UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

ASSOCIATION OF AMERICAN UNIVERSITIES, *et al.*,

Plaintiffs,

v.

Case No.

DEPARTMENT OF HEALTH & HUMAN SERVICES, *et al.*,

Defendants.

DECLARATION OF JOHN H. SHAW

I, John H. Shaw, declare as follows:

1. I am the Vice Provost for Research at Harvard University ("Harvard" or the "University") in Cambridge, Massachusetts. I have held that position since January 1, 2022. I am also the Harry C. Dudley Professor in the Faculty of Arts & Sciences, and a Professor of Environmental Science and Engineering in the John A. Paulson School of Engineering & Applied Sciences. I make this declaration in support of Plaintiffs' Complaint and Motion for a Temporary Restraining Order.

2. As Vice Provost for Research, I have personal knowledge of the contents of this declaration, or have knowledge of the matters based on my review of information and records gathered by Harvard University personnel, and could testify thereto.

3. Harvard is a major research institution that receives substantial annual funding from the National Institutes of Health ("NIH"). In fiscal year 2024, for example, Harvard received a total of \$684 million in sponsored funding from the federal government, \$488 million of which came from NIH. By the end of the fiscal year—which ended on June 30, 2024—Harvard had

1

approximately 1,570 active NIH grants across the University, many of which were multi-year awards.

4. The funding Harvard receives from NIH supports critical and cutting-edge medical research, which millions of Americans benefit from and depend on. For example:

- a. Harvard's cancer research includes identifying mechanisms that drive tumor metastasis and therapeutic development, with the goal of targeting and suppressing cancer at its earliest stages; mapping the metabolic signaling pathways that drive both diabetes and cancer, to restore proper cellular function and prevent disease; and developing a new machine learning method to model the behavior of all 25,000 human genes as they respond to high-intensity treatments such as chemotherapy, which the National Cancer Institute cited as an advancement in basic cancer research that will lay the groundwork for future clinical breakthroughs.¹
- b. Harvard's infectious disease research includes understanding and addressing the global threat of multidrug-resistant infections; developing new tools for global pandemic prevention; and developing new therapeutic antibodies to treat or cure viral diseases.
- c. Harvard's microbiome research includes developing new frontiers in precision medicine that can help individuals reduce their risk of cancer and other diseases.
- d. Harvard's toxin reduction research includes studying the harm from microplastics on sperm counts and fertility; and developing life-saving

¹ "Advances in Cancer Biology Research," https://www.cancer.gov/aboutnci/organization/dcb/progress/cancer-biology-advances (last accessed Feb. 10, 2025).

guidance for vulnerable groups exposed to high levels of toxins, including firefighters and children in rural communities.

e. Harvard's neurological research includes identifying numerous modifiable risk factors for Parkinson's disease and multiple sclerosis, which creates the potential to significantly cut disease incidence and reduce healthcare costs; and efforts to better understand the role of infections in seeding neurodegenerative disorders, with important implications for prevention, diagnosis, and treatment.

5. Indirect costs, also called Facilities and Administrative ("F&A") costs, are real and essential reimbursement of costs incurred by the institution for supporting the entire research enterprise. The NIH's proposal to cut indirect cost rates to 15% would seriously jeopardize all of the research projects described in paragraph 4; examples selected from a very large number of additional research projects that likewise seek to further fundamental understanding of disease, biology, human genetics, and other areas of unmet clinical need, all of which are supported by indirect costs.

6. Indirect costs include constructing and maintaining state-of-the-art facilities required to meet the current technical requirements of advanced research, as well as the procurement and maintenance of equipment necessary to conduct such research. Without this equipment, we cannot conduct the research. For example, with respect to the areas of research described in paragraph 4:

a. Cancer research requires sophisticated equipment, data storage, and computing power to interrogate and synthesize genomics, proteomics, and metabolomics, and to leverage bioinformatics for data analysis.

- b. Infectious disease research requires multiple specialized facilities, including advanced centers for bioimaging and genomic studies, a biosecurity Level 3 pathogen core facility, a gnotobiotic mouse facility, and a biosecurity Level 2 insectary. This equipment is essential for basic and preclinical research that leads directly to new insights into diagnosis, treatment, and prevention of infectious diseases such as tuberculosis, HIV, and malaria.
- c. Microbiome research requires a -80 degree Celsius cryogenic freezer and other specialized equipment to interrogate how changes in the gut microbiome affect susceptibility or resistance to debilitating diseases including cancer, gastrointestinal disorders, and kidney diseases.
- d. Toxin reduction research relies on sophisticated equipment such as mass spectrometry, specialized assays, and significant lab bench space to identify and develop strategies to address a wide array of toxins that cause or exacerbate diseases.
- e. Neurological research requires significant investments in international and longitudinal data collection, storage, and analysis.

7. Physical space costs are one of the largest components of indirect costs, and the amount of space available to researchers has a direct and obvious impact on the amount of research that can be done at the University.

8. In addition, indirect costs fund the expenses associated with the administration of awards, including staff who ensure compliance with a vast number of regulatory mandates from agencies such as NIH.² These mandates serve many important functions, including protecting

² "NIH Grants Policy Statement," HHS (Apr. 2024),

https://grants.nih.gov/grants/policy/nihgps.pdf_

Case 1:25-cv-10346 Document 2-14 Filed 02/10/25 Page 6 of 11

human and animal subjects involved in research; ensuring research integrity; properly managing and disposing of chemical and biological agents used in research; preventing financial conflicts of interest; managing funds; preventing intellectual property, technologies, or national security expertise from being inappropriately accessed by foreign adversaries; and providing the high level of cybersecurity, data storage, and computing environments mandated for regulated data.

9. Recovery of Harvard's indirect costs is based on rates approved by the "cognizant federal agency," which for Harvard is the Department of Health and Human Services ("HHS"). Harvard periodically submits an indirect rate proposal to HHS. The proposal then undergoes a review before a rate agreement is approved. Those rates are always established consistent with guidelines set forth by the Office of Management and Budget through its uniform regulation at 2 C.F.R. part 200.

10. The established indirect cost rate (applicable to most grants) is 69% for the University Area through fiscal year 2025, with a reduction to 68.5% for fiscal years 2026-2028; and 69.5% for the Medical School, including the School of Dental Medicine, through fiscal year 2025, with a reduction to 69% for fiscal years 2026-2028. The T.H. Chan School of Public Health is currently working under a provisional-until-amended rate of 54.7% and is in the midst of finalizing that rate through fiscal year 2028.

11. A sudden and unexpected reduction in the indirect cost rate would be disastrous. In fiscal year 2024, Harvard received \$354 million of direct NIH funding and \$135 million of F&A recovery on NIH awards. A reduction in the rate to 15% would have reduced the indirect funding by \$103 million on a full-year basis, to \$31 million. In fiscal year 2025, Harvard expects to receive \$367 million of direct NIH funding and \$140 million of F&A recovery on NIH awards is allocated for indirect costs. A reduction in the rate to 15% would reduce the indirect funding by \$107 million

5

Case 1:25-cv-10346 Document 2-14 Filed 02/10/25 Page 7 of 11

on a full-year basis, more than double the University's operating surplus last year. And over the next five years, Harvard anticipates receiving an average of \$402 million a year from the NIH for annual direct costs. Based on the established indirect cost rates described in paragraph 10, the University thus expects to receive approximately \$154 million in indirect cost recovery on an annual basis.

12. If the indirect cost rate is cut to 15 percent, that would reduce the University's anticipated annual average indirect cost recovery by \$118 million annually, to \$36 million a year, for a five-year total of \$590 million in cuts to funding that is essential to support the University's research activities.

13. This reduction will have deeply damaging effects on the University's research enterprise from day one. Most critically, it will necessarily and immediately result in staffing reductions across the board, which will immediately slow down research projects, present potential health and safety risks, and even jeopardize national security interests. For example:

- a. Harvard's Institutional Review Board ("IRB") is charged with reviewing and managing all research involving human subjects, to ensure the ethical treatment of subjects and the protection of their privacy. Without appropriate funding for indirect costs, the University would have to reduce staffing on the IRB, which would immediately impact its ability to review research projects. That would in turn lead to substantial delays in critical research that relies on human subjects, including projects funded by NIH.
- b. Harvard's Environmental Health and Safety Office is charged with the oversight and management of hazardous chemicals and biological agents in laboratories. Reduction in staffing would be inevitable in the short term if

6

there were a significant reduction in indirect cost recovery, and the impact would grow in the longer term if the situation persists. Such reductions would lead to reduced frequency of inspections, and would jeopardize the proper disposal of hazardous materials from research laboratories. Both of these effects would pose potential hazards not just to laboratory staff, but also to the general population in the vicinity of the laboratories.

c. Over the past five years, research security and the protection of intellectual property ("IP") from foreign adversaries has been a major focus for the federal government, and all universities are required to implement programs protecting IP from foreign influence. These programs are funded *exclusively* by indirect cost recovery. NIH's reduction in indirect costs would immediately and directly impact the University's ability to manage these mandated programs in the interest of national security.

14. The University has for decades relied on the payment of indirect costs. And until now, we have been able to rely on the well-established process with the government to inform our budgeting and planning. Operating budgets rely on an estimate of both direct and indirect sponsored funding to plan for annual staffing needs (*e.g.*, post-docs, PhD students, and other research staff), infrastructure support (*e.g.*, IT networks, regulatory compliance, and grant management support), and facility and equipment purchases. And in some cases, the University has long-term obligations—for example, with respect to tenured faculty salaries or admitted PhD students—and it relies on budgeted grant funding, including associated indirect cost recovery, to fulfill these commitments.

Case 1:25-cv-10346 Document 2-14 Filed 02/10/25 Page 9 of 11

15. In addition to the immediate impacts and reliance interests described above, there are longer term impacts that are both cumulative and cascading. Research is an "additive process," meaning that each discovery is the foundation upon which new information is added, gradually leading to major scientific discoveries. This process requires long-term commitment to conducting uninterrupted scientific work. It also requires continuously investing in upgrading facilities and instrumentation to meet the needs of rapidly changing science and technology.

16. Such has been the foundation of our partnership with the federal government for the past 75 years: We have provided the infrastructure for critical research—thereby taking the upfront risk—and the federal government has provided funding, including reimbursement for the expenses associated with facilities, equipment, and the growing IT and administrative demands needed to support this research enterprise.

17. Slowing down or halting this research—even temporarily—due to inadequate support personnel, facilities, or equipment will have long-lasting effects. Research that has been paused often has to be repeated, as its result may no longer be reliable due to changed conditions—for example, cell cultures that have been unattended to, which generally see impact within days if not attended to in a timely manner, or chemicals that have expired. Advances in technology or other findings might also render paused work obsolete. These impacts, far from being hypothetical, were realized and documented during the short-term pauses necessitated by the COVID-19 pandemic.³

18. Disruptions to Harvard's research will also have negative effects in the Cambridge and Boston area, the state of Massachusetts, and the broader region. Harvard is one of the state's

³ Mike Lauer, "Continued Impact of COVID-19 on Biomedical Research," NIH (Nov. 4, 2020), https://nexus.od.nih.gov/all/2020/11/04/continued-impact-of-covid-19-on-biomedical-research; "Examples of COVID-19 Impacts on the Research Enterprise," AAMC (Apr. 2021), https://www.aamc.org/media/54391/download.

largest employers—in 2023, over 18,700 Massachusetts residents were directly employed by Harvard—and it collaborates with state and local partners to help solve regional challenges through joint research and innovation. The University's research also fuels spending in the regional economy, including by driving discoveries that launch new ventures, attract private investment, and make a positive social impact. A massive reduction in Harvard's research budget would immediately and seriously jeopardize these contributions to the local region.

19. Finally, slowdowns or halts in research by Harvard and other American universities will allow competitor nations that are maintaining their investments in research to surpass the United States on this front, threatening both our Nation's national security and its economic dominance.

20. Nor can the University cover the funding gap itself. While the University maintains a significant endowment, it is neither feasible nor sustainable for Harvard to use endowment funds or other revenue sources to offset shortfalls in indirect cost recovery, for several reasons including:

- a. The majority of the University's endowment—around 70 percent—is restricted to specific donor-designated purposes, such as scholarships, faculty chairs, and academic programs. Harvard is not legally permitted to use those funds to cover research infrastructure costs.
- b. As a non-profit institution, Harvard reinvests nearly all of its revenue into mission-critical activities, leaving little margin to absorb unexpected funding gaps. In other words, unlike for-profit organizations, the University does not generate significant surpluses that could be redirected without impacting core academic priorities such as educational programs and financial aid support for students.

c. After sponsored research support and endowment revenue, Harvard's next largest source of revenue is student tuition. But the University is focused on affordability for its students and cannot simply increase tuition rates to cover losses in indirect cost recovery.

19. Moreover, absorbing the cost of a lower indirect cost rate, even if it were possible, would create long-term budget pressures on the University—which would in turn force reductions in key investments supporting Harvard's faculty, students, staff, research, and teaching infrastructure, as well as other critical activities needed to maintain Harvard's academic excellence.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on February 10, 2025, at Cambridge, Massachusetts.

CATHS

John H. Shaw Vice Provost for Research Harry C. Dudley Professor of Structural & Economic Geology, FAS Professor of Environmental Science and Engineering, SEAS