IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

ASSOCIATION OF AMERICAN MEDICAL COLLEGES; THE AMERICAN ASSOCIATION OF COLLEGES OF PHARMACY; THE ASSOCIATION OF SCHOOLS AND PROGRAMS OF PUBLIC HEALTH; THE CONFERENCE OF BOSTON TEACHING HOSPITALS, INC.; and GREATER NEW YORK HOSPITAL ASSOCIATION, 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 ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the U.S. Department of Health and Human Services, Defendants.	Case No. 1:25-CV-10340-AK

DECLARATIONS IN SUPPORT OF
PLAINTIFFS' MOTION FOR INJUNCTIVE RELIEF

Plaintiffs in the above-captioned case hereby submit the following declarations in support of their motion for injunctive relief:

1. Dr. Valerie Montgomery Rice, President and Chief Executive Officer, Morehouse School of Medicine (Exhibit A);

2. Dr. Jeannette South-Paul, Executive Vice President and Provost, Meharry Medical College (Exhibit B);

3. Dr. Gyongyi Szabo, Chief Academic Officer, Beth Israel Deaconess Medical Center and Beth Israel Lahey Health (Exhibit C);

4. Gilbert Hai Tran, Senior Specialist Leader, Attain Partners (Exhibit D);

5. Dr. Anupam Agarwal, Senior Vice President for Medicine and Dean of Heersink School of Medicine, University of Alabama at Birmingham (Exhibit E);

6. Dr. L. Lee Hamm, Senior Vice President and Dean, Tulane University School of Medicine (Exhibit F);

7. Rob Rutenbar, Senior Vice Chancellor for Research, University of Pittsburgh (Exhibit G);

8. Dr. C. Ronald Kahn, Chief Academic Officer, Joslin Diabetes Center (Exhibit H);

9. Dr. Tina L. Cheng, Chief Medical Officer, Cincinnati Children's Hospital Medical Center (Exhibit I);

10. Dr. Clifford Hudis, Chief Executive Officer, American Society of Clinical Oncology (Exhibit J);

11. Calaneet Balas, Chief Executive Officer and President, The ALS Association (Exhibit K); and

12. Patricia A. Gentile, Interim Executive Director, LAM Foundation (Exhibit L).

Dated: February 18, 2025

Respectfully submitted,

ROPES & GRAY LLP

/s/ John P. Bueker

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EXHIBIT A

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

ASSOCIATION OF AMERICAN MEDICAL COLLEGES, *et al.*, Plaintiffs, v. NATIONAL INSTITUTES OF HEALTH, *et al.*, Defendants.	C.A. No. 1:25-CV-10340-AK

DECLARATION OF VALERIE MONTGOMERY RICE, MD, FACOG

I, Valerie Montgomery Rice, MD, FACOG, declare as follows:

1. I am the President and CEO of The Morehouse School of Medicine ("MSM"). I have held this position since September 2014. I make this declaration as a representative of MSM based on my personal knowledge and experience. MSM is a member of the Association of American Medical Colleges. As MSM's President and CEO, I oversee and am ultimately responsible for our education, research, patient care, and community programs. In my official capacity and based on my personal knowledge and other sources of information that I have obtained and reviewed in my

official capacity, I am familiar with, and if called upon to do so, would be competent to testify to, the facts and circumstances set forth herein.

2. The MSM emerged from humble beginnings in 1975 when Morehouse College, under the leadership of President Hugh M. Gloster and Dr. Louis Sullivan, the founding Dean and President of MSM, embarked on an ambitious mission to address the critical shortage of Black physicians and healthcare disparities in underserved communities. What began as a two-year medical education program with just 24 students in a single trailer has evolved into one of the nation's leading medical institutions. In 1981, MSM became an independent institution and established its four-year medical program, marking a pivotal moment in its commitment to diversifying the healthcare workforce and advancing health equity.

3. The impact of MSM's mission has been profound and far-reaching. To date, the institution has graduated 3,283 healthcare professionals, including 1,867 physicians, with approximately 60 percent of its MD graduates practicing in Georgia. This significant presence of MSM-trained physicians throughout the state exemplifies the institution's success in addressing healthcare disparities in underserved rural and urban communities. MSM consistently leads all U.S. medical schools in the percentage of graduates practicing primary care—between 65 and 70 percent annually—demonstrating its unwavering commitment to its founding mission of serving those most in need.

4. As one of only four longstanding historically Black medical schools in the country, MSM plays a crucial role in addressing the persistent underrepresentation of Black physicians in the healthcare workforce. We are driven by our mission and ultimately defined by our ability to create and advance health equity. This focus on health equity requires us to think differently about the role

of medical education. It requires us to think differently about how we train students and residents, pursue scientific discovery, treat patients, and engage with the many communities we serve.

5. Since I became President and CEO a decade ago (the first and only woman to hold that position), MSM has dramatically expanded its physical footprint, academic programs, research initiatives and physician class size. MSM is home to world-renowned research centers and institutes, including The Cardiovascular Research Institute; The David Satcher Global Health Equity Institute; The National Center for Primary Care; The Neuroscience Institute; Clinical Research Center; Prevention Research Center; Research Centers in Minority Institutions (RCMI); Institute of Translational Genomic Medicine; Center for Maternal Health Equity; Cancer Health Equity Institute and The Satcher Health Leadership Institute. From the genetic epidemiology of cardiovascular disease in ethnic populations to the physiology of sleep disorders, MSM leads rigorous basic science, clinical, community health, and policy research to improve the health and well-being of people everywhere.

6. Despite lacking a significant endowment in contrast to most other medical schools and because of its focus on community-based and health-services research, MSM continues to excel in its mission of training culturally competent healthcare providers, public health professionals, and the next generation of diverse scientists; conducting innovative research; and delivering patient-centered care. MSM stands as a testament to the power of vision, perseverance, and commitment to health equity in medical education and patient care.

7. As one of only a few historically Black graduate institutions, MSM has had, for its entire 50 years of existence, a critical, continuous, and uninterrupted partnership with the federal government and several granting agencies in fulfilling its mission of training the next generation of diverse medical and scientific professionals. We depend on government funding to help supply our

faculty, staff, and students with state-of-the-art labs and equipment, multidisciplinary research and collaborative opportunities, and bold and intentional integration between basic science research and clinical practice needed to further cultivate their research portfolios. This fruitful collaboration has generated scientific discoveries and work force development that have greatly impacted not only the State of Georgia but the entire nation and the globe. These impacts have historically been made with only a fraction of the resources that have been allotted to or acquired by majority serving institutions over their many decades of existence.

8. MSM's research stature and reputation have grown exponentially over the last decade, fueled in large part by significant investment in our research infrastructure. That infrastructure is at the heart of the Facilities and Administration ("F&A") costs of performing government-funded research. Our research portfolio in cancer, cardiovascular disease, neuroscience, and HIV/AIDS, among other health challenges impacting underserved communities, is especially well-established as a result of support from leading research funders like the National Institutes of Health ("NIH"). For example, our Institute of Translational Genomic Medicine recently secured one of only four Cancer Grand Challenge awards funded in part by NIH/NCI and Cancer Research UK to work toward overcoming the stark racial, environmental, and geographic disparities in cancer care and outcomes; our Circadian Rhythms and Sleep Group was the first to demonstrate that peripheral tissues, and not just the brain, may contribute to sleep regulation, and it developed a novel *in vivo* imaging technique to observe neuronal responses for the circadian rhythm in the hypothalamus; our Clinical Translation Impact of Sequencing Research conducted the first study to show seizure type can be identified using blood RNA expression profiling and is developing an RNA-signature blood test of Alzheimer's disease; and we have recently established an NIH-funded Center for Maternal Health Equity to address the significant maternal morbidity and mortality rates

experienced by expectant mothers in the United States. Lastly, during the COVID pandemic, MSM demonstrated its ability to recruit and enroll one of the largest cohorts of diverse subjects in the COVID-19 vaccine trials. MSM, as an NIH-funded Clinical Research Center, is highly dependent on F&A funding from NIH and would, if that funding were cut, be handicapped in delivering these life-saving services in the future.

9. The new NIH guidance that has been recently temporarily restrained in U.S. District Court in Boston not only deeply threatens essential federal funding but cuts at the core of our institutional progress with the great potential to sever a critical lifeline that will deeply and irrevocably harm MSM's ability to continue our mission.

10. MSM receives grant funding from NIH for both direct and F&A costs. Over the last 12 months, MSM has received $47 million in research funding from NIH that is at risk as a result of the proposed rate cut, with approximately $13 million allocated to F&A costs. If NIH capped the F&A costs at 15 percent, MSM would experience a funding reduction of $3.6 million before the end of its fiscal year on June 30, 2025. Our annual budget was prepared in reliance on these funds. For an institution of our relatively small size, such a reduction would pose a significant threat to our mission.

11. If these funding cuts are not prevented, they will have a significant effect on MSM's workforce. MSM will quickly need to impose a hiring freeze, to consider rescinding existing offers to new faculty, and to leave other existing vacancies unfilled. MSM will also likely need to impose a 2 percent across-the-board salary cut at the institution. Most significantly, if the funding cuts are allowed to go into effect, MSM will be forced to lay off approximately 66 employees (about 4.4 percent of our employee base). This staffing cut will include not only research, but also clinical staff.

Critically, the vast majority of our researchers also teach our medical students. Cuts in our research funding will negatively impact our ability to train medical students and educate PhD candidates.

12. To provide perspective, in Georgia, there are 149 counties designated as medically underserved. Over the last ten years, MSM has diminished the gap in care by increasing the number of students who apply and matriculate from these counties and, more importantly, the number of graduates who return to practice in those underserved communities. Ten years ago, MSM received applications from only 34 percent of Georgia's counties; today, MSM receives applications from 94 percent of counties in Georgia. MSM now has alumni practicing in 57 Georgia counties—the vast majority of which are designated as medically underserved. MSM is also establishing regional campuses in both Columbus and Albany, Georgia, to expand its outreach to the state's medically underserved populations through research and patient care.

13. If these funding cuts are not prevented, MSM will also quickly lose resources to support and maintain essential laboratories, including our basic life science facilities. And MSM will lose resources for critical services supporting our Center for Laboratory and Animal Research and our Clinical Research Center.

14. These funding cuts will significantly and negatively impact MSM's research agenda—research efforts that not only lead to key scientific discoveries, but that also train the next generation of Black scientists and culturally-aware doctors and that foster exploration and medicine with the goal of reducing and hopefully ultimately eliminating health disparities in this country.

[Signature on next page]

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed this 12th day of February 2025 in Atlanta, Georgia

/s/ Valerie M. J. Rice

Valerie Montgomery Rice, MD, FACOG
President and CEO
Morehouse School of Medicine

EXHIBIT B

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

ASSOCIATION OF AMERICAN MEDICAL COLLEGES; THE AMERICAN ASSOCIATION OF COLLEGES OF PHARMACY; THE ASSOCIATION OF SCHOOLS AND PROGRAMS OF PUBLIC HEALTH; THE CONFERENCE OF BOSTON TEACHING HOSPITALS, INC.; and GREATER NEW YORK HOSPITAL ASSOCIATION, 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.	C.A. No. 1:25-CV-10340-AK

DECLARATION OF JEANNETTE SOUTH-PAUL, M.D., DHL (HON), FAAFP

I, Dr. Jeannette South-Paul, declare as follows:

1. I am the Executive Vice President and Provost of the Meharry Medical College ("Meharry"). I have held this position since December 2021. I make this declaration as a representative of Meharry based on my personal knowledge and experience. Meharry is a member of the Association of American Medical Colleges ("AAMC"), and I previously chaired the Advisory Committee for the AAMC Minority Faculty Leadership Seminar. As Meharry's Executive Vice President and Provost and a member of our Executive Leadership Council, I have an oversight role over and visibility into our education, research, patient care, and community outreach functions. In

my official capacity and based on my personal knowledge and other sources of information that I have obtained and reviewed in my official capacity, I am familiar with, and if called upon to do so, would be competent to testify to, the facts and circumstances set forth herein.

Overview

2. Founded in 1876, Meharry Medical College is a historically Black institution located in Nashville, Tennessee, that is driven by the mission to serve disadvantaged communities—rural and urban—worldwide by educating and training highly qualified physicians, researchers, scientists, and dentists who are compassionate, caring, and creative. Today, Meharry includes a medical school, a dental school, a graduate school of research, an applied computational sciences school, and it is home to the Center for Health Policy at Meharry Medical College. Meharry is recognized as a top producer of primary care physicians, and it graduates 41 percent of all Black dentists in the country. Meharry is also a leading producer of African-American Ph.D. degrees in biomedical science. *Diverse Issues in Higher Education* annually lists Meharry as a leading national educator of African Americans with M.D. and D.D.S. degrees and Ph.D. degrees in the biomedical sciences.

3. Meharry has more than $23 million in active Fiscal Year 2025 funding from the National Institutes of Health ("NIH"). This funding fuels vital research in areas including kidney disease, sepsis, cancer, influenza, and COVID-19, undergirding Meharry's advancement of science to benefit all people.

4. Meharry is facing more than $2 million in losses should the proposed 15 percent Facilities and Administrative ("F&A") cost cap on NIH grants be implemented. In absolute numbers, the loss is small, compared to larger well-resourced institutions, but is significantly more impactful given the limited resources available to underwrite the critical costs of research that the current funding supports. A 15 percent F&A cost cap would be catastrophic for Meharry.

5. As a smaller, private research institution, Meharry does not benefit from the same level of endowment funding as larger institutions. The Medical College's student body comprises 1,226 students across our schools. To educate these students Meharry spends an average of more than $194,000 per student. Because of the chasm in funding, the cap will not only harm the research enterprise, compromising critical research into diseases that impact millions of Americans, but also threaten the stability of the Medical College, its faculty, staff, and students by diverting dollars from these other areas to gap-fill for unfunded F&A costs. The imposition of a cap would require a realignment of budget priorities, as Meharry does not have the wealth of resources to draw from to replace lost funding. Immediate consequences will include job cuts, and the closure of important research programs. Once a program is shuttered and personnel are released, it is challenging to re-establish and re-engage, setting back progress for decades to come.

6. Beyond Meharry's walls, adjustments to operations that would result from the proposed caps will have far-reaching implications as Meharry will be forced to shrink expenses and eliminate efforts that currently support scientific advancement, economic growth and development, and public health.

The Importance of Understanding F&A Costs

7. Like many other institutions, Meharry relies heavily on grant funding to support its clinical and research operations. Forecasting this funding is vital for strategic planning, budgeting preparation, and accurate resource allocation.

8. F&A rates, which have already been negotiated and approved by federal agencies, represent real costs associated with research and operational activities. This includes costs related to administration, facilities, and utilities. Without F&A rates, it would be impossible to ensure that all aspects of research and operations are adequately funded.

9. By utilizing estimated grant funding and F&A rates, Meharry develops a comprehensive operating budget that reflects both fixed and variable costs. This approach allows the institution to manage resources effectively, ensuring that critical programs and initiatives are sustained despite fluctuations in funding.

10. Meharry's reliance on the financial metrics outlined above enables proactive planning for future fiscal challenges. This information allows the institution to identify potential shortfalls and adjust operations accordingly. It also supports long-term sustainability by ensuring that grant proposals align with our strategic goals and operational needs.

The Impact of the F&A Cost Cap

11. The reduction of F&A costs will have a swift and adverse effect on the College's fiscal well-being, staff, and ongoing research. We can say with certainty that the loss of the already-negotiated and accepted funding will result in layoffs of key personnel within the Office of Research and Innovation and impair our ability to maintain current research programs. Alternatively, the College would be forced to cut personnel or operational expenses in other areas of the College. In effect, in order to subsidize the unfunded part of NIH-related research, we would need to cut other critical programs. As an institution devoted to a mission that is reflected in its motto *Worship of God through Service to Mankind*, programmatic expenses that would unfortunately be targets for these cuts include those that are of most benefit to the underserved communities we care for –including urban and rural areas throughout Tennessee and Kentucky, where the dental and medical providers deliver mobile services to areas lacking easily available healthcare options. Making a choice between the continuation of critical research and public health outreach is not one that we would evaluate lightly, as each choice carries the weight of abandonment to those we exist to serve.

Broader Impact

12. The negative ramifications of the F&A cap extend far beyond our College's campus and well into the communities we serve across the nation and around the world.

Community.

13. Meharry's mission is to serve all who are at risk of receiving substandard care. This ethos extends to the research and community programs the College conducts, particularly, but not limited to, HIV/AIDS, vaccine use and pregnancy-related morbidity and mortality. By diverting funds from other areas of critical need, the 15 percent cost cap will inhibit Meharry from being able to adequately run and provide much needed resources and programs to the Nashville community. Additionally, Meharry prides itself on conducting community-based research that has proven beneficial to the local, national, and international effort to limit the transmission of HIV/AIDS.

14. If the funding caps are implemented, and research is terminated, the community in Nashville, particularly North Nashville, suffers. The redirection of resources to fill the gap will have a noticeable and immediate impact on those who are socioeconomically disadvantaged. Community members across Nashville, the state of Tennessee, and southern Kentucky would experience an increase in negative health outcomes as the College would no longer be financially positioned to provide the free and reduced cost care that it currently does.

National Security.

15. Having a healthcare workforce that is composed of professionals with a variety of skills and a wide breadth of knowledge is essential to ensuring that our country is prepared to encounter any future public health disasters, including pandemics and bioterrorism.

16. The 2020 pandemic is the most recent example of how research contributes to a robust and life-saving public health response. Within 12 months, the science and research community was able to stand up a safe and effective vaccine that was rooted in knowledge gained

from decades of basic research. This scientific feat translated to 8 million fewer confirmed cases of COVID-19, more than 120,000 fewer deaths, and 700,000 fewer hospitalizations during the first six months.

17. Meharry, its leadership team, students, faculty, and staff played a critical role in educating, administering COVID-19 tests and then vaccines to the city of Nashville. In 2020, at the height of the pandemic Meharrians developed the mass public testing protocol, and ran the city's testing, and later vaccination sites. This effort, combined with the leadership of Meharry President and CEO, who delivered daily COVID-19 updates and briefings to the city, prevented panic and restored confidence.

18. Because the 15 percent cap will force Meharry to cut back on its research efforts and divert resources from its community healthcare programs, Meharry's response to a future pandemic will almost certainly be less impactful.

Economic Contributions.

19. Workforce Development: Today Meharry includes five schools: the School of Medicine, the School of Dentistry, the School of Graduate Studies, the School of Applied Computational Sciences, and the School of Global Health. Thousands of physicians, dentists, researchers, data scientists, and public health experts educated by Meharry have gone on to pursue the College's mission to serve the underserved in rural and urban communities around the world.

20. Because the 15 percent cap will force Meharry to reduce its workforce, there will be fewer faculty members to train the next generation of Meharrians, and so our class sizes will have to decrease.

21. Local Economic Impact: The Nashville healthcare industry contributes an overall economic benefit of $68 billion and more than 333,000 jobs to the local economy annually. Meharry proudly contributes to the economy in both seen and unseen ways. Visibly, the College attracts

brilliant students, faculty and staff who relocate to Nashville and use their salaries to participate in the economy. Less visibly, Meharry provides more than $20 million annually in uncompensated care to those who are underinsured or lack insurance. Meharry's role in indigent care is crucial, it eases the financial burden on other healthcare systems in Nashville by providing care to community members who might otherwise seek treatment in emergency departments.

22. Because the 15 percent cap will force Meharry to downsize, Meharry will necessarily attract fewer students and staff (and their associated economic benefits) to the Nashville area. And, because Meharry will be forced to transfer resources away from patient care to make up for the loss in research F&A funds, other emergency departments will see their costs of providing indigent care increase.

Social Stability.

23. The College's reach goes beyond its small physical footprint in North Nashville and extends well into Middle Tennessee and southern Kentucky. Meharry serves as a beacon of hope and care for the community the College engages with and provides access to total healthcare, including oral, behavioral health services and free education. And because so many Meharry alumni provide care in underserved urban and rural areas, the fewer doctors Meharry trains and graduates, the more underserved those areas will become.

24. The 15 percent F&A rate cap will force Meharry to reduce class sizes, leading to fewer Meharry graduates providing critical patient care in underserved areas.

Dangers of Replacing NIH Funding with Endowment Funds

25. Meharry's endowment, while growing, remains much lower than peer institutions. It would be a fallacy to believe that the College could simply rely on its endowment to fill the $2 million gap caused by a NIH funding cap. Relying on endowment funds to replace operational funds would jeopardize the long-term financial stability of the institution.

26. Accessing the College's limited endowment is not a sustainable solution for the following reasons:

27. Endowed funds are restricted in their use. A significant portion of the Meharry endowment is restricted as donors have designated contributions for specific use. These restrictions severely limit the College's ability to reallocate these funds to cover F&A costs of research that appear among general operating expenses. Along with the narrow and defined use for endowed funds there are also regulatory and compliance standards that must be factored into the usage.

28. Endowment value will fluctuate based on the volatility of the market. Due to the fluctuation in the market, the amount of funds free from restriction, and available at a given time, is not consistent. The volatility makes it impractical to use as a reliable source for recurring operational expenses, which typically increase over time.

29. Impact on future fundraising. As a college with a smaller endowment that is heavily dependent on cultivating donor relationships, it is critical that Meharry demonstrate appropriate management and use of endowment funds to maintain donor confidence. A deviation from a spending policy that reflects best practices would signal instability to donors. Despite how critical research is to the mission of Meharry, the use of endowment funds to sustain it has long term consequences that would threaten Meharry's survival.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed this 13th day of February, 2025 in Nashville, Tennessee

Jeannette South-Paul, M.D., DHL (Hon), FAAFP
Executive Vice President and Provost
Meharry Medical College

EXHIBIT C

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

ASSOCIATION OF AMERICAN MEDICAL COLLEGES; THE AMERICAN ASSOCIATION OF COLLEGES OF PHARMACY; THE ASSOCIATION OF SCHOOLS AND PROGRAMS OF PUBLIC HEALTH; THE CONFERENCE OF BOSTON TEACHING HOSPITALS, INC.; and GREATER NEW YORK HOSPITAL ASSOCIATION, 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 ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the U.S. Department of Health and Human Services, Defendants.	C.A. No. 1:25-CV-10340-AK

DECLARATION OF GYONGYI SZABO, M.D., Ph.D

I, Dr. Gyongyi Szabo, declare as follows:

1. I am the Mitchell T. Rabkin, M.D. Chair, Professor of Medicine and Faculty Dean at Harvard Medical School and Chief Academic Officer at both the Beth Israel Deaconess Medical Center ("BIDMC")—a Harvard teaching hospital and a member of both the Association of American Medical Colleges and the Council of Boston Teaching Hospitals—and Beth Israel Lahey Health ("BILH")—the second largest healthcare system in New England. I lead all basic, translational, and clinical research activities, innovation, education and faculty development for BIDMC and BILH. I

was formerly Associate Dean for Translational Sciences and Director of the M.D./Ph.D (Medical Science Training Program) at the University of Massachusetts Medical School. I also served as Vice Chair for Research in the Department of Medicine and as Associate Vice Provost for Interprofessional Education at the University of Massachusetts Medical School. I have published more than 200 peer-reviewed articles and over 100 reviews and book chapters on liver diseases and immunology, among other topics, and I was the inaugural Editor-in-Chief of Hepatology Communications, a peer-reviewed journal that publishes articles on all aspects of liver structure, function, and disease. I am a fellow of the American Association for the Study of Liver Diseases (where I served as President in 2015), the American Gastroenterological Association, and the American College of Physicians. I also serve or have served on advisory boards of several federal agencies including the National Advisory Council for the National Institutes on Alcohol Abuse and Alcoholism (NIAAA) and most recently on the Board of Scientific Advisors of NIAAA, and several leading academic institutions, and pharmaceutical companies. I have received several professional awards and recognitions, including the 2020 Distinguished Scientific Achievement Award from the American Liver Foundation. I received my medical degree from the University Medical School in Debrecen, Hungary, my doctoral degree from the Hungarian Academy of Sciences, and a member of the Hungarian Academy of Sciences.

2. In my official capacity and based on my personal knowledge and other sources of information that I have obtained and reviewed in my official capacity, I am familiar with, and if called upon to do so, would be competent to testify to, the facts and circumstances set forth herein.

3. A world leader in medical research, BIDMC has an over $300 million research portfolio and oversees over 3,000 active clinical and basic research studies. Its staff includes 2,000 principal investigators, technicians, and other research professionals. BIDMC also shares important clinical and research programs with institutions such as the Dana-Farber/Harvard Cancer Center, the

Joslin Diabetes Center, and Children's Hospital. The Harvard-Thorndike Laboratory, the oldest clinical research laboratory in the United States, has been based at BIDMC since 1973.

4. BIDMC consistently ranks as a national leader among independent hospitals in National Institutes of Health ("NIH") funding. In fiscal year 2024, BIDMC received more than $49.1 million in indirect, or Facilities and Administrative ("F&A"), research support from NIH. BIDMC's provisional F&A rate for most grants is 72.9 percent.

5. Funding from NIH has allowed BIDMC researchers to carry out hundreds of research projects and clinical trials that have led to significant scientific and medical breakthroughs. In 2016, for example, researchers from BIDMC's Cancer Center and the Dana-Farber Cancer Institute led a clinical trial that showed that a personalized cancer vaccine markedly improved outcomes for patients suffering from acute myeloid leukemia, a potentially lethal blood cancer. To take another example, in 2021, BIDMC investigators led a study that provides insights into the mechanistic links between physical fitness and overall health and the reasons why the same exercise can have different effects in different people—results that could help determine which types of exercise are most likely to benefit a particular person. More recently, in 2024, BIDMC psychiatrists led groundbreaking research that revealed a connection between cognitive impairment and brain network organization, offering potential opportunities for early detection of and intervention for psychotic disorders before they fully manifest in patients.

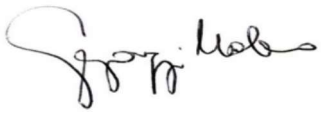
6. NIH's proposed reduction in indirect funding would have a devastating impact on BIDMC's ability to carry out its important research. Specifically, a 15% F&A rate would result in an annualized loss of $31.5 million for BIDMC. The consequences would be immediate, including the need for BIDMC to terminate its leases for laboratory buildings and to lay off hundreds of employees like researchers, physicians, nurses, laboratory technicians, financial analysts,

housekeeping staff, and food service workers. The likely results of the cut also include the elimination of BIDMC's research educational programs like internships, fellowships, symposia, and other programs that will affect hundreds of students at the high school, undergraduate, graduate, and postdoctoral levels—contributing to the loss of an entire generation of future scientists.

7. The impact on patients will be even worse, including the elimination of a significant number of BIDMC's clinical research programs and the premature termination of clinical trials—trials which facilitate cutting-edge care to patients and have led to breakthrough, lifesaving treatments for patients suffering from cancer and other diseases. Based on my decades of clinical research experience, it is not an exaggeration to say that patient care will suffer from the NIH's proposed funding reduction and that such reduction could even cause the avoidable loss of patients' lives.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed this 17th day of February, 2025 in Boston, Massachusetts.



/s/

Gyongyi Szabo, M.D., Ph.D
Chief Academic Officer
Beth Israel Deaconess Medical Center and Beth Israel Lahey Health

EXHIBIT D

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

ASSOCIATION OF AMERICAN MEDICAL COLLEGES; THE AMERICAN ASSOCIATION OF COLLEGES OF PHARMACY; THE ASSOCIATION OF SCHOOLS AND PROGRAMS OF PUBLIC HEALTH; THE CONFERENCE OF BOSTON TEACHING HOSPITALS, INC.; and GREATER NEW YORK HOSPITAL ASSOCIATION, 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 ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the U.S. Department of Health and Human Services, Defendants.	C.A. No. 1:25-CV-10340-AK

DECLARATION OF GILBERT ("GIL") HAI TRAN

I, Gilbert Hai Tran, declare as follows:

1. I am currently the Senior Specialist Leader in the Attain Research practice at Attain Partners, a leading provider of consulting services to educational institutions, non-profits, hospital, and healthcare organizations.

2. Previously, I served as a Senior Policy Analyst with the Office of Management and Budget (OMB), Office of Federal Financial Management. During my 27-year tenure at OMB, I played an integral role in developing and then administering the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, 2 C.F.R. §§ 200, *et*

seq., commonly referred to as the Uniform Grant Guidance. I served as the OMB lead and the point of contact for all Federal agencies on all indirect costs and Single Audits issues for grants.

3. I have spent my entire 43-year career working in financial and grant administration and management. After receiving a Bachelor of Science in accounting from George Mason University, I worked at Georgetown University for four years as a senior financial officer in the Office of Sponsored Programs. There, I was responsible for administering research grants made to the University by governmental agencies and private foundations. I managed the University's cash drawdown for the grant expenditures and assisted in the preparation of the University's indirect cost proposals in accordance with OMB requirements. After that, I worked for eight years as a manager with the leading accounting firm KPMG Peat Marwick in its Grant Management Services practice in the Washington, D.C. At KPMG, among other things, I helped clients compile the financial information necessary to apply for federal grants, prepare and negotiate federal indirect cost rates, and assisted in the design and development of systems to administer grant costs. After leaving KPMG, I then spent three years at the U.S. Department of Health and Human Services (HHS), Division of Cost Allocation, where I was a senior grant cost negotiator and manager in the State and Local Government Branch. I managed the review and negotiation of Statewide Cost Allocation Plans and University's indirect cost proposals and rates. After leaving HHS, as I noted above, I spent the next twenty-seven years at OMB, as Senior Policy Analyst with OMB's Office of Federal Financial Management. In this position, I assisted in the development and creation of the Uniform Grant Guidance in 2013, which combined eight separate OMB Circulars into a single document and provides uniform guidance for administrative requirements, cost principles and audit requirements for all types of grantees. I retired from public service in December 2022. In August 2023, I joined Attain Partners.

4. I am a Certified Public Accountant. I have been recognized and honored for my professional contributions with several awards, including OMB's Robert Damus Award, the National Grants Management Association's Newton Award, the Association of Government Accountants' Frank Greathouse Distinguished Leadership Award, and the National Colleges and University Research Administrators Association's Joseph F. Carrabino Award.

Grants and Grant Making

5. Grants reimburse research institutions for the cost of conducting research in one of two different but equally important ways. First, costs attributable to a specific research project, such as project specific research salaries or supplies, are reimbursed as "direct costs." Second, " indirect costs" that support the institution's research mission as a whole, but that are not specific to a single research project, are allocated across all of the institution's activities including research projects that they support. These allocated costs include (1) the facilities maintenance costs associated with shared laboratory space, electricity costs, campus security, technology management and security, the purchase price of shared laboratory equipment, the expense of a collectively used hazardous waste disposal facility, and (2) the cost of shared administrative services associated with financial management, award billing and reporting, departmental administration, research administration, legal counsel, and human subject protection.

6. For decades, the federal government has reimbursed these "indirect" costs through an institution-specific negotiated Facilities & Administrative (F&A) or indirect cost (IDC) rate.

7. The Uniform Grant Guidance (UGG), which I helped to develop when I was serving at OMB as described above, sets forth a detailed set of rules about how these institution-specific F&A cost rates are supposed to be developed and negotiated, and what costs they can and what costs they cannot include.

8. As I have seen from all sides, the process of developing and negotiating an institution-specific F&A rate with the federal government is often long and involved, and rigorous, but always begins with concrete evidence of an institution's actual costs. This evidence-based negotiation begins with the institution submitting an indirect cost proposal that includes financial statements audited by a certified public accountant that provide historical detail on the costs for which the institution is allowed to seek reimbursement under the UGG. The proposal follows the strict UGG guidelines for the types of costs that can be included in a pool (such as operations and maintenance) and for the allocation of these costs to benefiting activities (such as research or instruction). Based on my experience as a senior cost negotiator at the HHS Division of Cost Allocation, a review and negotiation of a University's indirect cost proposal could take months, include several rounds of requests for additional documentation and possibly an on-site visit to review the space allocation statistics and the building use allowance claims. For institutions with federal expenditures of more than $1 million, the institutions are subject to an annual single audit that reviews the institution's financial statements, internal controls, and the application of the negotiated rates to the federal grants. And, even after an F&A rate is agreed with a research institution, the government retains the rights to audit the institution's spending and to seek adjustments to the agreed-upon rate based on the results of its auditing.

9. Only a subset of costs incurred by a research institution are reimbursable as indirect costs. Most generally, the UGG provides that the cost must be one that is necessary and relates directly to the institution's specific research mission. For example, a university's expenditures on fundraising or athletic facilities, or even classroom buildings, are not includable in the university's F&A rate because these expenses do not further the university's research mission. This rule ensures

that all costs included in the institution-specific negotiated F&A rate are costs that are necessary for the institution to carry out the funded research projects.

10. The UGG next divides indirect costs into two broad categories: "facilities" and "administrative" costs. "Facilities" costs typically include, among others, utilities, building and facility construction, maintenance and repairs, campus security, shared laboratory equipment, radiation safety and hazardous waste disposal, library resources, and property insurance. "Administrative" costs typically include, among others, financial management, payroll, human resources, legal counsel, human subject protection, and data and technology management and security. To help control costs at universities, for example, the UGG applies different caps to the amounts that may be allocated to these different categories of expenses. In particular, the administrative component of the rate is capped at 26% (since 1991), the department administrative allocation to research is capped at 3.6%, and the utility cost adjustment for research is capped at 2%.

11. In my experience, the range of institution-specific negotiated F&A rates that results from this rigorous and evidence-based negotiation process vary widely depending on the type, location, and research focus of the institution. In my view, this variation in rates is not reflective of any difference in the relative negotiating power of these different institutions but rather is a function of a variety of other factors related to their cost structure. For instance, public universities tend to have lower indirect-cost rates, because some of their indirect costs, such as building maintenance, are already paid for by the state government. State governments often pay to maintain, or at least defray a portion of the costs of maintaining, buildings on their public university campuses. Thus, this maintenance expense is not included in these universities' F&A rates. To use another example, research institutions located in places with high land costs and higher costs of living typically have higher negotiated rates because real estate and facilities maintenance are more expensive in these

areas, as is the cost of the salary and benefits paid to employees who work in those geographies. Institutions engaged in research using very expensive equipment, shared across projects, also tend to have higher F&A rates. Institutions with newer research buildings will often have interest costs that would result in higher F&A rates. In this way, evidence-based, institution-specific F&A rates avoid both undercompensating some institutions with higher-cost structures and overcompensating those with lower-cost structures.

12. Although I have heard it asserted that these indirect cost rates in federal grants promote inefficiency, my experience and observations over a 43-year career in grant administration and management have shown me the opposite. F&A rates permit and promote the sharing of services necessary to complete research across a range of projects in a cost-effective manner. A simple illustration proves my point: it is far more cost efficient for a single research administrator at a hospital to track spending on research projects being carried out in multiple laboratories throughout the hospital (assuming the administrator has the time) than to hire an administrator for each individual laboratory. By allocating indirect costs across multiple grants and research projects, institutions can share services and avoid duplication of the services necessary to complete research, such as waste disposal, IT security, and human subject and conflict of interest compliance.

13. I understand that in proposing an across-the-board cut to previously negotiated F&A rates for a standard rate, NIH points to the low indirect cost rates allowed by certain private foundations and readily accepted by universities. The belief appears to be that: when the universities accept the lower rates from private foundations, the federal government is subsidizing these projects with the reimbursement of a full negotiated indirect cost rate. That is a total misconception. Indeed, the guidelines in the UGG contain several provisions reflecting that this is not the case. Specifically, the "allocability" principle in the UGG requires that all indirect costs are allocated to the benefitting

activities in accordance with the benefits received, regardless of the source of funding. The calculation of the indirect cost rate involves a mathematic division of the overhead costs (as numerator or pool) by the total direct costs of all the activities (denominator or base). For the research indirect cost rate, all overhead costs identified for the research activities are accumulated in the numerator, and all direct costs for the research activities (federal, private industry, foreign, university, state) are accumulated in the denominator. The UGG contains this specific language related to this restriction: "Each institution's indirect (F&A) cost rate process must be appropriately designed to ensure that Federal sponsors do not in any way subsidize the indirect (F&A) costs of other sponsors, specifically activities sponsored by industry and foreign governments." *See* 2. C.F.R. § Appendix III to Part 200 C.1.a(3). In the Disclosure Statement (DS-2) for universities with CAS-covered contracts, universities must certify that proper "allocation of indirect costs are made to programs that pay less than full indirect costs." HHS's Cost Allocation Service, which reviews and establishes indirect cost rates for most other universities, has recommended several review steps in its Best Practices Guide, 2017, to comply with the UGG subsidizing prohibition requirements.

14. Research institutions also often attain and use private foundation funding in materially different ways than NIH grants. For example, during my time at Georgetown University, one of my job responsibilities was to ensure that any researchers who accepted private foundation funding with a lower F&A rate were aware of the university's federal negotiated rate and decided private funding would be used only to augment the funding on an already existing and related research project that was separately receiving federal grant funding or funding from another source with an F&A rate that was at least as generous as Georgetown's negotiated federal rate. Moreover, in my experience, to offset any lower F&A rates paid by private foundations, applicants applying for private foundations grants may include among their direct costs expenses that could not be

reimbursed as a direct cost under the UGG such as rent or equipment. Our Director of Sponsored Programs approved all exceptions for projects with lower than negotiated F&A rates, fully aware that university funds must be used to cover the shortfall in indirect costs on those projects. In short, because the rules are different, any comparison of public and private F&A rates is uninformative. It is comparing apples to oranges.

15. Once an institution has completed the federal indirect cost proposal process and negotiated an institution-specific negotiated F&A rate, under the UGG, that negotiated rate applies to *all* subsequent grants made to that institution typically for a two-to four-year period. In accordance with the UGG, for universities, the negotiated rate is used for the life of the project. As I have seen throughout my career, this certainty is critical to grant recipients, particularly universities with huge investments in research facilities to advance the research frontier. Without this certainty, research institutions would be unable to budget for and plan their future spending, thus severely handicapping their ability to commit to performing multi-year research projects.

Impact of the Proposed Rate Cut

16. Counsel for the Association of American Medical Colleges (AAMC) asked me whether it is possible to quantify the impact of NIH's proposed IDC rate cut on research institutions nationwide. As I explained to counsel, NIH makes publicly available and publishes on its website with some delay data on all the grants that it makes nationwide to all research institutions receiving an NIH research grant in a given fiscal year. The most recent year for which data are available is Fiscal Year 2024. Those data can be found at NIH ExPORTER FY24 Project Data: https://reporter.nih.gov/exporter

17. To answer counsel's question, I downloaded this data into a standard Microsoft Excel spreadsheet and created some simple pivot tables to summarize the voluminous NIH data of 68,395

projects made by NIH in 2024. In particular, I relied on the following fields found in NIH's publicly available grant data: Project Number, Organization City, Organization Name, Organization Zip Code, Direct Costs, Indirect Costs, Total Costs.

18. To calculate the impact of indirect funding loss using the standard rate of 15%, I performed the following steps:

i. I excluded all projects with less than a 15% effective rate (indirect cost amount/direct cost amount) as these are most likely training grants that will not have their rates increased to 15%;

ii. I converted the direct costs for each project into modified total direct costs (MTDC) using an estimated factor of 85%. MTDC, as defined in the UGG, excludes equipment, subawards amount over $50,000, patient care costs and others;

iii. I applied the new standard rate of 15% to the MTDC to arrive at the projected indirect cost recovery for each project; and

iv. I compared the budgeted indirect cost with the projected indirect cost recovery on each project to determine the loss in indirect cost recovery.

19. As shown in Exhibit A, my calculations demonstrate that the proposed NIH rate cut will result in an estimated aggregate loss of $6.5 Billion for all the NIH projects in 2024. This cut would have a significant negative impact on NIH grant recipients in each state, the District of Columbia, and Puerto Rico, thus nationwide. The estimated loss of funding by state is shown in Exhibit A. My analysis is consistent with the impact that NIH itself has reported, $4.4 Billion, which appears to reflect only the last eight months of FY 2024 (or a 8/12 ratio).

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed this 15 day of February, 2025 in Washington, D.C.

/s/ Gil Tran

Gilbert Hai Tran

Exhibit A - Estimated Funding Loss by State				
State Name	**Budgeted Direct**	**Budgeted Indirect**	**Calculated Indirect under Feb 07 Notice**	**Loss of Funding under Feb 07 Notice**
Alaska	12,424,750	2,547,211	1,186,857	1,360,354
Alabama	290,184,740	92,393,012	34,412,925	57,980,087
Arkansas	81,021,901	27,755,740	9,249,741	18,505,999
Arizona	273,563,584	88,957,135	32,038,039	56,919,096
California	3,726,271,006	1,373,795,210	420,853,358	952,941,852
Colorado	395,024,759	139,317,093	45,675,568	93,641,525
Connecticut	563,542,589	240,297,674	64,618,901	175,678,773
District of Columbia	166,958,237	52,733,966	18,659,398	34,074,568
Delaware	64,313,934	20,419,931	6,900,487	13,519,444
Florida	702,386,314	237,176,113	84,682,803	152,493,310
Georgia	562,087,991	204,317,066	65,779,686	138,537,380
Hawaii	49,676,225	18,673,719	6,003,830	12,669,889
Iowa	149,900,817	59,759,674	17,442,118	42,317,556
Idaho	17,863,851	5,409,756	2,116,300	3,293,456
Illinois	923,397,975	344,716,062	104,054,729	240,661,333
Indiana	298,518,014	116,558,146	35,839,864	80,718,282
Kansas	103,055,025	36,617,648	11,712,758	24,904,890
Kentucky	168,179,585	66,253,589	19,607,726	46,645,863
Louisiana	152,913,296	51,238,708	17,619,829	33,618,879
Massachusetts	2,470,788,457	926,474,488	277,149,849	649,324,639

Maryland	1,110,144,654	340,348,315	108,702,970	231,645,345
Maine	88,611,467	38,947,806	10,243,311	28,704,496
Michigan	736,348,435	279,169,008	86,120,657	193,048,351
Minnesota	526,279,114	202,480,952	61,942,044	140,538,908
Missouri	653,700,031	231,008,928	75,431,790	155,577,138
Mississippi	50,387,725	14,720,945	5,084,354	9,636,591
Montana	30,355,339	8,613,663	3,194,316	5,419,347
North Carolina	1,438,037,152	414,199,660	133,848,315	280,351,345
North Dakota	21,385,197	6,453,330	2,602,756	3,850,574
Nebraska	99,229,076	40,474,811	12,183,995	28,290,816
New Hampshire	93,559,216	39,950,517	11,330,474	28,620,043
New Jersey	273,542,874	106,642,201	32,174,028	74,468,173
New Mexico	86,359,164	32,902,275	10,308,177	22,594,098
Nevada	24,980,439	8,105,168	3,102,946	5,002,222
New York	2,522,650,313	1,013,112,661	279,085,535	734,027,126
Ohio	715,041,241	284,905,900	84,150,045	200,755,855
Oklahoma	113,943,412	42,411,079	13,793,736	28,617,343
Oregon	303,764,692	99,746,719	34,380,002	65,366,717
Pennsylvania	1,597,380,823	610,589,420	183,129,113	427,460,307
Puerto Rico	49,304,532	11,490,865	4,286,273	7,204,592
Rhode Island	188,458,611	62,102,699	21,044,632	41,058,067
South Carolina	190,461,935	63,622,801	21,779,293	41,843,508
South Dakota	19,267,115	7,659,001	2,377,206	5,281,795

Tennessee	600,109,690	222,056,074	63,941,048	158,115,026
Texas	1,385,721,155	514,905,802	156,337,427	358,568,375
Utah	216,779,522	79,186,855	25,227,793	53,959,062
Virginia	387,668,683	124,822,224	38,746,589	86,075,635
Vermont	40,474,594	14,732,708	4,805,214	9,927,494
Washington	904,587,940	329,547,970	108,128,601	221,419,369
Wisconsin	440,173,209	152,703,309	48,799,382	103,903,927
West Virginia	40,630,478	13,104,555	4,782,966	8,321,589
Wyoming	8,469,629	3,162,192	1,048,003	2,114,189
Others (Non US)	43,230,492	2,690,233	2,298,877	-
Total	**26,173,110,999**	**9,521,982,587**	**2,930,016,632**	**6,591,574,599**

EXHIBIT E

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

ASSOCIATION OF AMERICAN MEDICAL COLLEGES, *et al.*, Plaintiffs, v. NATIONAL INSTITUTES OF HEALTH, *et al.*, Defendants.	)	Civil Action No. 25-CV-10340-AK

DECLARATION OF DR. ANUPAM AGARWAL

I, Dr. Anupam Agarwal, declare the following:

1. My name is Dr. Anupam Agarwal. I am over the age of majority, of sound mind, and competent to execute this Declaration. The statements and facts contained within this declaration are true and correct, and they are based either on my personal knowledge or on my review of business records.

2. The University of Alabama at Birmingham ("UAB") is a comprehensive metropolitan public research university and academic medical center. It is a member of the Association of American Medical Colleges.

3. I have been employed at UAB since November 1, 2003. I currently serve as the Senior Vice President for Medicine and Dean of the UAB Heersink School of Medicine. In these roles, I am familiar with the funding the National Institutes of Health ("NIH") provides to UAB to conduct federally sponsored, peer-reviewed scientific research.

4. UAB received $470 million in grant funding from the NIH in fiscal year 2024. UAB used those funds to conduct research addressing the leading causes of death in the United States,

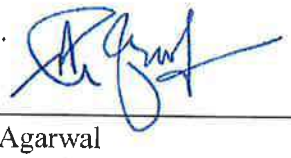
such as cancer, Alzheimer's, stroke, Parkinson's, heart disease, and diabetes. NIH funding also allows UAB to conduct research on other diseases and disorders that devastate lives and families.

5. The NIH reimburses UAB for Facilities & Administrative ("F&A" or "indirect") costs on NIH-sponsored grants issued to UAB at a negotiated, institution-specific rate. UAB's current negotiated rate is 48.5 percent. If the Defendants implement, apply, or enforce the Supplemental Guidance to the 2024 NIH Grants Policy Statement: Indirect Cost Rates (NOT-OD-25-068), reducing the indirect cost rate to 15 percent for all grants issued to UAB, UAB estimates that it will lose $70 million a year in funding from the NIH.

6. This drastic lowering of the NIH indirect cost rate (and subsequent loss of funding) will greatly and negatively impact UAB's ability to conduct clinical trials and therefore impacting patient care, as well as to purchase and maintain equipment, facilities, digital security, and other infrastructure necessary to conduct critical research. If the reduced indirect cost rate of 15 percent is enforced, advancements in virtually all areas of research at UAB will slow, jeopardizing life-saving research and resulting in job and economic losses in both Birmingham and the state of Alabama.

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

Executed on February 12, 2025, in Birmingham, Alabama.



Dr. Anupam Agarwal

EXHIBIT F

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

ASSOCIATION OF AMERICAN MEDICAL COLLEGES; THE AMERICAN ASSOCIATION OF COLLEGES OF PHARMACY; THE ASSOCIATION OF SCHOOLS AND PROGRAMS OF PUBLIC HEALTH; THE CONFERENCE OF BOSTON TEACHING HOSPITALS, INC.; and GREATER NEW YORK HOSPITAL ASSOCIATION, 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.	C.A. No. 1:25-CV-10340-AK

DECLARATION OF L. LEE HAMM, M.D.

I, Dr. L. Lee Hamm, declare as follows:

1. I am the Senior Vice-President & Dean of the Tulane University School of Medicine ("Tulane") in New Orleans, Louisiana. I have served in this role for twelve years. Before that, I was Chair of Tulane's largest department, Internal Medicine, for seven years. I have been at Tulane for 32 years. Tulane is a member of the Association of American Medical Colleges. As the Senior Vice-President & Dean of the Tulane School of Medicine, I have an oversight role and visibility into our education and research functions. In my official capacity and based on my personal knowledge and other sources of information that I have obtained and reviewed in my official capacity, I am

familiar with, and if called upon to do so, would be competent to testify to, the facts and circumstances set forth herein.

2. Tulane emphasizes a comprehensive and interdisciplinary approach to training future physicians, offering a diverse range of programs that integrate cutting-edge technology, community engagement, and hands-on clinical experience. Our diverse departments, centers, and institutes each contribute significantly to Tulane's academic and research excellence. They collectively reflect Tulane's commitment to interdisciplinary collaborations, innovative research, and the advancement of medical science and patient well-being.

3. Tulane University received more than $111M in research support from the National Institutes of Health ("NIH") in fiscal year 2024, of which more than $32 million was for indirect, or Facilities and Administrative ("F&A") costs. The School of Medicine is the largest unit of the University that receives these monies, although the schools of Science and Engineering and Public Health and Tropical Medicine also receive significant NIH funding. Tulane's negotiated F&A rate for most grants is 53 percent, but certain centers, such as the Tulane National Primate Research Center, receive higher rates due to the extensive costs associated with their research.

4. Tulane's research, which has been predominantly funded by the NIH, has produced life-saving and life-improving advances in many diseases including prostate cancer, breast cancer, interstitial lung disease and pulmonary fibrosis, diabetes, hypertension, stroke, heart disease, tuberculosis, HIV, Ebola and other similar hemorrhagic fevers, inflammatory bowel disease, alcohol induced liver disease, Alzheimer's dementia, the role of diet and genetics in cancer and cardiovascular disease, among others. In addition, the NIH has helped fund the training of the next generation of preeminent scientists including physician scientists, public health experts, and bioengineers. Much of this work is basic, focusing on the genetic and molecular networks within

cells that become affected by disease. Other work involves patient trials of those suffering from these diseases which have only limited treatments. The ultimate goal is prevention or complete cure, and healthy aging.

5. While the exact expense reductions at Tulane resulting from the new NIH guidance have not been established yet, if our funded research is to go on, we will continue to incur indirect expenses by necessity. For example, our research facilities have to be maintained, our advanced information technology infrastructure needs to continue, and our support services have to be supplied. To keep up with those expenses, we will have to make other cuts. Expense reductions will initially come from staffing cuts of people (including faculty, post-docs, and staff) who are not directly funded by NIH at that moment in time—but who might otherwise be in the near future. In addition, our facility upkeep will be lessened and our information technology and other research equipment will not be upgraded. Support staff will be minimized to the extent feasible. As a result, Tulane's research, science, and breakthrough medical advances will be markedly less after a single year. And, most unfortunately, if the cuts persist, their negative impact will be generational.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed this 12th day of February, 2025 in New Orleans, Louisiana

/s/ L. Lee Hamm

L. Lee Hamm, M.D.
Senior Vice-President & Dean
Tulane University School of Medicine

EXHIBIT G

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

ASSOCIATION OF AMERICAN MEDICAL COLLEGES, *et al.* Plaintiffs, v. NATIONAL INSTITUTES OF HEALTH, *et al.*, Defendants.	Civil Action No. 25-CV-10340-AK

DECLARATION OF ROB RUTENBAR

I, Rob A. Rutenbar, declare as follows:

1. I am the senior vice chancellor for research at the University of Pittsburgh (Pitt) in Pittsburgh, PA. I have held that position since 2017. In this position, I direct the Pitt Research Unit, which supports the full breadth of the University's research enterprise, from pursuing and securing funding and supporting university principal investigators through effective research administration services.

2. As senior vice chancellor 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 University of Pittsburgh personnel, and could testify thereto.

3. The University of Pittsburgh receives substantial annual funding from the National Institutes of Health ("NIH") – in FY24, the University received over $661 million in

direct awards and the total number of awards was 1,238. The University also receives NIH funding as a sub-awardee, which has been at an average rate of approximately 275 new awards totaling $65 million a year over the past 3 years.

4. The funding the University of Pittsburgh receives from NIH supports critical and cutting-edge medical research, which millions of Americans benefit from and depend on. **Here are just a few examples:**

a. **Physical Medicine and Rehabilitation** - A study that involved deep brain stimulation allowed a survivor of a severe traumatic brain injury to walk and communicate with loved ones. This team is currently recruiting for a new trial and expanding to stroke victims. Stroke is the leading cause of long-term disability in the United States. The team has worked on a number of related studies that have restored movement to those who had lost it.

b. **Psychiatry -** The University's Alzheimer's research validated a new blood test platform that can simultaneously measure more than 100 biomarkers of Alzheimer's disease, designed to allow for early intervention that is not yet possible.

c. **Ophthalmology** - In one of many pioneering vision research studies at Pitt, researchers partially restored sight in patients who are blind.

d. **Pediatrics –** A nasal swab test that was developed to replace invasive bronchoscopy for diagnosing specific childhood asthma subtypes. This paves the way for more effective life-saving treatments for children.

e. **Hematology and Medical Oncology –** Found that a combined chemotherapy and immunotherapy drug that reduces the risk of death or invasive disease by 46% in the most high-risk breast cancer patients.

f. **Public Health –** Researchers are leading a groundbreaking study to understand mobility decline in older adults and how certain biological pathways play a role in disability, dementia and death and in the decline of muscle power and fitness with aging. The goal of this study is to develop new strategies to prevent or mitigate conditions related to aging and mobility.

5. Indirect costs are essential for supporting this research. The NIH's proposal to cut indirect cost rates to 15% would end or seriously jeopardize all of the research projects described in paragraph 4.

6. Indirect costs include research space, security, waste cleanup, data management, information technology and other staff support. For example, on Pitt's campus in Oakland there is 1.4 million square feet of research labs either owned or leased by the University, which would be impacted by the reduction in indirect funding. Without this infrastructure, we cannot conduct the research.

7. For example, with respect to the areas of research described in Paragraph 4:

a. The Alzheimer's biomarker study uses positron emission tomography (PET) scanning technology with an experimental human PET scanner and cryo-electron microscopy for molecular imaging.
b. The deep-brain stimulation study that restored movement to arms and hands uses ROSA One(R) Robot Assistance Platform for surgeries and high-resolution CT scanner for all studies for brain imaging.
c. The pediatric asthma study relied on Pitt's high-throughput sequencing and bioinformatics analysis core facilities.

d. The Her-2 positive breast cancer treatment discovery was made through the inpatient clinical trials unit.
e. The study that partially restored visual function in a blind patient utilized the gene vector core.

8. 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 of Pittsburgh. Additionally, several major building projects underway at the University of Pittsburgh will be affected by the loss of indirect funds. Among them is BioForge, a 185,000-square-foot, state-of-the-art facility for manufacturing innovations in novel cell and gene treatments and therapies. Another is a 306,000-square-foot, 10-story building to be used by the School of Health and Rehabilitation Sciences, the Department of Computational and Systems Biology and other areas in the university's School of Medicine, as well as Pitt EDGE, the university's online programming, for all of the university's six Health Sciences schools, which focuses on workforce development in high need health science sectors.

9. In addition, indirect costs fund the administration of awards, including staff who ensure compliance with a vast number of regulatory mandates from agencies such as NIH.[1] These mandates serve many important functions, including protecting 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

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf

high level of cybersecurity, data storage, and computing environments mandated for regulated data.

10. Recovery of the University of Pittsburgh's indirect costs is based on predetermined rates that have been contractually negotiated with the federal government.

11. Through fiscal year 2025, the University of Pittsburgh's predetermined indirect cost rate is 59%.

12. The impact of a reduction in the indirect cost rate would be devastating. Of the $791million in NIH expenses incurred by the University of Pittsburgh in FY24, approximately $571 million was spent for direct costs, and $220 million was incurred for indirect costs. Similarly, in FY 2025, the University of Pittsburgh expects to spend $589 million for NIH direct costs, while $227 million will be incurred for indirect costs (total of $816 million). And over the next five years, the University of Pittsburgh anticipates spending an average of $644 million from the NIH for annual direct costs. Based on the predetermined indirect cost rate of 59%, which was agreed upon by the federal government, the University expects to receive approximately $248 million annually, on average, in indirect cost recovery over the next five years.

13. If—contrary to what the University of Pittsburgh has negotiated with the federal government—the indirect cost rate is reduced to 15%, that would reduce the University's anticipated annual indirect cost recovery by $168 million, to $595 million in FY 2025 (if the change were retroactive to July 2024).

14. The impact of the IDC reduction would be felt immediately, limiting access to new interventions and putting those enrolled in clinical trials in jeopardy. It will also

negatively impact the regional economy given the significant financial impact on one of the region's largest employers.

15. The University of Pittsburgh has for decades relied on the payment of indirect costs. And until now, we have been able to rely on the well-established process for negotiating indirect cost rates 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 of Pittsburgh has long-term obligations—for example, such as tenured faculty salaries, staff, admitted graduate and professional school students —and it relies on budgeted grant funding, including associated indirect cost recovery, to fulfill these commitments.

16. In addition to the immediate impacts and reliance interests described above, there are longer term impacts that are both cumulative and cascading. Halting laboratory and other research midstream can effectively waste years of effort. It can disrupt residencies and doctoral studies of clinicians and scientists in ways that could be impossible to restart. Clinical trials — in cancer, childhood diseases and many other conditions — that are disrupted also put patients in jeopardy and in some cases may not be able to be restarted. Clinical trials follow very strict timelines on enrollment/medication/treatment schedules, as well as reporting of adverse events. These are directly tied to the availability of funds, personnel and facilities. A delay in treatment and/or follow up obviously harms a patient during a time-sensitive, critical period of medical care. It can also invalidate the meticulous data collection necessary to determine the efficacy and safety of a new treatment. This has

downstream effects on the individuals currently enrolled in clinical trials, future participants who may benefit from a trial, and eventually at the general population level with the delays in drug approval and establishment of new best practices.

17. Disruptions to University of Pittsburgh's research will also have negative effects in the Pittsburgh area, the Commonwealth of Pennsylvania and the broader region. Of the University's 16,000 employees, over 8,500 have research-related roles and more than 96% of these staff members are Pennsylvania residents. The University collaborates with state and local partners to help solve regional and broader 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 the University of Pittsburgh's research budget would immediately and seriously jeopardize these staffing levels and contributions.

18. Finally, slowdowns or halts in research by the University of Pittsburgh 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. It also will discourage young people from going into research, causing a national brain drain.

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 of Pittsburgh —which would in turn force reductions in key investments supporting university's faculty, students, staff, research, and teaching infrastructure, as well as other critical activities needed to maintain the University of Pittsburgh's academic excellence.

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

Executed on Feb. 13, 2025, at Pittsburgh, PA.

Signed by:
Rob A. Rutenbar
05E7033D8383427...

Rob A. Rutenbar

EXHIBIT H

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

ASSOCIATION OF AMERICAN MEDICAL COLLEGES; THE AMERICAN ASSOCIATION OF COLLEGES OF PHARMACY; THE ASSOCIATION OF SCHOOLS AND PROGRAMS OF PUBLIC HEALTH; THE CONFERENCE OF BOSTON TEACHING HOSPITALS, INC.; and GREATER NEW YORK HOSPITAL ASSOCIATION, 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 ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the U.S. Department of Health and Human Services, Defendants.	C.A. No. 1:25-CV-10340-AK

DECLARATION OF C. RONALD KAHN, M.D.

I, Dr. C. Ronald Kahn, declare as follows:

1. I am the Chief Academic Officer and Head of the Section on Integrative Physiology and Metabolism at Joslin Diabetes Center, Inc. ("Joslin"), and the Mary K. Iacocca Professor of Medicine at Harvard Medical School. I served as Research Director of Joslin from 1981 to 2000 and President of Joslin from 2000 to 2007. I also chaired the Congressionally mandated Diabetes Research Working Group that developed the strategic plan for National Institutes of Health ("NIH")–funded diabetes research for more than the past twenty years. I have received more than seventy awards and honors, including the Wolf Prize in Medicine, Kober Medal of the Association of

American Physicians, and the highest honors of the American Diabetes Association, U.S. and British Endocrine Societies, Juvenile Diabetes Research Foundation, European Association for the Study of Diabetes, and the American Association of Clinical Endocrinologists. I have been elected to the National Academy of Science and the National Academy of Medicine. I have authored more than 700 original publications and 200 reviews and chapters. I hold B.S., M.S., and M.D. degrees from the University of Louisville. I also hold an honorary Master of Science from Harvard University and honorary Doctorates from the University of Paris, University of Louisville, University of Geneva, Washington University in St. Louis, Louisiana State University, and the University of Copenhagen.

2. In my official capacity and based on my personal knowledge and other sources of information that I have obtained and reviewed in my official capacity, I am familiar with, and if called upon to do so, would be competent to testify to, the facts and circumstances set forth herein.

3. Based in Boston, Massachusetts and founded in 1898, Joslin is an independent research and clinical organization focused on diabetes and related metabolic diseases. It is the oldest and largest diabetes research organization in the United States and the world. Joslin emphasizes a comprehensive and interdisciplinary approach to research and clinical care, as well as the training of future physicians and scientists. It offers a range of programs that integrate cutting-edge research with clinical care and community engagement. Our research and clinical staffs not only contribute significantly to Joslin's leadership in the field, but also contribute to the position of the United States internationally in diabetes research. They collectively reflect Joslin's commitment to interdisciplinary collaborations, innovative research, and the advancement of medical science and patient well-being.

4. Joslin's research, which is predominantly funded by the NIH, has produced important advances that have changed the way diabetes and its complications are recognized, understood, and treated. For example, in the area of Type 1 Diabetes (T1D), which affects young children as well as adults, Joslin was a leader in defining the autoimmune basis of this disease and how this autoimmunity leads to destruction of insulin producing beta-cells in the pancreas—a finding that has led to multiple clinical trials to prevent T1D. In the area of Type 2 Diabetes (T2D), which affects over 35 million Americans and is associated with obesity and multiple other cardiometabolic abnormalities, Joslin researchers have identified the fundamental mechanisms of insulin action and how they are altered in T2D. We have also identified the mechanisms by which obesity and body fat drives T2D—as well as the lifestyle factors, such as exercise, that can improve it. Finally, in the area of diabetes complications, researchers at Joslin were not only the first to employ laser photocoagulation, but also the first to discover the role of vascular endothelial growth factor (VEGF) in this process, a finding that led to the development of anti-VEGF drugs that have saved the sight of millions of people with diabetes and other disorders of the eye. In each of these areas, Joslin's work spans from very basic research, dissecting the genetic and molecular networks within cells that become affected by disease, to clinical trials of those suffering from these diseases and their complications—all with the ultimate goal of prevention or cure of these disorders. Finally, with the help of NIH funding, Joslin has been a major site of training of the next generation of physicians and scientists across the country.

5. Joslin received more than $24 million in research support from the NIH in fiscal year 2024, of which more than $9.2 million was for indirect, or Facilities and Administrative ("F&A") costs. Joslin's negotiated F&A rate for most grants is 71 percent.

6. We are still analyzing the full impact of the proposed reductions in NIH indirect funding at Joslin, the proposed changes would reduce Joslin's research budget by an estimated 30%. Furthermore, it is already clear that these reductions would have not just short-term impact but would likely affect the survival of the whole program. NIH is the largest single component of our funding, and Joslin requires NIH funding to cover all of our costs, both direct and indirect, for our important research work to continue. This includes not only support for the scientists and their supplies, but also support of our research facilities and their maintenance, our information technology infrastructure, our clinical research center, and many other essential needs to support our research programs. If NIH indirect funding is limited significantly below actual costs, there is really no way to effectively fund essential research functions. Like most organizations, Joslin receives some foundation grants with lower indirect cost rates, but these grants are sustained through fundraising efforts in order to offset the lower indirect rate and other existing funding gaps. Even at present, Joslin needs to limit the number of these foundation grants every year to stay within a budget that can be met through donor support. If Joslin needed also to raise the funds to support its existing NIH-grant F&A costs, it would be forced to more than double its fundraising efforts. Based on my more than forty years in multiple leadership roles at Joslin, I can say with certainty that this is simply not possible or realistic.

7. Accordingly, in my estimation, if NIH reduces its indirect cost support to 15% as has been proposed, Joslin would be forced to either markedly reduce the size of its research effort through layoffs and other cuts, convert to a clinical-only operation by eliminating various research programs, or, most likely, cease to exist entirely. This would be a great loss to people with diabetes throughout the United States and the world.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed this16th day of February, 2025 in Boston, Massachusetts.

/s/ C. Ronald Kahn

C. Ronald Kahn, M.D.
Chief Academic Officer
Joslin Diabetes Center, Inc.

EXHIBIT I

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

ASSOCIATION OF AMERICAN MEDICAL COLLEGES; THE AMERICAN ASSOCIATION OF COLLEGES OF PHARMACY; THE ASSOCIATION OF SCHOOLS AND PROGRAMS OF PUBLIC HEALTH; THE CONFERENCE OF BOSTON TEACHING HOSPITALS, INC.; and GREATER NEW YORK HOSPITAL ASSOCIATION, 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 ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the U.S. Department of Health and Human Services, Defendants.	C.A. No. 1:25-CV-10340-AK

DECLARATION OF TINA L. CHENG, M.D.

I, Dr. Tina L. Cheng, declare as follows:

1. I am over the age of majority, of sound mind, and competent to execute this Declaration. The statements and facts contained herein are true and correct, and they are based either on my personal knowledge or on my review of business records.

2. Cincinnati Children's Hospital Medical Center ("CCHMC") is a nonprofit, comprehensive pediatric health system. As a leader in research and education, CCHMC is consistently ranked as one of America's best children's hospitals by U.S. News & World Report and is one of the top recipients of pediatric research grants from the National Institutes of Health

("NIH"). We are affiliated with the University of Cincinnati College of Medicine and a member of the Association of American Medical Colleges.

3. I have been employed at CCHMC and the University of Cincinnati since November 2020. I currently serve as the B.K. Rachford Professor and Chair of the Department of Pediatrics, University of Cincinnati, Director of the Cincinnati Children's Research Foundation, and Chief Medical Officer at CCHMC. In these roles I am familiar with the funding that the NIH provides to CCHMC to conduct federally sponsored, peer-reviewed scientific research.

4. Cincinnati Children's received $212 million in grant funding from the NIH in fiscal year 2024. CCHMC used those funds to conduct research addressing diseases of childhood and adolescence and their impact on adults, including asthma, allergies, autoimmune disorders, autism spectrum disorders, obesity, childhood cancers, and mental health. Many of these conditions are highlighted in the White House's Making America Healthy Again executive order. Pediatric research at the NIH is relatively underfunded. However, investing in research early in life can prevent or mitigate development of disease, making it a valuable investment. NIH funding allows us to study diseases and disorders, preventing death and disability, and reducing the impact of chronic diseases into adulthood. For example, discovery science and clinical trials research at CCHMC contributed to the discovery of surfactant proteins, genes, and treatments that have saved the lives of countless premature babies with respiratory distress syndrome. Finally, NIH has supported CCHMC in the training of the next generation of groundbreaking scientists.

5. The NIH reimburses CCHMC for Facilities & Administrative costs on NIH-sponsored grants issued to CCHMC as a negotiated, institution-specific rate. CCHMC's current negotiated rate is 60.5 percent. If the Defendants implement, apply, or enforce the Supplemental Guidance to the 2024 NIH Grants Policy Statement: Indirect Cost Rates (NOT-OD-25-068),

reducing the indirect cost rate to 15 percent for all grants issued to CCHMC, CCHMC estimates that it will lose $40 million or more per year in support of critical research.

6. This drastic lowering of the NIH indirect cost rate (and subsequent loss of funding) will greatly and negatively impact CCHMC's ability to conduct research impacting the health of children, adolescents, and adults, as well as jeopardizing the pre-eminence of the United States in the biomedical sciences. Indirect funds allow us to purchase and maintain equipment, facilities, information technology, digital security, and other infrastructure necessary to conduct critical research. The federal share of research support has declined over the years. CCHMC currently makes substantial investment in medical research to cover gaps and leverage extramural funding as well as provide direct support for research. If the reduced indirect cost rate of 15 percent is enforced, it will jeopardize life-saving research and result in job and economic losses in both Cincinnati and the state of Ohio.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed this 18th day of February, 2025 in Cincinnati, Ohio.

/s/ Tina L. Cheng

Dr. Tina L. Cheng
Chief Medical Officer
Cincinnati Children's Hospital Medical Center

EXHIBIT J

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

ASSOCIATION OF AMERICAN MEDICAL COLLEGES; THE AMERICAN ASSOCIATION OF COLLEGES OF PHARMACY; THE ASSOCIATION OF SCHOOLS AND PROGRAMS OF PUBLIC HEALTH; THE CONFERENCE OF BOSTON TEACHING HOSPITALS, INC.; and GREATER NEW YORK HOSPITAL ASSOCIATION, 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 ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the U.S. Department of Health and Human Services, Defendants.	C.A. No. 1:25-CV-10340-AK

DECLARATION OF Clifford Hudis, MD

I, Clifford Hudis, MD, declare as follows:

1. I am Chief Executive Officer of the American Society of Clinical Oncology, Inc. ("ASCO" or the "Society"). In my role, I oversee ASCO programs and policies that help to realize our vision for a world in which cancer is prevented or cured, and every survivor is healthy. Through its funding of clinical trials of new treatments, the National Institutes of Health play a critical role in achieving that vision. In my official capacity and based on my personal knowledge and other

sources of information that I have obtained and reviewed in my official capacity, I am familiar with, and if called upon to do so, would be competent to testify to, the facts and circumstances set forth herein.

2. At some point during their lifetimes, an estimated 40.5% of Americans will be diagnosed with cancer, a disease that can develop anywhere in the body. There are many types of cancer, and they can differ greatly in the ways they grow, spread, and respond to treatment. Cancer is among the leading causes of death worldwide. Despite significant strides made in preventing and treating cancer, it remains the second leading cause of death for adults and a leading cause of death for children of all ages in the U.S. In 2024, the nation was predicted to experience a historic high in new cancer diagnoses, over 2 million cases. While cancer diagnoses traditionally have been more common among older Americans, there is a noticeable shift, with individuals aged 50 to 64 growing in numbers for people with cancer.

3. Founded in 1964, ASCO is a professional organization for physicians and oncology professionals caring for people with cancer. Together with our network of more than 51,000 oncology professionals, we work to realize our mission of conquering cancer through research, education, and promotion of the highest quality patient care. ASCO provides resources in education, policy, the pioneering of clinical research, and above all, advancing the care for patients with cancer. ASCO and its affiliates, including Conquer Cancer, the ASCO Foundation ("Conquer Cancer"), have awarded more than 2,200 grants to cancer researchers carrying out cutting edge science. In 2024, Conquer Cancer awarded more than $11 million to fund research to improve the lives of cancer patients.

4. Federally funded cancer research has had a role in every major advance against this disease. For many cancer patients, participation in clinical trials is a critical standard of care option.

The National Institutes of Health ("NIH") is the largest public funder of cancer research in the world. It fosters collaboration among researchers, institutions, and life sciences companies. This collaborative approach accelerates the pace of discovery and ensures that research findings are translated into real-world applications. Millions of Americans are alive and active in their communities thanks to federally funded cancer research. A record 18 million American cancer survivors are alive today, up from just 3 million in 1971, and mortality rates have declined 29% since 1991. The National Cancer Institute ("NCI") of the NIH fills urgent, unmet needs by supporting research that private industry has little incentive to conduct, such as studies focused on prevention and screening, treatment for rare cancers, and studies comparing the effectiveness and safety of apparently similar treatments, and has funded most of the foundational science behind exciting new cancer treatments like CAR-T and immunotherapy. The NIH clinical research system is a widely respected and highly effective engine for progress against cancer. NIH-supported research enables innovative clinical research designs, which accelerate the benefits of cancer research across the United States while decreasing risk to patients.

5. Drastic cuts, particularly with little notice, such as those set forth in the February 7, 2025 directive issued by the NIH, are likely to hurt patients with cancer and could end America's pre-eminence as a leader in cancer research. These cuts are likely to halt or otherwise compromise existing trials and prevent planned clinical studies, impede the work of sophisticated medical labs across the country, alter the future of young researchers, diminish Americans' access to new cancer treatments for years to come, and jeopardize our historic technical and scientific leadership. We expect that, if the NIH's Facilities and Administration ("F&A") rate is reduced as directed, it will be materially harder for universities and institutions be able to attract and employ physician researchers who also provide treatment to patients in addition to their clinical trial responsibilities,

removing a vital source of care for cancer patients around the country. This loss would be acutely felt outside of urban centers, at the hospitals, medical centers, and community clinics across the country that participate in our national clinical trials system. Without funding to support vital infrastructure, some of these sources of care will not be able to sustain trial participation.

6. For many cancer patients, participation in clinical trials is a critical standard of care option. NIH support for innovative trial design allows patients to safely participate in, and more quickly benefit from cancer research. A 2022 study found that over the last 40 years, clinical trials performed within federally funded trials prolonged the lives of patients with cancer by at least 14.2 million life-years and cost approximately just $326 in federal investment per each life-year added. Notably, rate cuts would likely affect human subjects research protections, an essential component of ethical research conducted in the United States.

7. Children with cancer are likely to bear a disproportionate amount of this pain – studies have found that it takes an average additional 6.5 years for a newly developed treatment to move into pediatric trials after it has been approved for adults. Because children are also enrolled in clinical trials at higher rates than adults, this funding cut would be likely to disproportionately impact the care of sick children and their families. Approximately 15,000 children are diagnosed with cancer annually in the United States—and most of these children will be treated on a federally funded and supported trial if one is available. If funding is drastically reduced under the NIH directive, cancer patients, especially children, may have reduced access to cutting edge treatments due to the inevitable reduction in the number of institutions able to conduct cancer clinical trials.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed this 18th day of February, 2025 in Alexandria, Virginia.

DocuSigned by:
EFEAF44FD7904D9...

Clifford Hudis, MD

Chief Executive Officer

American Society of Clinical Oncology, Inc.

EXHIBIT K

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

ASSOCIATION OF AMERICAN MEDICAL COLLEGES; THE AMERICAN ASSOCIATION OF COLLEGES OF PHARMACY; THE ASSOCIATION OF SCHOOLS AND PROGRAMS OF PUBLIC HEALTH; THE CONFERENCE OF BOSTON TEACHING HOSPITALS, INC.; and GREATER NEW YORK HOSPITAL ASSOCIATION, 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 ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the U.S. Department of Health and Human Services, Defendants.	C.A. No. 1:25-CV-10340-AK

DECLARATION OF CALANEET BALAS

I, Calaneet Balas, declare as follows:

1. I am CEO and President of The ALS Association, a leading national nonprofit organization dedicated to fighting Amyotrophic Lateral Sclerosis ("ALS") through advocacy, research, and patient support. In my official capacity and based on my personal knowledge and other sources of information that I have obtained and reviewed in my official capacity, I am familiar with, and if called upon to do so, would be competent to testify to, the facts and circumstances set forth herein.

2. ALS is a fatal neurodegenerative disease with no known cure and limited treatment options. Clinical research is vital to advancing our understanding of the disease and improving patient care. The proposed funding cuts from the National Institutes of Health ("NIH") will drastically limit the ability of academic medical centers to initiate and sustain clinical trials, leading to:

a. Delays in Critical ALS Trials. ALS clinical trials require substantial funding, infrastructure, and expertise provided by leading academic institutions. The NIH's proposed reduction in indirect, or Facilities and Administrative ("F&A"), funding will inevitably delay new trials and hinder recruitment efforts. F&A fundings allows for trial sites to hire and sustain trial personnel such as research coordinators and provide training for initiation and recruitment of trials.

b. Fewer Trial Opportunities for Patients. ALS progresses rapidly, and access to experimental treatments through clinical trials is often the only hope for patients. If academic medical centers scale back or cancel trials due to the NIH's proposed funding reduction, patients will lose access to potentially life-extending or life-improving treatments. Only about 10 percent of ALS patients participate in trials because of the limited trial opportunities in a rare disease like ALS. Reduction in trials will mean even fewer people living with ALS will be able to be recruited and retained for trials. Fewer trials also means that there are less opportunities to test safety and efficacy of experimental therapies that could slow, stop, or restore disease function.

c. Hindrance to Drug Development. NIH-funded research has been instrumental in identifying promising ALS therapies. Cutting IDC reimbursements will slow innovation and discourage researchers from pursuing high-risk, high-reward projects. F&A

costs are also usually used by universities to offset the costs for laboratory training and stipends for early-stage scientists such as post-docs and junior faculty. Cuts to F&A funding will most certainly lead to layoffs for younger and emerging scientists, which will create a vacuum in workforce and reduce novel and innovative ideas coming into the research ecosystem for decades to come.

3. The ALS community already faces barriers to clinical trial access due to stringent eligibility criteria and limited trial availability. The NIH's February 7, 2025 directive would exacerbate these challenges by reducing the number of institutions able to sponsor ALS trials. This reduction will have a disproportionately harmful impact on patients, particularly those in underserved or rural areas who rely on academic medical centers for access to cutting-edge therapies. We know that clinical trial sites currently rely on both nonprofit and government entities for funding of multi-disciplinary care centers as part of the university research network. The NIH's proposal will mean fewer clinics, fewer care personnel, and reduced capacity to provide multidisciplinary care, which has been shown to be one of the most effective treatments for ALS.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed this _18th_ day of February, 2025 in Arlington, Virginia.

/s/

Calaneet Balas
President and CEO
The ALS Association

EXHIBIT L

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

ASSOCIATION OF AMERICAN MEDICAL COLLEGES; THE AMERICAN ASSOCIATION OF COLLEGES OF PHARMACY; THE ASSOCIATION OF SCHOOLS AND PROGRAMS OF PUBLIC HEALTH; THE CONFERENCE OF BOSTON TEACHING HOSPITALS, INC.; and GREATER NEW YORK HOSPITAL ASSOCIATION, 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 ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the U.S. Department of Health and Human Services, Defendants.	C.A. No. 1:25-CV-10340-AK

DECLARATION OF PATRICIA A. GENTILE, Ed.D

I, Patricia A. Gentile, declare as follows:

1. I am Interim Executive Director at the LAM Foundation, a 501(c)(3) nonprofit organization. In my official capacity and based on my personal knowledge and other sources of information that I have obtained and reviewed in my official capacity, I am familiar with, and if called upon to do so, would be competent to testify to, the facts and circumstances set forth herein.

2. Lymphangioleiomyomatosis (LAM) is a rare and deadly lung disease that almost exclusively affects women. The LAM Foundation has been the global leader in LAM research and patient support for thirty years. Founded by a mother of a LAM patient and her pulmonologist, the

organization has grown to register more than 4,200 diagnosed women with LAM worldwide, three quarters of whom reside in the United States. Through its efforts, seventy-four international LAM clinics have been established, and a dedicated network of researchers has emerged.

3. Public investment—especially through funding from the U.S. Department of Defense ("DoD") and the National Institutes of Health ("NIH")—has been the driving force behind breakthroughs in LAM diagnosis and treatment. In collaboration with NIH, the LAM Foundation played a critical role in securing Food and Drug Administration approval for Rapamune (Sirolimus) in 2015, the first and only drug proven to slow LAM progression. Further research led to the discovery of VEGF-D, a biomarker that enables earlier and less invasive diagnosis, eliminating the need for a lung biopsy in many cases. Early detection of LAM is crucial, and federal funding continues to propel advancements in diagnostic technology. Artificial intelligence and machine learning are revolutionizing radiology, offering the potential to identify LAM with greater accuracy and efficiency. Without sustained NIH support, these life-saving innovations will stall, and women will continue to go undiagnosed until it is too late.

4. Unlike more common diseases, LAM has not attracted significant investment from the pharmaceutical industry. The LAM Foundation's ability to fund early-stage research has been pivotal in bridging this gap, providing seed grants that have resulted in nearly **$90 million in public and private funding**, including crucial NIH support. However, without the ability for research institutions to apply for grants with sustainable indirect costs, promising scientific discoveries will never reach the clinical trials stage.

5. History has proven that public investment in rare disease research yields an enormous return—not only for LAM patients but for the broader medical community. For example, Rapamune has since been found effective for Castleman's Disease and for TSC-LAM, benefitting both men and

women. Below is a chart from The LAM Foundation in 2023, demonstrating the significant return on investment of a private-public funding model in advancing medical research and benefiting the American public:

Subsequent funding success by award category:

	Number of TLF awards	TLF award (M $)	Subsequent TLF-related grants (number)	Subsequent TLF-related grants (M $)	Subsequent related NIH grants (number)	Subsequent related NIH grants (M $)	Subsequent related DoD grants (number)	Subsequent related DoD grants (M $)
F - Fellowship Award (ended 2014)	31	$3.92	6	$9.34	2	$1.33	1	$0.15
C-Career Development (started 2017)	8	$1.18	0	$0.00	1	$1.85	0	$0.00
S - Special Project Award	18	$0.83	3	$3.55	1	$0.92	0	$0.00
SG - Seed Grant Award	4	$0.04	0	$0.00	0	$0.00	0	$0.00
P - Pilot Award	52	$1.57	3	$2.64	8	$17.34	4	$1.60
E - Established Investigator Award	24	$3.41	6	$9.49	8	$14.16	10	$5.50
PB - Patient Benefit Award	6	$0.14	0	$0.00	0	$0.00	0	$0.00
B-Biomarker Innovation Grant	6	$0.19	2	$4.10	5	$11.44	9	$4.37
Br-Bridge Grant	1	$0.10	1	$1.84	0	$0.00	0	$0.00
D - Designated Award	1	$0.15	0	$0.00	0	$0.00	0	$0.00
G - Grant in Aid	3	$0.20	0	$0.00	0	$0.00	0	$0.00
P - Pilot Clinical Trial	1	$0.05	0	$0.00	0	$0.00	0	$0.00
TOTAL	155	$11.77	21	$30.96	25	$47.04	24	$11.62

6. Further research is needed to refine treatment strategies, explore next-generation mTOR inhibitors, and investigate gene and cell-based therapies that may offer curative potential. Despite successes, 20% of LAM patients do not respond to Rapamune and require alternate treatment options. Without sustained public funding, the hope for new therapies will be extinguished, leaving thousands of women with no viable path forward.

7. The NIH's proposed cut to the indirect, or Facilities and Administrative ("F&A") cost rate, would cripple the abilities of universities and research institutions to conduct groundbreaking studies in rare diseases like LAM. If the F&A rate is reduced, institutions will be forced to scale back or abandon vital research efforts, not just for LAM but for countless other life-threatening conditions. The NIH's proposed rate reduction would set back decades of progress, jeopardizing both current and future research that saves lives.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed this 17 day of February, 2025 in Cincinnati, Ohio.

/s/ pgentile

Dr. Patricia Gentile
Interim Executive Director
The LAM Foundation

CERTIFICATE OF SERVICE

Counsel for Plaintiffs in the above captioned case certify that they have submitted the foregoing document with the clerk of court for the District of Massachusetts, using the electronic case filing system of the Court. Counsel for Plaintiffs hereby certify that they have certified all parties electronically or by another manner authorized by Fed. R. Civ. P. 5(b)(2).

Dated: February 18, 2025

/s/ John P. Bueker

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