General acts as the chief legal representative of the state, and is authorized under section 24-31-101, C.R.S., to pursue this action.

19. The State of Connecticut is a sovereign state in the United States of America. Connecticut is represented by Attorney General William Tong, who is the chief law enforcement officer of Connecticut.

20. The State of Delaware is a sovereign state in the United States of America. Delaware is represented by Attorney General Kathy Jennings, who is the chief law enforcement officer of Delaware.

21. The State of Hawai'i is a sovereign state of the United States of America. Hawai'i is represented by Attorney General Anne Lopez who is the chief law enforcement officer of Hawai'i.

22. The State of Maine is a sovereign state of the United States of America. Maine is represented by Attorney General Aaron Frey who is the chief law enforcement officer of Maine.

23. The State of Maryland is a sovereign state of the United States of America. Maryland is represented by Attorney General Anthony G. Brown who is the chief legal officer of Maryland.

24. The State of Minnesota is a sovereign state of the United States of America. Minnesota is represented by Attorney General Keith Ellison who is the chief legal officer of Minnesota.

25. The State of New Jersey is a sovereign state in the United States of America. New Jersey is represented by Attorney General Matthew Platkin, who is the chief law enforcement officer of New Jersey.

26. The State of New York is a sovereign state in the United States of America. New York is represented by Attorney General Letitia James, who is the chief law enforcement officer of New York.

27. The State of Nevada is a sovereign state of the United States of America. Nevada is represented by Attorney General Aaron Ford who is the chief law enforcement officer of Nevada.

28. The State of New Mexico is a sovereign state of the United States of America. New Mexico is represented by Attorney General Raúl Torrez who is the chief law enforcement officer of New Mexico.

29. The State of North Carolina is a sovereign state of the United States of America. North Carolina is represented by Attorney General Jeff Jackson who is the chief law enforcement officer of North Carolina.

30. The State of Oregon is a sovereign state in the United States of America. The State of Oregon is represented by Attorney General Dan Rayfield, who is the chief legal officer of Oregon. Attorney General Rayfield is authorized by statute to file suit in federal court on behalf of the State of Oregon to protect the interests of the state. ORS 180.060.

31. The State of Rhode Island is a sovereign state in the United States of America. Rhode Island is represented by Attorney General Peter F. Neronha, who is the chief law enforcement officer of Rhode Island.

32. The State of Vermont is a sovereign state of the United States of America. Vermont is represented by Attorney General Charity Clark, who is the chief law enforcement officer of Vermont. Attorney General Clark is authorized to initiate litigation on Vermont's behalf.

33. The State of Washington is a sovereign state in the United States of America. Washington is represented by Attorney General Nicholas W. Brown. The Attorney General of Washington is the chief legal adviser to the State and is authorized to act in federal court on behalf of the State on matters of public concern.

34. The State of Wisconsin is a sovereign state of the United States of America. Wisconsin is represented by Attorney General Josh Kaul who is the chief law enforcement officer of Wisconsin.

B. Defendants

35. Defendant the National Institutes of Health is an agency of the United States Government, established pursuant to 42 U.S.C. § 281, and is housed within the U.S. Department of Health and Human Services.

36. Defendant Matthew Memoli, M.D., M.S., is Acting Director of NIH. He is sued in his official capacity.

37. Defendant U.S. Department of Human and Health Services is a federal cabinet agency that houses NIH. HHS is a Department of the Executive Branch of the U.S. Government and is an agency within the meaning of 5 U.S.C. § 551.

38. Defendant Dorothy Fink, M.D., is the Acting Secretary of HHS. She is sued in her official capacity.

FACTUAL BACKGROUND

NIH's Funding of Medical and Public Health Research in the United States

39. The NIH is the primary source of federal funding for medical and public health research in the United States. In Fiscal Year 2023, NIH spent over $35 billion on almost 50,000 competitive grants to more than 300,000 researchers.

40. NIH grants have funded public health research that have led to innumerable scientific breakthroughs, ranging from the Human Genome Project to the development of the MRI to the discovery of treatments for cancers of all types. Dozens of NIH-supported scientists have earned Nobel Prizes for their groundbreaking scientific work.

41. Most NIH-funded research occurs outside of federal government institutions, including at state universities and colleges, private institutions of higher education, and other research institutions. This approach allows NIH to fund a diverse array of institutions, promote competition for research grants, and facilitate the training of the next generation of researchers.

42. Plaintiff States' state universities and colleges, as well as other research institutions, depend heavily on NIH funding to support medical research. At any given time, individual research universities may depend on thousands of NIH grants that support independent research projects across multiple university facilities.

43. The NIH competitive grantmaking process begins with a notice of funding opportunities for a specific topic followed by new application submissions. *See* NIH Grants Policy Statement, U.S. Dep't of Health & Hum. Servs. (rev. Apr. 2024) ("NIHGPS"), at I-51.

44. After a formal review process that includes peer review, the NIH issues a legally binding Notice of Award ("NOA") to selected grant recipients stating that funds may be requested. *Id.* at IIA-59.

45. The grant awards are generally not lump-sum awards. Rather, they are grant amounts using cost-based accounting systems, under which grant recipients are authorized to recover their actual, documented costs for conducting research after the grant is awarded.

46. An NOA is issued for the initial budget period and each subsequent budget period, and it reflects any future-year expectations for the continuation of the funded project.

47. "Once the [NOA] is signed or money is drawn, the [NOA] and the grant terms are binding on the grantee and the government." *U.S. ex rel. Bauchwitz v. Holloman*, 671 F. Supp. 2d 674, 681 (E.D. Pa. 2009). "An [NOA] constitutes an 'obligation,'" and the NIH is "committed to funding the grant for the current budget period due to dependency upon the

annual Congressional appropriations process." *Id.* Accordingly, any failure of the NIH to comply with the terms of an NOA in the middle of a budget period—such as by modifying payment of "go forward expenses"—would constitute a breach of the NIH's obligations.

Direct Costs and Indirect Costs of Research Programs

48. After receiving an NIH grant, a grantee submits annual Research Performance Progress Reports, outlining their "direct costs" and their "indirect costs" to the agency.

49. "Direct costs" are those costs that are attributed directly to a specific research project supported by the grant.

50. For example, direct costs may include the cost of a specialized piece of equipment designated for that research project, salaries for the research staff who perform the research, stipends for graduate students, research equipment, and materials and supplies used in experiments (e.g., reagents).

51. "Indirect costs" are those costs that are necessary for research but cannot be attributed and allocated directly to a specific research project.

52. Indirect costs may include expenses such as building construction and maintenance, utilities, laboratory equipment, and cleaning costs. Indirect costs may also include research administration, which includes the work of safety and regulatory committees that are mandated by the federal government for certain research programs, as well as other support staff whose services apply to multiple research projects. In addition, indirect costs may include equipment necessary to comply with specialized ventilation requirements, or research quarters and facilities suitable for optimizing biosafety and radiation safety.

53. Indirect costs are just as vital as direct costs because they likewise cover necessary costs for research projects. Indirect costs are an essential part of the cost of scientific progress and medical advances.

54. Indirect costs are vital to conducting research that advances American stature in international technological advancement, medical research, and life-saving technologies. They support the fundamental expense of simply providing a location and staff to facilitate the research that would otherwise not be funded through direct costs.

55. For example, a university which is funded to conduct cancer therapy research also must fund the physical maintenance of a laboratory and pay for the staff who manage the laboratory and lab equipment, such as operational staff who are not themselves researchers.

56. "Indirect costs" are defined in 45 C.F.R. § 75.414(a) to include "facilities" and "administration."

57. The "facilities" category of indirect costs is "defined as depreciation on buildings, equipment and capital improvements, interest on debt associated with certain buildings, equipment and capital improvements, and operations and maintenance expenses." *Id.* This category includes the costs of the physical infrastructure necessary for carrying out research, such as construction and maintenance of specialized facilities and laboratories. Facilities costs are indirect costs because they cannot be attributed to an individual project. Nevertheless, if those facilities expenditures are not made, research in that building cannot occur.

58. For example, a single building may house numerous research groups engaging in multiple NIH-funded projects, such that the cost of the building's construction and maintenance cannot be attributed solely to one individual project. Nevertheless, without the building's construction and maintenance, research in that building cannot occur.

59. The "administration" category is defined as "general administration and general expenses such as the director's office, accounting, personnel, and all other types of expenditures not listed specifically under one of the subcategories of 'Facilities'" (including cross allocations from other pools, where applicable). 45 C.F.R. § 75.414(a). This category includes costs related to the administrative and compliance activities required to conduct federally sponsored research, such as human and animal research review boards, financial reporting and purchasing, training and education, and managing potential conflicts of interest.

60. For example, a single employee or group of employees may handle necessary administrative activities across multiple NIH grants, and the costs of employing those individuals cannot be attributed to an individual research project.

The Negotiation and Establishment of Indirect Cost Rates with the Federal Government

61. Federal regulations require research institutions to express their indirect costs as a rate: the proportion of their total costs that cannot be attributed or allocated to individual research projects.

62. As a simplified example, a federal grant may award $100,000 to a grant recipient to conduct a specific research project. If the grant recipient's indirect cost rate is 20%, then the grant award becomes $120,000, after adding the indirect costs.

63. Federal regulations prescribe a detailed methodology for negotiating indirect cost rates. Typically, a single agency, such as HHS, negotiates an indirect cost rate with a research institution. As part of those negotiations, federal regulations require institutions to conduct comprehensive cost analyses that follow detailed federal directives governing reasonable and allowable indirect costs. For example, if an institution seeks to recover the cost of building

maintenance, it must document those costs and then attribute those costs to their research programs.

64. The federal agency then reviews and verifies these proposals, resulting in extensive back-and-forth negotiation on an indirect cost rate.

65. Once the indirect cost rate for a research institution is negotiated, the research institution and the federal agency most typically enter into a Negotiated Indirect Cost Rate Agreement ("NICRA"). That indirect cost rate is then binding on the entire federal government during the period that the negotiated rate is in effect. The default term for such agreements, under the OMB regulations, is five years.

66. After the indirect cost rate is agreed upon and the actual indirect costs are incurred, federal agencies can conduct audits to ensure that the negotiated indirect cost rate conforms to the actual indirect costs that are incurred. The indirect cost rate is then adjusted if the audit establishes that the institution has recovered excess costs.

Indirect Cost Rates in the Administration of NIH Grants

67. NIH is required to use the indirect cost rate negotiated with a research institution in its NICRA unless a deviation from that rate is "required by statute or regulation" or is "approved by a Federal awarding agency head or delegate based on documented justification as described in [45 C.F.R. § 75.414(c)(3)]." 45 C.F.R. § 75.414(c)(1).

68. To deviate from a negotiated indirect cost rate, 45 C.F.R. § 75.414(c)(3) requires that "[t]he HHS awarding agency must implement, and make publicly available, the policies, procedures and general decision making criteria that their programs will follow to seek and justify deviations from negotiated rates."

69. Pursuant to 45 C.F.R. § 75.414(c)(4), "the HHS awarding agency must include in the notice of funding opportunity the policies relating to indirect cost rate reimbursement, matching, or cost share as approved." Moreover, "the HHS agency should incorporate discussion of these policies into their outreach activities with non-Federal entities prior to the posting of a notice of funding opportunity." *Id.*

70. The NIHGPS sets out for NIH grant recipients "the policy requirements that serve as the terms and conditions of NIH grant awards." Regarding reimbursement of indirect costs, the NIHGPS 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." NIHGPS at IIA-68.

71. The NIHGPS further provides that "[i]f a subrecipient already has a negotiated indirect cost rate established with their cognizant agency for indirect cost, the negotiated rate must be used." *Id.* at IIA-69.

72. Negotiated rates vary from institution to institution.

73. The primary reason for this variation is that different institutions conduct different types of research. Scientific laboratories tend to be far more expensive to build and maintain than generic office buildings. As such, an institution engaging in biomedical research will likely have a higher indirect cost rate than an institution primarily engaged in social science research.

74. Even in the context of biomedical research, some types of research require incurring more indirect costs than others. If a particular institution invests in an expensive piece of lab equipment that supports multiple lines of research, that institution will have higher indirect cost rates than a different institution that does not use expensive shared lab equipment, or an institution that has expensive equipment devoted to only one line of research.

75. Institutions with higher-than-average negotiated indirect cost rates are typically those that support facility-intensive types of research, including: biocontainment laboratories that support immunology, virology, and microbiology research involving dangerous biological pathogens; cord blood bank and stem cell transplant facilities; animal facilities; and resources to support genomic, proteomic and metabolomics analysis and processing.

76. Local conditions may also affect indirect cost rates. The costs of construction, renovation, utilities, and wages vary significantly by region.

Prior Attempts to Limit Indirect Cost Rates Governing NIH Grants

77. In 2017, the first Trump Administration released a budget proposal that would have slashed the indirect cost rate to a uniform, across-the-board rate of 10%.

78. The budget proposal generated alarm that such a change would bring research programs throughout the country to a halt.

79. To avert those consequences, Congress enacted an appropriations rider prohibiting HHS or NIH from spending appropriated funds "to develop or implement a modified approach to" the reimbursement of "indirect costs" and "deviations from negotiated rates." Consolidated Appropriations Act, 2018, Pub. L. No. 115-141, 132 Stat. 348, § 226.

80. That rider has since remained in effect, unbroken year by year, through every appropriations law governing HHS.

81. It remains in effect to this day, in the now-operative statute. *See* Further Consolidated Appropriations Act, 2024, Pub. L. No. 118-47, § 224.

NIH's Rate Change Notice

82. On February 7, 2025, the Office of the Director of NIH issued a document, titled "Supplemental Guidance to the 2024 NIH Grants Policy Statement: Indirect Cost Rates"

(hereinafter, "Rate Change Notice"). The Rate Change Notice announced that "[f]or any new grant issued, and for all existing grants to [institutions of higher education, or "IHEs"] retroactive to the date of issuance of this Supplemental Guidance, award recipients are subject to a 15 percent indirect cost rate." It further explained that "[p]ursuant to this Supplemental Guidance, there will be a standard indirect rate of 15% across all NIH grants for indirect costs in lieu of a separately negotiated rate for indirect costs in every grant."

83. The Rate Change Notice purports to rely on 45 C.F.R. § 75.414(c)(1) for authority to set a single, uniform indirect cost rate of 15%. But that regulatory provision requires that, in order to deviate from a negotiated indirect cost rate absent a statutory or regulatory requirement to do so, NIH must comply with 45 C.F.R § 75.414(c)(3)'s requirement that the agency "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." 45 C.F.R § 75.414(c)(3). And pursuant to the regulatory provision that immediately follows, NIH "must include" such "policies relating to indirect cost rate reimbursement" "in the notice of funding opportunity." 45 C.F.R § 75.414(c)(4).

84. The Appendix to this regulation, referenced in the Rate Change Notice, and entitled "Appendix III to Part 75—Indirect (F&A) Costs Identificaton and Assignment, and Rate Determination for Institutions of Higher Education (IHES)," reinforces the inappropriateness of relying on this regulation to make such a categorical change. In particular, it states in § C.7: "Except as provided in paragraph (c)(1) of §75.414 Federal agencies must use the negotiated rates for indirect (F&A) costs in effect at the time of the initial award throughout the life of the Federal award. Award levels for Federal awards may not be adjusted in future years as a result of

changes in negotiated rates. 'Negotiated rates' per the rate agreement include final, fixed, and predetermined rates and exclude provisional rates."

85. Notices of funding opportunity provided to insittutions in Plaintiff States did not contain policies issued pursuant to 45 C.F.R § 75.414(c)(3) upon which NIH now seeks to justify deviations from their negotiated rates to the 15% rate announced in the Rate Change Notice. Rather, according to NIH, the Rate Change Notice itself "implements and makes publicly available NIH's updated policy deviating from the negotiated indirect cost rate for new grant awards and existing grant awards, effective as of the date of this Guidance's issuance."

Plaintiff States' Indirect Costs and Negotiated Indirect Cost Rates

86. Institutions in each of the Plaintiff States have negotiated indirect cost rates with NIH and have executed agreements setting forth those rates.

87. Some Plaintiff States' institutions of higher education are arms or instrumentalities of Plaintiff States, and the injuries to those institutions are also injuries to Plaintiff States. Plaintiff States therefore have standing to bring this suit on their behalf. *See Biden v. Nebraska*, 143 S. Ct. 2355, 2365-68 (2023); *Peters v. Bd. of Trs. of S. Ill. Univ.*, 816 N.E.2d 1, 3 (Ill. App. Ct. 2004) ("There are numerous decisions finding that a state university and its board of trustees are arms of the State.").

88. The Rate Change Notice will have immediate, severe destructive effects on research universities, medical schools, and scientific institutes and programs throughout the country. These institutions not only contribute significantly to protecting the health of the plaintiff states' citizens through their research, but are also important economic drivers for the plaintiff states – employing thousands of their citizens and leveraging additional investment in the states.

89. In Federal fiscal year 2024, 219 organizations in Massachusetts received NIH funding to support 5,783 projects. The total funding was $3.46 billion, of which approximately $1 billion or more were to support indirect costs of the projects.

90. Included in these figures are 501 awards to UMass campuses for a total of $248 million, or which more than $80 million were for indirect costs. The UMass system, with its five campuses, is the largest provider of talent to the Massachusetts economy.

91. The University of Massachusetts Chan Medical School ("UMass Chan Medical School") receives a total of approximately $200 million in NIH grant funding annually. Approximately $62 million of this funding is derived from indirect cost allocations.

92. UMass Chan Medical School has a NICRA with NIH, effective as of June 6, 2023. The Indirect Cost Rate in UMass Chan Medical School's NICRA is 67.5%, with certain direct cost categories (such as equipment, patient care costs, and subcontracts) exempted from calculating the indirect cost rate, resulting in a blended indirect cost rate of just under 45% on the NIH grant portfolio of UMass Chan Medical School.

93. UMass Chan Medical School has relied on its NICRA in preparing its operating budget and in incurring obligations to support its research programs. The loss of these funds will immediately impact UMass Chan Medical School's ability to draw critical funds used to pay expenses associated with utilities and basic maintenance on the operational research facilities, debt service, payroll, and other infrastructure associated with UMass Chan Medical School's research and clinical trials.

94. The Rate Change Notice, cutting indirect cost rates to 15%, would result in a loss to UMass Chan Medical School of $40 to $50 million annually that UMass Chan Medical School uses to support its research programs.

95. For UMass Chan Medical School, NIH's reduction of the indirect cost rate will eliminate approximately $40 to $50 million dollars in funding that UMass Chan Medical School uses to support its research programs. The loss of these funds will immediately impact UMass Chan Medical School's ability to draw critical funds used to pay expenses associated with utilities and basic maintenance on the operational research facilities, debt service, payroll, and other infrastructure associated with UMass Chan Medical School's research and clinical trials.

96. In Federal fiscal year 2024, UMass Amherst will receive approximately $44.8 million dollars in funding from NIH. Of that total amount, approximately $13.1 million dollars are for indirect costs, based on the NIH Federal indirect cost rate of 61%.

97. An example of an NIH-funded project at UMass Amherst is "Massachusetts AI and Technology Center for Connected Care in Aging and Alzheimer's Disease (MAITC)," supported by the National Institute on Aging. The project is a collaboration of UMass Amherst and Brigham and Women's Hospital, also involving Brandeis University, Massachusetts General Hospital, and Northeastern University. MAITC fosters interdisciplinary research on the development, validation, and translation of AI-enhanced technologies to improve connections between older adults, caregivers, and clinicians in order to more effectively support the care of people living with Alzheimer's disease and related dementias. MAITC provides support to other universities and private sector entities to support projects that accomplish this mission. Administrative support for the project is provided in part from the F&A reimbursements from NIH.

98. In Michigan, the University of Michigan, the State's flagship research university, conducts life-saving and groundbreaking medical and technological research. In 2024, the University of Michigan conducted approximately $801 million in NIH-funded research. The

University of Michigan has negotiated an Indirect Cost Rate of 56%. A reduction to 15% would eliminate approximately $181 million in funding. This would impact 425 NIH-funded trials currently underway, including 161 trials aimed at saving lives.

99. Michigan State University is the nation's pioneer land-grant university, and maintains human health research initiatives including translational neuroscience (with a focus on Alzheimer's and Parkinson's diseases), pediatrict and human development (including autism), obstetrics, gynecology, reproductive health, cancer and stroke. MSU receives NIH funding of approximately $136 million, and has negotiated an Indirect Cost Rate of 57%. A reduction to 15% would mean a loss of approximately $27 million that MSU uses to support its research programs. This would disrupt such important initiatives as Grand Rapids Innovation Park, MIRACLE Center, and MSU's partnership with Henry Ford Health. The precipitous reduction in funding would imperil thousands of Michigan jobs, not only in health science research, but also up to a thousand construction jobs, as MSU and Henry Ford Health are currently constructing a new research building in Detroit.

100. Wayne State University in Detroit receives a total of $80 million in NIH grant funding annually. Wayne State University's negotiated indirect cost rate is 54%. A reduction to 15% will mean an immediate impact on Wayne State University's ability to pay expenses related to facilities operational costs and debt service, research personnel, clinical trials, grants management, regulatory compliance, core research facilities and services, equipment and supplies, and more.

101. Illinois is home to dozens of world-class universities, public and private, including ten universities recognized by the Carnegie Classification of Institutions of Higher

Education as having "high" or "very high" research activity.[1] According to NIH's grants database, all ten of Illinois's high-research universities received NIH grants for the 2022, 2023, and 2024 fiscal years.[2]

102. At least nine public Illinois universities currently have NIH grants or subgrants: Chicago State University, Eastern Illinois University, Governor's State University, Illinois State University, Northeastern Illinois University, Northern Illinois University, Southern Illinois University, the University of Illinois Chicago, and the University of Illinois Urbana-Champaign. Five of these universities—Illinois State University, Northern Illinois University, Southern Illinois University, the University of Illinois Chicago, and the University of Illinois Urbana-Champaign—are high-research universities that obtain substantial grant funding from NIH.

103. The Rate Change Notice would have a devastating effect on Illinois's research institutions, forcing them to curtail planned spending, reduce their scientific output, and limit research opportunities for students.

104. The University of Illinois Chicago ("UIC") and the University of Illinois Urbana-Champaign ("UIUC"), for example, received more than $325 million in NIH funding during FY 2024. The universities rely on those funds to conduct life-saving medical research, including roughly 400 ongoing clinical trials, that researchers cannot undertake without the laboratories, high-speed data processing, hazardous waste disposal, regulatory compliance staff, patient safety

[1] *See* Search Results for Doctoral Universities with High or Very High Research Activity in Illinois, Carnegie Classification of Insts. of Higher Educ., https://carnegieclassifications.acenet.edu/institutions/?inst=&basic2021__du%5B%5D=15&basic2021__du%5B%5D=16&stabbr%5B%5D=IL (last visited Feb. 9, 2025).

[2] *See NIH Awards by Location & Organization*, NIH, https://report.nih.gov/award/index.cfm (last visited Feb. 9, 2025).

protocols, maintenance, and basic administrative support covered by NIH grants as indirect costs.

105. UIC and UIUC currently have negotiated base indirect cost rates of approximately 60% for on-campus research. The Rate Change Notice would reduce those rates by nearly 75%, costing the University of Illinois system approximately $67 million in annual funding. In the short term, the cutback would force the universities to redirect funds from other projects, reducing their ability to deliver critical education, research, and service functions. In the long term, UIC and UIUC would inevitably need to reduce their research activities, including by conducting fewer clinical trials, likely producing fewer medical breakthroughs for the public.

106. Southern Illinois University also relies on roughly $20.2 million in currently active NIH awards to conduct cutting-edge medical research that has yielded new treatments for cancer, neurodegenerative disorders like Alzheimer's disease and Parkinson's disease, and diabetes. The University also depends on NIH funding to prepare students to enter careers in science, technology, engineering, and mathematics. Those activities create an array of indirect but unavoidable costs, including for lab and equipment maintenance, researcher support for investigation and presentation opportunities, research safety protocols, student researcher development, and infrastructure support.

107. Southern Illinois University's three campuses currently have negotiated indirect cost rates of between 44.5% and 48.5%. The Rate Change Notice would reduce those rates by nearly two thirds and cost the University approximately $4.5 million in funding. This loss of funding would impair the University's ability to maintain research facilities; to obtain equipment and supplies; to fund research compliance practices; and to develop facilities for new faculty—

and, thus, to hire those new faculty. It would also harm the University's efforts to provide students with research experience.

108. Other Illinois public universities would experience similar harms. Both Illinois State University and Northern Illinois University, for instance, would see their indirect cost rates reduced by roughly 70%, resulting in the loss of hundreds of thousands of dollars across the two institutions. These cuts would cause the universities to reduce or eliminate positions for staff or students and lessen their research outputs.

109. In Arizona, the University of Arizona had over $170 million in NIH funding in FY 2024. Arizona State University's Tempe Campus was awarded over $65 million in NIH funding in FY 2024. A reduction in the indirect cost rate would result in the loss of millions of dollars in Arizona's state university funding.

110. In California, the University of California's ("UC") 21 health professional sciences schools, five NCI-designated cancer centers, and six academic medical centers are widely recognized as among the best in the nation, and they are international leaders in the education of health professionals, in research that develops new cures and treatments, and in public service that provides healthcare for all Californians regardless of ability to pay. The University of California is one of the nation's leading research institutions, with almost 9% of all U.S. academic research being conducted by UC researchers. Biomedical advancements at UC include the first radiation treatment for cancer, research contributing to the first flu vaccine, the discovery of the role of LDL and HDL cholesterol in heart disease, the invention of modern gene editing, and much more. Federal funds are UC's single most important source of support for its research, accounting for more than half of UC's total research awards. In FY 2023, UC received a total of over $2 billion in NIH contract and grant funding. The reduction of federal funding to

the UCs as set forth in the NIH Notice would be devastating for the UC system. It would result in broad reduction of services, including impact on education, delivery of care to patients, and research. Many individuals (including faculty, staff, and students), programs, and initiatives receiving federal funding almost certainly would be forced to significantly scale back or halt their research. This outcome will be potentially devastating to the research projects, to the training of new medical personnel, and to the University's research enterprise, regardless of discipline.

111. The California State Universities are largest public university system in the United States, and consists of 23 campuses. In the last audited year, the CSU campuses received approximately $158 million in NIH funds. The Negotiated Indirect Cost Rate for those funds ranged from 20 to 50%, and the new cap will impact their ability to maintain their current programs.

112. In Colorado, research institutions received a total of $566.8 million in NIH grants in 2024. Of the 47 grant recipients in Colorado, the University of Colorado Anschutz Medical Campus ("AMC") received the most funding with $360 million in annual awards. The AMC is the state's only academic medical research campus and supports more than 1,000 clinical trials with more than 14,000 enrollments in research studies last year in a broad array of investigations across the health spectrum. This includes new cancer therapies, studies of novel cardiovascular devices, and new approaches for Alzheimer's disease among many others.

113. The AMC has a NICRA with NIH, effective as of May 2023. The Indirect Cost Rate in the AMC NICRA is 56%. AMC's total effective indirect cost rate, calculated as the average of active awards, for NIH funding is 34.2%. NIH's reduction of the AMC's indirect cost rate will eliminate approximately $74 million in annual funding that the AMC uses to support its

research programs. The loss of these funds will immediately impact the AMC's ability to draw critical funds used to pay expenses and continue its research.

114. NIH is one of the top federal sponsors of the University of Colorado, Boulder campus, with annual awards totaling $77.9 million in FY 2024. NIH funding at the University of Colorado Boulder includes funding for biomedical research, pharmaceutical developments, circulation and vascular therapies, research essential to improving health and well-being by understanding cognitive decline, reducing substance abuse, improving access to health care, reducing crime and violence, enhancing resilience and response to natural disasters, and more.

115. The University of Colorado Boulder has a Negotiated Indirect Cost Rate Agreement with NIH, effective as of July 1, 2021. The Indirect Cost Rate in the University of Colorado Boulder's NICRA is 56.5%. The University of Colorado Boulder's total blended indirect cost rate, calculated as the average indirect cost rate of active awards, for NIH funding is 46.7%. NIH's reduction of the University of Colorado Boulder's indirect cost rate will eliminate approximately $11.7 million based on FY 2024 expenditures that the University of Colorado Boulder uses to support its research programs. The loss of these funds will immediately impact the University of Colorado Boulder's ability to draw critical funds used to pay expenses associated with maintaining the University's critical research infrastructure and support.

116. Colorado State University has a robust NIH-funded research portfolio, including public health, veterinary translational medicine, infectious disease, prion-related diseases, and cancer research. This research is supported by approximately $203.3 million from the NIH for grants with active project periods as of February 10, 2025. CSU has a Negotiated Indirect Cost Rate Agreement with the Department of Health and Human Services, effective as of September 29, 2022. The current Indirect Cost Rate in CSU's NICRA is 54% for On Campus Organized

Research. CSU's total blended indirect cost rate for NIH funded grants with active project periods as of February 10, 2025 is 45.3%.

117. NIH's reduction of CSU's indirect cost rate for grants will eliminate approximately $4.2 million in funding annually that CSU uses to support its research programs. The reduction of these reimbursements will immediately impact CSU's ability to draw critical funds essential to its ability to perform research.

118. In Connecticut, the University of Connecticut ("UConn") has a NICRA with HHS, effective as of September 27, 2024. The current Indirect Cost Rate in UConn's NICRA for on-campus research is 61%. University of Connecticut at Hartford ("UCH") has a NICRA with DHHS, effective as of March 29, 2022, with a current indirect cost rate of 66.5%.

119. The blended indirect cost rate for NIH funding across UConn and UCH was 42.73% for fiscal year 2024. NIH's reduction of indirect cost rates will eliminate approximately $35 million annually in funding that is used to support their research programs. The loss of these funds will immediately impact UConn's and UCH's ability to draw funds used to pay for, among other things, maintaining research facilities and supporting administrative functions that ensure compliance with NIH rules and regulations, which are designed to ensure research is conducted safely and lawfully.

120. In Delaware, Delaware State University ("DSU") has a NICRA with NIH, effective as of September 11, 2024. The Indirect Cost Rate in DSU's NICRA is 46% for on-campus work and 26% for work off campus.

121. NIH's reduction of DSU'S indirect cost rate will eliminate approximately $1.4 million year in NIH funding that DSU uses to support its biomedical research programs. The loss of these funds will immediately impact DSU's ability to draw critical funds used to pay

expenses associated with research, including salaries of research support personnel, stipends for doctoral students, maintenance of facilities, and other infrastructure supporting research.

122. In Hawai'i, the University of Hawai'i at Mānoa is Hawai'i's flagship research university, and the University of Hawai'i system of ten campuses includes the John A. Burns School of Medicine (JABSOM), the University of Hawai'i Cancer Center (a National Cancer Institute designated center), the School of Pharmacy, the Nancy AtmosperaWalch School of Nursing and Dental Hygiene, and the Myron Thompson School of Public Health. All of these Schools, Colleges and Centers conduct translational and fundamental research, and the University is supported by 175 awards and subawards from the NIH with a current value of $211 million. NIH's reduction of the University of Hawai'i's current negotiated indirect cost rate of 56.5 percent at the JABSOM and the Cancer Center alone will eliminate approximately $15 million in funding that the University of Hawaii uses to support its research programs, including ongoing clinical trials and debt service payments.

123. In Maine, the University of Maine System has a NICRA with NIH, effective as of April 23, 2024. The Indirect Cost Rates in the NICRA range from 26.00% to 47.70%. The University of Maine System's on campus research indirect cost rate for NIH funding is 47.70%.

124. NIH's reduction of the University of Maine System's indirect cost rate will eliminate approximately $1.4 million in funding that the university uses to support its research programs. The loss of these funds will immediately impact the university's ability to draw critical funds used to pay expenses associated with operation and maintenance of complex facilities and critical research equipment, procurement of goods, compliance with applicable laws and grant provisions, payroll related to individuals not directly associated with the awards, and similar costs.

125. In Maryland, the University of Maryland at Baltimore ("UMB") conducts life-saving research that is supported annually by $245 million in direct funding from NIH and $75 million in passthrough funding from NIH. UMB has a NICRA with NIH, effective as of October 24, 2023. The Indirect Cost Rate in UMB's NICRA is 55.5%.

126. NIH's reduction of UMB's Indirect Cost Rate will eliminate $49.5 million annually in NIH indirect and passthrough funding that UMB uses to support its research programs.

127. In Minnesota, according to NIH's own database, NIH has awarded more than $67 million to institutions in Minnesota in 2025, primarily the Mayo Clinic and University of Minnesota.

128. In Nevada, the University of Nevada, Las Vegas ("UNLV") advances research in genomics, personalized medicine, brain health, and other health areas supported by $44.8 million from NIH. UNLV's Indirect Cost Rate is 51% pursuant to its NICRA with NIH. Its total blended indirect cost rate for NIH funding is 47.2%. NIH's reduction of the indirect cost rate to 15% will eliminate approximately $2.7 million in funding annually. The loss of these funds will hinder UNLV's ability to pay facilities costs, make payroll, retain staff, and maintain infrastructure used to support research and ongoing clinical trials, among other negative impacts.

129. The University of Nevada, Reno ("UNR") advances interdisciplinary research supported by $72.3 million from NIH. UNR's indirect cost rate is 47% pursuant to its NICRA with NIH. UNR's total blended indirect cost rate for NIH funding is 24.1%. NIH's reduction of UNR's indirect cost rate will eliminate approximately $4 million per year in indirect costs funding. This loss will negatively impact infrastructure used to support research, clinical trials, staff and payroll, regulatory compliance, and facilities costs and maintenance.

130. Nevada State University ("NSU") is Nevada's state college. Its research is supported by $633,871 from NIH and is a subaward of UNR. NSU's indirect cost rate is 39% pursuant to its NICRA with the Department of Health and Human Services (DHHS). Its total blended indirect cost rate for NIH funding is 30%. NIH's reduction of indirect costs to 15% will eliminate approximately $15,177 in funding used for the development of new projects, academic programs, and staff; software and technology; facilities repairs and maintenance; and other research infrastructure.

131. In New Jersey, institutions received a total of more than $405 million in NIH grant funding in FY 2024.[3] The institutions that receive such funding include public institutions of higher education and research, such as Rutgers, the State University of New Jersey, Rutgers Biomedical and Health Sciences, Rowan University, Rowan University School of Osteopathic Medicine, the College of New Jersey, Montclair State University, the New Jersey Institute of Technology, and more. Moreover, public and private research institutions in New Jersey collaborate on cutting-edge research. That includes NIH-supported programs in consortium with Princeton University at Rutgers Cancer Institute of NJ, which is New Jersey's sole National Cancer Institute-designated Comprehensive Cancer Center. NIH funds also support the New Jersey Alliance for Clinical and Translational Science, a partnership among four institutions: Rutgers University, Princeton University, the New Jersey Institute of Technology, and RWJBarnabas Health.

132. A 15% indirect cost rate cap would seriously harm State entities and their ability to pursue existing and future research. For example, Rutgers is the recipient of approximately

[3] https://report.nih.gov/award/index.cfm?ot=&fy=2024&state=NJ&ic=&fm=&orgid=&distr=&rfa=&om=n&pid=&view=statedetail

$250 million of NIH funding, which currently supports nearly 1,200 separate grants and more than 2,400 employees. Its previously-negotiated rate agreement with HHS set the rate for F&A costs at 57% of modified total direct costs for on-campus research. Applying a 15% rate would have an immediate impact on Rutgers' ability to pay for infrastructure used to support research, eliminating approximately $21.6 million in funding for this fiscal year ending June 30, 2025 and a projected $57.5 million for the fiscal year ending June 30, 2026.

133. In New Mexico, the University of New Mexico has a NICRA with NIH, effective as of Juy 1, 2022. The Indirect Cost Rate in the University of New Mexico NICRA is 52.5%. The University of New Mexico's total blended indirect cost rate for NIH funding is 26.47%. NIH's reduction of University of New Mexico's indirect cost rates will eliminate approximately $14.5 million in funding per year that University of New Mexico uses to support its research programs to advance the health and economy of New Mexico.

134. The loss of these funds will immediately impact University of New Mexico's ability to draw critical funds used to pay expenses associated with facilities, administrative costs including associated salaries and benefits, technology and related infrastructure, and regulatory compliance costs, in support of research. The loss of indirect costs will result in inadequate support systems for clinical trials.

135. In New York, at present, there are over $5 billion in open NIH grants to institutions within New York state. A preliminary analysis indicates that, if the NIH Rate Change Notice goes into effect, New York institutions stand to lose approximately $850 million.

136. The State University of New York ("SUNY") system alone faces a possible $21 million in lost revenue from February 10, 2025, through June 30, 2025. The SUNY system

ultimately will lose over $78 million through the life of current grants, if the NIH Rate Change goes into effect.

137. In Oregon, research institutions in the State of Oregon, including Oregon Health and Science University ("OHSU"), University of Oregon, and Oregon State University, received more than $400 million in NIH grant awards in recent years. OHSU, Oregon's only academic health center and a leader in medical research, received more than $297 million in NIH grants and contracts in 2023. OHSU's NICRA is 56% for on-campus organized research. Implementation of the Rate Change Notice would deprive OHSU of approximately $80 million in funding. That loss of funds would have an immediate impact on OHSU's ability to fund critical facilities, research compliance, and animal care. It would also compromise OHSU's ability to carry out ongoing clinical trials and could immediately and directly impact patient care.

138. In Rhode Island, the new 15% cap on NIH indirect cost reimbursement rate will have significant impacts on the University of Rhode Island and its ability to be an economic engine for the State of Rhode Island. Based on indirect costs received to date in FY 25, the 15% NIH cap is estimated to impact the University of Rhode Island at a monthly loss of $240,000 and $2.8 million per year.

139. In Vermont, the University of Vermont and State Agricultural College (the "University of Vermont" or "UVM") is an instrumentality of the State of Vermont. It is Vermont's flagship research university, and is being awarded a Research 1 ("R1") designation through the Carnegie classification system. In recent years, UVM has received over $50 million per year in NIH grants. Its current top negotiated indirect cost rate with NIH is 53%, and its current blended indirect cost rate across all supported activities is around 29%.

140. The reduction proposed in the NIH notice would eliminate approximately $8 million in NIH funding per year in research support for costs not currently allowed under federal guidance, but which are necessary to allow research to take place. The lowering of NIH indirect support will immediately impact UVM's ability to draw critical funds used to pay expenses associated with necessary grant administration tasks in compliance with federal spending and reporting guidelines, and to pay critical facility costs such as utilities and building safety.

141. Absent adequate federal support for these functions, alternative sources of support will be required. This could mean greater state investment in UVM or a rise in tuition rates to UVM students, which would either create additional educational affordability problems or impose additional costs on the State. Alternatively, loss of funding will result in a decline in UVM's ability to support research, which would lead to fewer grant dollars coming to Vermont. This would have a significant impact on UVM's ability to continue to drive economic development in Vermont. The normally accepted economic impact multiplier of 3 implies that a 20% decline in UVM's research activity (approximately $40 million total) would result in an economic loss to Vermont of $120 million annually.

142. In addition, NIH-supported clinical trials at the University of Vermont and the University of Vermont Medical Center help bring novel treatment opportunities to Vermont. Indirect costs associated with NIH-funded trials are a main source of support for UVM's clinical trials facility. As the state's only research university and university affiliated hospital/health network, declines in NIH indirect support for clinical trials facilities will lessen UVM's ability to provide medical advancement to the people of Vermont. This impact will be felt state-wide.

143. The loss of the negotiated indirect cost rate and significant decline in UVM's ability to support research there would also cause lasting harm to the University's research

program. The University forthcoming elevation to Carnegie Research 1 ("R1") status has significantly elevated the University's ability to recruit high performing researchers and research trainees to Vermont. Doctoral degrees granted by UVM are up 20% and research expenditures are up more than 70% over the last 5 years. Numerous UVM "spin-out" companies have received significant investment from private funders. All of these results have had a significant impact on Vermont communities and the state's economy, and elevated UVM's ongoing ability to attract high performing students to Vermont. A reversal of this research success and growth will undermine many years of university and state investment at a time where demographic challenges in the northeastern United States are undermining higher education enrollment and access to affordable, high-quality education.

144. In Washington, the University of Washinton ("UW"), with its flagship campus located in Seattle, WA, has a negotiated indirect cost rate with the NIH of 55.5% (blended) for on-campus activities, with organized research rates (excluding training grants) varying from 26% for research off campus to 83.1% for research in the Washington National Primate Research Center (WaNPRC). A broad, immediate, and inflexible cap of 15% for all indirect costs would instantly deprive UW of hundreds of millions of dollars it currently puts toward conducting the vital research and medical care contemplated by the NIH grant awards. UW has long relied on being able to negotiate these rates for years, and has built out its research facilities and headcount accordingly—nothing could have prepared UW for a sudden and stinging rebuke of the federal government's previous positions. The impacts would be devastating not only to the many staff members and faculty who would likely lose their livelihood, but could also prove deadly.

145. For instance, the UW School of Medicine is one of the top academic institutions to receive NIH, covering approximately 657 grants and more than $385 million in FY 2024 alone.

146. NIH's indirect cost rate reduction will eliminate approximately $90 to $110 million in funding that UW Medicine uses to support its research and clinical treatment programs. Because of these drastic funding reductions, UW would likely be forced to not only stop admitting new patients to some clinical trials, but to scale back ongoing clinical trials, such as those for kidney disease, diabetes, Alzheimer's, and pediatric cancer. While UW would do so only as is safe and ethical for currently enrolled participants, for patients that have placed their trust in UW for what is in many cases their last option at lifesaving care, and for those who held off of other treatment and clinical trial opportunities to pursue treatment at UW, any scaling back in their level of care would be a devastating breach of trust. The damage to these patients' lives and their relationship with their care team at UW would be nearly impossible to rectify.

147. Additionally, the inability to start new trials will delay lifesaving treatments that rely on decades of research. The indirect cost rate caps would also cripple UW Medicine's ability to continue its vital ongoing research efforts into Alzheimer's disease diagnosis, gene therapy treatments for Duchenne muscular dystrophy, pain management for traumatic brain injury patients, and identification of new markers that predict diabetic kidney disease in young adults with type 2 diabetes.

148. Similarly, UW's WaNPRC, one of only seven National Primate Research Centers in the world, would be particularly devastated. WaNPRC supports 800 nonhuman primates, employs 170 people with expertise in veterinary care and animal research and provides the specialized lab spaces and equipment unique to nonhuman primate research. A cut in indirect

cost rate will result in loss of nearly $5 million per year in resources needed to support WaNPRC's infrastructure—costs that it cannot afford to bear. If WaNPRC facilities are shuttered, WaNPRC will also have to reduce or eliminate the 800 nonhuman primates in its care. WaNPRC has performed vital research, including brain-interface research that enables people to control robotic limbs with brain activity coded by a computer; the first controlled brain-function study in a nonhuman primate, which led to technology restoring movement in people with spinal cord injuries; and the first cochlear implants that provided a cure for deafness.

149. As a result of the Rate Change Nottice, ongoing, lifesaving research would likely be halted and potentially lost, such as current research into a novel gene therapy strategies into a cure for chronic HIV infection; stem-cell based therapy used to repair damaged heart muscle; and development of a novel tool to study the causes of stroke that could lead to new interventions to prevent or treat strokes in people.

150. Washington State University ("WSU"), with five physical campuses and four Research Extension Centers located throughout the State of Washington, has a negotiated indirect cost rate for NIH funding of 53% for on-campus research, and 26% for off-campus research. Immediately capping WSU's rate at 15% for all NIH projects would instantly cut over $5 million from WSU this year alone, sending shockwaves throughout WSU, and significantly disrupting the substantial progress WSU has made to serve its students and its community as a prominent research institution. WSU relied on these negotiated rates when building out its facilities, budgeting for research projects and equipment, deciding on which and how many students to admit and faculty/staff to employ, and determining how to prioritize its own institution-wide funding allocations.

151. Certain WSU departments, such as the Office of the Campus Veterinarian, which supports nearly all projects in WSU's large animal-based research portfolio (and all of its veterinary services), are almost wholly dependent on these indirect costs to stay afloat, as costs associated with much of the housing and care of animals cannot be charged back as direct costs. NIH costs also represent 30% of the research portfolio at WSU's College of Veterinary Medicine, which is home to the Washington Animal Disease Diagnostic Laboratory, the only accredited veterinary medical laboratory within Washington, and a facility that regularly detects, monitors, and conducts responses to current and potential future disease outbreaks such as rabies, tularemia, and including the current avian flu outbreak. Without the indirect costs that largely pay for animal care, WSU's animal researchers would likely be forced to significantly reduce or eliminate research animal colonies. This loss would set WSU researchers back decades, endangering not just the livelihoods of the dozens of employees and staff WSU who would likely have to be laid off or furloughed, but also denying the public at large the benefit of the critical research and real-time data that these facilities give, such as the regular testing of eggs, poultry, and milk for diseases (including avian influenza).

152. As a result of the Rate Change Notice, WSU would also likely be forced to close facilities like the Spokane vivarium and the analytical core services that support WSU's biomedical, drug discovery, and drug delivery programs, including high impact cancer research. WSU would likely have to diminish or shutter the work of its Biosafety laboratory that is crucial for detection and treatment of emerging viruses and pathogens in the Pacific Northwest, like the emerging avian influenza pandemic. WSU's Elson S. Floyd School of Medicine would be decimated, grinding to a halt their lifesaving research into Alzheimer's disease, cancer, speech pathology, and substance abuse, endangering the viability of WSU's clinical trials and the

wellbeing of their patients, and severely hindering the ability of WSU to provide effective education to the next generation of doctors. Critical NIH-funded programs like Sharma Lab's Targeted Nanotherapies for the Treatment of Prostate Cancer, in the College of Arts and Sciences, are in active testing right now for a novel drug treatment for advanced prostate cancer, the second leading cause of cancer-related deaths among men in the U.S. If their work is disrupted, they risk potentially irreplaceable data loss and endangering the ultimate viability of potentially lifesaving treatments.

153. In Wisconsin, UW-Madison is Wisconsin's flagship research university. It operates under the premise that research and education should influence the lives of others beyond the boundaries of the campus. Research at UW-Madison drives innovation related to treating adult and pediatric cancer, Alzheimer's, diabetes, degenerative neurologic diseases, and more. Further, the research enterprise supports training and development of UW-Madison students. This research is supported by $513 million from the HHS, which primarily comes from the NIH.

154. UW-Madison has a NICRA with HHS, covering all federal agencies, and effective as of January 17, 2025. The indirect cost rate in UW-Madison's NICRA is 55.5%. This rate is composed of 26% for administrative costs and 29.5% for facility costs. Administrative costs are the general costs to administer research, such as accounting, payroll, and research oversight and are capped by federal law at 26%. Facility costs include the maintenance and depreciation of the research facilities.

155. NIH's reduction of UW-Madison's negotiated indirect cost rate would eliminate approximately $65 million in funding in the current year, and result in a similar reduction in resources available to support research each year. The loss of these funds will immediately

impact the university's ability to draw critical funds used to pay expenses associated with its research enterprise. This includes the costs to support strict federal regulatory compliance mandated for federally funded research that are intended to, for example, promote national security interests and maintain the nation's competitive edge through export controls and measures to prevent malign foreign influence; protect human and animal participants in research; protect public investments in research; ensure the safe conduct of research involving hazardous biological agents, recombinant DNA, and radiation; and ensure the integrity of research funded by American taxpayers.

156. In sum, across all Plaintiff states, implementing this 15% cap will mean the abrupt loss of hundreds of millions of dollars that are already committed to employing tens of thousands of researchers and other workers, putting a halt to countless life-saving health research and cutting-edge technology initiatives. Not only that, but the sudden cut of funding will have ripple effects into the private sector as it disrupts numerous partnerships with private institutions.

CAUSES OF ACTION

Count I
Substantive Violation of the Administrative Procedure Act
Agency Action That Is Arbitrary and Capricious and an Abuse of Discretion
5 U.S.C. § 706(2)(A)

157. Plaintiff States incorporate by reference the allegations contained in the preceding paragraphs.

158. Defendants include "agenc[ies]" under the APA, 5 U.S.C. § 551(1), and the Rate Change Notice is an agency action subject to review under the APA.

159. The Rate Change Notice marks the consummation of NIH's decisionmaking process because it announces the agency's decision to immediately implement a policy that will

dramatically change the awarding of funds, and disbursement of go forward expenses "for all current grants . . . as well as for all new grants issued."

160. The Rate Change Notice is an action by which rights or obligations have been determined or from which legal consequences will flow because it purports to immediately change indirect rates paid pursuant to pre-existing federal grants that have already been awarded to recipients and incorporated in budgets.

161. The APA requires that a court "hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, [or] an abuse of discretion." 5 U.S.C. § 706(2)(A).

162. The Rate Change Notice is arbitrary and capricious because it does not identify a basis for setting an across-the-board rate of 15%. The Rate Change Notice makes no effort to determine that 15% is the accurate rate at which indirect costs are actually incurred by Plaintiff States in general or any institution of higher education in particular.

163. The Rate Change Notice is arbitrary and capricious because it fails to account for the substantial reliance interests grant recipients have in the terms of grants awarded by the NIH, all of which include specifically negotiated indirect cost rates expressly accepted by the government upon the commencement of each budget period of every grant-funded project. Changing political considerations or priorities are not alone sufficient to justify significant changes in policy. Rather, an agency must weigh reliance interests against policy concerns. There is no indication that the Acting Director meaningfully weighed those reliance interests against the putative policy concerns laid out in the Rate Change Notice.

164. The Rate Change Notice is arbitrary and capricious because it fails to recognize the practical consequences that an immediate, across-the-board, categorical cap on the indirect cost rate will produce, let alone justify why such consequences could possibly be warranted.

165. The Rate Change Notice is arbitrary and capricious because it indicates the reversal of factual findings of grantmaking agencies, memorialized in NICRAs and agreed upon by Plaintiff States, and thus the NIH must provide an even more substantial justification than would usually be required to reverse long-standing policy. Previously established indirect cost rates were not arbitrarily-selected by recipient institutions; rather, they are the result of extensive, data-driven negotiation and engagement between Plaintiff States and teams of cost accounting experts representing the interests of government granting agencies. These rates are intended to reasonably reflect the true and genuine indirect costs incurred by Plaintiff States to deliver their obligations under federal grant awards and finance critical university infrastructure from utilities to building maintenance to disposal of hazardous waste.

166. By lowering the indirect cost rate, the NIH is implicitly asserting that the indirect costs incurred by institutions conducting research are different from the rates it had previously identified through actual examination of the institutions' accounting systems and operating costs.

167. If an agency's new interpretive guidance leads to new factual findings that contradict an agency's previous conclusions, more substantial justification is required by the agency to justify its new position. *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 106 (2015).

168. The Rate Change Notice is arbitrary and capricious because it fails to articulate why immediate implementation should be imposed upon activity conducted in current budget periods under current awards, notwithstanding the immense disruption that will cause.

169. The Rate Change Notice is arbitrary and capricious because it fails to consider alternatives to the agency action that might lesson the impact of the agency action on grant recipients.

170. The Rate Change Notice is arbitrary and capricious because it does not provide an explanation or basis for the timing of its announcement, one business day before the effective date of the rate change.

171. The Rate Change Notice is arbitrary and capricious because it does not explain the reasons why rates used by non-governmental funding organizations pertain to the indirect cost rates used and negotiated by NIH with its grant recipients, and why rates used by such organizations should serve as benchmarks for NIH's indirect cost rates.

172. The Rate Change Notice is arbitrary and capricious because it does not explain why NIH has departed from its past practice of negotiating indirect cost rates with grant recipients and complying with the terms of such negotiated agreements.

173. Pursuant to 5 U.S.C. § 706 and 28 U.S.C. § 2201, Plaintiff States are entitled to a declaration that the Rate Change Notice violates the APA because it is arbitrary and capricious.

174. Plaintiff States are also entitled to vacatur of the Rate Change Notice pursuant to 5 U.S.C. § 706, all appropriate preliminary relief under 5 U.S.C. § 705, and a preliminary and permanent injunction preventing Defendants from enforcing the Rate Change Notice.

175. Plaintiff States are also entitled to vacatur of the Rate Change Notice pursuant to 5 U.S.C. § 706, all appropriate preliminary relief under 5 U.S.C. § 705, and a preliminary and permanent injunction preventing Defendants from enforcing the Rate Change Notice.

Count II
Substantive Violation of the Administrative Procedure Act
Agency Action Not in Accordance with Law (Further Consolidated Appropriations Act)
5 U.S.C. § 706(2)(A)

176. Plaintiff States incorporate by reference the allegations contained in the preceding paragraphs.

177. Defendants include "agenc[ies]" under the APA, 5 U.S.C. § 551(1), and the Rate Change Notice is an agency action subject to review under the APA.

178. The APA requires that a court "hold unlawful and set aside agency action, findings, and conclusions found to be . . . not in accordance with law." 5 U.S.C. § 706(2)(A).

179. Section 224 of the Further Consolidated Appropriations Act, 2024, Public Law 118-47 ("Section 224"), provides: "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."

180. As a result of continuing resolutions, Section 224 remains in effect. Continuing Appropriations and Extensions Act, 2025, Pub. L. No. 118-83, §§ 101, 106; Further Continuing Appropriations Act, 2025, Pub. L. No. 118-158, § 101.

181. By radically slashing payment of indirect costs, the Rate Change Notice violates the statutory requirement that the regulatory "provisions relating to indirect costs … 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." Section 224.

182. The Rate Change Notice violates Section 224's prohibition of a "modified approach" to the "provisions relating to indirect costs."

183. The Rate Change Notice has the effect of "intentionally or substantially expand[ing] the fiscal effect of the approval of" deviations from negotiated rates "beyond the proportional effect of such approvals in such quarter." The "fiscal effect" of the deviation in negotiated rates down to 15% across all projects is vastly greater than the "fiscal effect" of any prior deviations, which were individualized and program-specific.

184. Plaintiff States are also entitled to vacatur of the Rate Change Notice pursuant to 5 U.S.C. § 706, all appropriate preliminary relief under 5 U.S.C. § 705, and a preliminary and permanent injunction preventing Defendants from enforcing the Rate Change Notice.

Count III
Substantive Violation of the Administrative Procedure Act
Agency Action Not in Accordance with Law (45 C.F.R. § 75.414)
5 U.S.C. § 706(2)(A)

185. Plaintiff States incorporate by reference the allegations contained in the preceding paragraphs.

186. Defendants include "agenc[ies]" under the APA, 5 U.S.C. § 551(1), and the Rate Change Notice is agency action subject to review under the APA.

187. The APA requires that a court "hold unlawful and set aside agency action, findings, and conclusions found to be . . . not in accordance with law." 5 U.S.C. § 706(2)(A).

188. 45 C.F.R. § 75.414(c)(1) states: "Negotiated indirect cost rates must be accepted by all Federal agencies. A Federal agency may use a rate different from the negotiated rate for either a class of Federal awards or a single Federal award only when required by Federal statute or regulation, or when approved by the awarding Federal agency in accordance with paragraph (c)(3) of this section." In other words, using a different rate than the negotiated indirect cost rate (absent a statutory or regulatory requirement to do so) requires compliance with 45 C.F.R. § 75.414(c)(3).

189. 45 C.F.R. § 75.414(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."

190. By pronouncing a single, uniform and categorical "policy" setting indirect cost rates at 15% regardless of the otherwise applicable negotiated rate, NIH violated 45 C.F.R. § 75.414(c)(3).

191. Under the plain text of Section 75.414(c)(3), "policies, procedures, *and* general decision making criteria" must all be present for a departure from the negotiated rate to be authorized under Section 75.414(c)(3). Here, NIH published no "procedures" and no "general decision making criteria." Instead, it prescribed a single, uniform "policy" setting indirect cost rates at 15%.

192. The phrase "policies, procedures, and general decision making criteria that … programs will follow to seek and justify deviations from negotiated rates" implies that NIH will announce a policy that it will use to *seek* an altered rate. The NIH's new policy, set out in the challenged Guidance, did not do that—instead, the policy unilaterally *sets* a rate.

193. The phrase "seek and justify deviations from negotiated rates" implies an individualized analysis of whether deviations are appropriate, not a unilateral declaration of a 15% rate that applies across the board. The word "programs" also implies that deviations will occur at a program level, which supports the view that there will be an individualized analysis. The phrase "justify deviations from negotiated rates" further indicates that negotiated rates are the default and the "deviation" is the exception—not that negotiated rates will be abandoned across the board.

194. Section 75.414(c)(4) states: "As required under § 75.203(c), the HHS awarding agency must include in the notice of funding opportunity the policies relating to indirect cost rate reimbursement, matching, or cost share as approved." The Federal Register notice promulgating the provision on which Section 75.414(c) is modeled makes clear that any attempt to depart from negotiated rates must first be "established" and then "inclu[ded] … in the announcement of funding opportunity."

195. Defendants did not comply with the requirements of 45 C.F.R. § 75.414(c)(4). Defendants' notice of funding opportunities did not include HHS's new policy, and HHS cannot retroactively alter existing grant agreements.

196. Plaintiff States are also entitled to vacatur of the Rate Change Notice pursuant to 5 U.S.C. § 706, all appropriate preliminary relief under 5 U.S.C. § 705, and a preliminary and permanent injunction preventing Defendants from enforcing the Rate Change Notice.

Count IV
Substantive Violation of the Administrative Procedure Act
Agency Action in Excess of Statutory Authority and Ultra Vires
5 U.S.C. § 706(2)(C)

197. Plaintiff States incorporate by reference the allegations contained in the preceding paragraphs.

198. Defendants also include "agenc[ies]" under the Administrative Procedure Act, 5 U.S.C. § 551(1), and the Rate Change Notice is agency action subject to the APA.

199. Under the APA, a court must "hold unlawful and set aside agency action, findings, and conclusions found to be . . . in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(C).

200. Defendants may only exercise authority conferred by statute.

201. In addition, "APA, as a general matter, forbids retroactive rulemaking." *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988).

202. The Rate Change Notice represents a retroactive action, because 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 (1994).

203. "Retroactivity is not favored in the law." *Bowen*, 488 U.S. at 208. Agencies cannot "promulgate retroactive rules unless that power is conveyed by Congress in express terms." *Id.*

204. No statute allows NIH to unilaterally alter all current grants retroactively.

205. No such power was conveyed by Congress here. Indeed, Congress has explicitly limited the NIH's authority to modify indirect cost rates retroactively. Further Consolidated Appropriations Act, 2024, Pub. L. No. 118-47, § 224, 138 Stat 460.

206. NIH does not rely on any statutory authority for such an exercise of authority.

207. NIH's action was therefore in excess of its statutory authority and unlawful.

208. Pursuant to 5 U.S.C. § 706 and 28 U.S.C. § 2201, Plaintiff States are entitled to a declaration that the Defendants lack legal authority to 15% limit on indirect costs contrary to the negotiated rates and has, in so doing, acted contrary to law and in violation of the APA.

209. Plaintiff States are also entitled to vacatur of the Rate Change Notice pursuant to 5 U.S.C. § 706, all appropriate preliminary relief under 5 U.S.C. § 705, and a preliminary and permanent injunction preventing Defendants from enforcing the Rate Change Notice.

Count V
Procedural Violation of the Administrative Procedure Act
Without Observance of Procedure Required by Law
5 U.S.C. § 706(2)(D)

210. Plaintiff States hereby incorporate by reference the foregoing paragraphs of this Complaint.

211. Under the APA, a court "shall . . . hold unlawful and set aside agency action, findings and conclusions found to be . . . without observance of procedure required by law." 5 U.S.C. § 706(2)(D).

212. Subject to enumerated exceptions not applicable here, federal agencies must complete the process of agency rulemaking before issuing a rule. 5 U.S.C. § 553(b).

213. The Rate Change Notice is a rule for purposes of the APA because it is an "agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy." 5 U.S.C. § 551(4).

214. "The APA generally requires that before a federal agency adopts a rule it must first publish the proposed rule in the Federal Register and provide interested parties with an opportunity to submit comments and information concerning the proposal. 5 U.S.C. § 553. Failure to abide by these requirements renders a rule procedurally invalid." *New Hampshire Hosp. Ass'n v. Azar*, 887 F.3d 62, 70 (1st Cir. 2018). Notice, and comment requirements, do not

apply, however, to interpretive rules intended mere "merely to 'advise the public of the agency's construction of the statutes and rules which it administers.'" *Id.*

215. On the other hand, a legislative, or substantive, rule that "creates rights, assigns duties, or imposes obligations, the basic tenor of which is not already outlined in the law itself" must go through notice-and-comment procedures. *Id.*

216. Defendants' issuance of the Rate Change Notice without notice and comment rulemaking, and without good cause to proceed without notice and comment rulemaking, is in violation of the APA.

217. The Rate Change Notice imposes "a standard indirect cost rate on all grants of 15% pursuant to its 45 C.F.R. § 75.414(c) authority," and thus plainly imposes a new obligation on recipient organizations that did not previously exist. As a result, it constitutes a substantive rule and can only be promulgated through notice-and-comment procedures.

218. The Rate Change Notice relies on 45 C.F.R. § 75.414(c)(1) and 45 C.F.R. § 75.414(c)(3) to justify a wholesale change in indirect cost rate determination policies, including to existing grants, that have previously been conducted through notice and comment rulemaking and imposed on a prospective basis only. *See, e.g.*, 56 Fed. Reg. 29530 (June 17, 1991) (proposing a revision to rules to impose a cap of 26 percent of modified total direct costs as reimbursement for administrative costs); 56 Fed. Reg. 50224 (Oct. 3, 1991) (finalizing the proposed revision and summarizing almost 300 comments).

219. HHS has voluntarily agreed to abide by the APA's notice and comment requirements for provisions governing grants and contracts because it "believes that its decision-making ought to be as transparent as appropriate to better enable the citizenry to comment on its proposed rules and demonstration projects," 45 C.F.R. Subpart A, furthering the objective of the

"Richardson Waiver," *see id.*, 36 Fed. Reg. 2,532 (Feb. 5, 1971) (requiring all agencies and offices within HHS to abide by the APA's public participation requirements in the formulation of rules related to grants).

220. Because the Rate Change Notice did not follow notice-and-comment procedures, as required by the APA, it is procedurally invalid.

221. Plaintiff States are also entitled to vacatur of the Rate Change Notice pursuant to 5 U.S.C. § 706, all appropriate preliminary relief under 5 U.S.C. § 705, and a preliminary and permanent injunction preventing Defendants from enforcing the Rate Change Notice.

PRAYER FOR RELIEF

WHEREFORE, the Plaintiff States pray that the Court:

a. Declare unlawful and set aside the Rate Change Notice (NOT-OD-25-068) as arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law under 5 U.S.C. § 706(2)(A), contrary to constitutional right, power, privilege, or immunity under 5 U.S.C. § 706(2)(B), in excess of statutory jurisdiction, authority, or limitations, or short of statutory right under 5 U.S.C. § 706(2)(C), and without observance of procedure required by law under 5 U.S.C. § 706(2)(D);

b. Issue a temporary restraining order and preliminary injunction barring the NIH, HHS and all of their officers, employees, and agents from taking any steps to implement, apply, or enforce the Rate Change Notice (NOT-OD-25-068) within Plaintiff States;

c. Order Defendants to file a status report with the Court within 24 hours of entry of a temporary restraining order, and at regular intervals thereafter, confirming the regular disbursement and obligation of federal financial assistance funds and reporting all steps that NIH, HHS and their officers, employees, and agents have taken to comply with the Court's temporary restraining order;

d. Issue a preliminary injunction barring the NIH, HHS and all of its officers, employees, and agents from taking any steps to implement, apply, or enforce the Rate Change Notice (NOT-OD-25-068) in any form or under any name within Plaintiff States;

e. Issue a permanent injunction barring the NIH, HHS and all of its officers, employees, and agents from taking any steps to implement, apply, or enforce the the Rate Change Notice (NOT-OD-25-068) in any form or under any name within Plaintiff States; and

f. Award such additional relief as the interests of justice may require.

Dated: February 10, 2025

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