

Nos. 25-1343, 25-1344, 25-1345

**IN THE UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT**

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

v.

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

(Caption continued on inside front cover)

On Appeal from the United States District Court for the District of Massachusetts, No. 1:25-cv-10340 (Hon. Angel Kelley)

BRIEF OF *AMICI CURIAE* AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, AMERICAN COLLEGE OF PHYSICIANS, AMERICAN PSYCHIATRIC ASSOCIATION, AMERICAN COLLEGE OF CHEST PHYSICIANS, AMERICAN COLLEGE OF EMERGENCY PHYSICIANS, AMERICAN COLLEGE OF RADIOLOGY, AMERICAN GERIATRICS SOCIETY, AMERICAN SOCIETY FOR CLINICAL PATHOLOGY, AMERICAN UROLOGICAL ASSOCIATION, COUNCIL OF MEDICAL SPECIALTY SOCIETIES, AND SOCIETY FOR MATERNAL-FETAL MEDICINE IN SUPPORT OF APPELLEES

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Plaintiffs-Appellees,

v.

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

Defendants-Appellants.

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

Plaintiffs-Appellees,

v.

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

Defendants-Appellants.

RULE 26.1 CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure, *amici curiae* state that they have no parent corporation and that no publicly traded corporation owns 10% or more of their stock. *Amici* are not aware of any publicly held corporation that has a direct financial interest in the outcome of this appeal.

TABLE OF CONTENTS

	Page
INTEREST OF THE <i>AMICI CURIAE</i>	1
INTRODUCTION AND SUMMARY OF THE ARGUMENT	7
ARGUMENT.....	9
A. NIH Funding Is Critical To The Advancement Of Medical Care.....	9
B. NIH Funding Also Is Critical For The Development Of Clinical Practice Protocols And Guidelines.....	14
C. Disrupting NIH Funding Will Set Back The Advancement Of Medical Care	23
CONCLUSION	28

TABLE OF AUTHORITIES

Rule and Regulation	Page(s)
45 C.F.R. § 75.414(a)	23
Fed. R. App. P. 29(a)(4)(E)	1
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INTEREST OF THE *AMICI CURIAE*

Amici are organizations of health care professionals. *Amici*'s members and their patients will be directly affected by the outcome of this case.¹

The American College of Obstetricians and Gynecologists (ACOG) is the nation's leading group of physicians providing evidence-based obstetric and gynecologic care. As a private, voluntary nonprofit membership organization of more than 60,000 members, ACOG strongly advocates for equitable, exceptional, and respectful care for all people in need of obstetric and gynecologic care; maintains the highest standards of clinical practice and continuing education of its members; promotes patient education; and increases awareness among its members and the public of the changing issues facing patients and their families and communities. ACOG advances its mission by preparing clinical practice guidelines and training materials for medical practitioners to use to treat their patients.

¹ No counsel for a party authored this brief in whole or in part, and no person other than *amici curiae*, their members, or their counsel contributed money that was intended to fund the preparation or submission of this brief. See Fed. R. App. P. 29(a)(4)(E). All parties have consented to the filing of this brief.

The American College of Physicians (ACP) is the largest medical specialty organization in the United States. Its membership includes 161,000 internal medicine physicians, related subspecialists, and medical students.

With more than 39,200 members, the American Psychiatric Association (APA) is the world's largest and leading organization of physicians who specialize in research, diagnosis, and treatment of mental and substance use disorders. APA creates and publishes the Diagnostic and Statistical Manual of Mental Disorders (DSM), and evidence-based recommendations for treatment of psychiatric disorders, including through publication of clinical practice guidelines and quality measures and the American Journal of Psychiatry – the world's leading psychiatric journal – disseminating current research to keep the field up to date on diagnosis and treatment of mental illness.

The American College of Chest Physicians (CHEST) is a global leader in pulmonary, critical care, and sleep medicine. Established in 1935, CHEST supports more than 21,000 clinicians through education, research, and advocacy. CHEST and its members rely on NIH-funded research to make informed clinical decisions, to advance guidelines used by clinicians

in day-to-day practice, and to advance respiratory, critical care, and sleep medicine.

The American College of Emergency Physicians (ACEP) represents more than 38,000 emergency physicians, emergency medicine residents, and medical students. ACEP promotes the highest quality of emergency care and is the leading advocate for emergency physicians, their patients, and the public. ACEP continually strives to improve the quality of emergency medical services through the development of evidence-based clinical policies, funding emergency medicine research, providing public education on emergency care and disaster preparedness, legislative and regulatory advocacy efforts, providing industry-leading continuing medical education in the form of educational conferences, online training, professional references and news magazines, and publishing *Annals of Emergency Medicine*, the specialty's leading peer-reviewed scientific journal.

The American College of Radiology (ACR) is a professional association comprised of more than 42,000 diagnostic radiologists, radiation oncologists, interventional radiologists, nuclear medicine physicians, and medical physicists, empowering them to deliver exceptional patient care through quality and safety, advocacy and innovation. ACR creates and

convenes communities of experts to serve as the voices of radiology, demonstrating value and setting standards to advance the field and practice.

The American Geriatrics Society (AGS) is a nationwide, not-for-profit society of geriatrics healthcare professionals founded in 1942 and dedicated to improving the health, independence, and quality of life of older people. AGS's 6,000-plus members include geriatricians, geriatrics nurse practitioners, social workers, family practitioners, physician associates, pharmacists, and internists who are pioneers in serious illness care for older individuals, with a focus on championing interprofessional teams, eliciting personal care goals, and treating older people as whole persons. AGS advocates for policies and programs that support the health, independence, and quality of life for people as they age.

The American Society for Clinical Pathology (ASCP) is the world's largest professional membership organization for pathologists and laboratory professionals. It is comprised of more than 100,000 anatomic and clinical pathologists, laboratory professionals, residents, and students. NIH-funded research is critical to enhancing the diagnostic information provided by pathologists and laboratory professionals for use by every clinical specialty, which is critical to patient care.

Founded in 1902 and headquartered near Baltimore, Maryland, the American Urological Association (AUA) is a leading advocate for the specialty of urology and has more than 26,000 members throughout the world. The AUA is a premier urologic association, providing invaluable support to the urologic community as it pursues its mission of fostering the highest standards of urologic care through education, research, and the formulation of health policy.

Founded 60 years ago, the Council of Medical Specialty Societies (CMSS) provides an independent forum for medical specialty societies to discuss issues of national interest and mutual concern, advancing the collective voice of specialty societies in support of physicians and the patients they serve. Over the years, it has expanded to encompass 55 specialty societies, representing over 800,000 physicians.

Founded in 1977, the Society for Maternal-Fetal Medicine (SMFM) is the medical professional society for maternal-fetal medicine subspecialists, who are obstetricians with additional training in high-risk pregnancies. SMFM represents more than 6,500 members who care for high-risk pregnant people and provides education, promotes research, and engages in advocacy to advance optimal and equitable perinatal outcomes for all people who desire and experience pregnancy. SMFM and its members are

dedicated to ensuring that all medically appropriate treatment options are available for individuals experiencing a high-risk pregnancy.

On February 7, 2025, the National Institutes of Health (NIH) issued a notice stating that it would reduce funding rates for indirect costs for all existing and future grants to 15%, instead of funding indirect costs at the separately negotiated rate in every grant (the Rate Change Notice). The question before this Court is whether the Rate Change Notice is arbitrary and capricious. The district court correctly held that the Rate Change Notice is unlawful and permanently enjoined the notice.

Amici submit this brief to explain how, if not enjoined, the Rate Change Notice will harm *amici*, their members, and patients. The Rate Change Notice will delay and impede critical research studies that inform *amici*'s development of clinical guidelines and other diagnostic and treatment manuals. Clinical guidelines are designed to marshal the best medical evidence in order to provide scientifically current recommendations about appropriate treatments and treatment protocols to the clinicians who provide frontline care to the American public. The Rate Change Notice threatens to set back medical treatment and advances in healthcare for years.

INTRODUCTION AND SUMMARY OF THE ARGUMENT

Amici file this brief to explain some of the profound effects on healthcare of the NIH's across-the-board cut to indirect costs in existing and future grants.

The NIH, which is funded through taxpayer dollars, is committed to scientific research and public health. The NIH plays a highly successful and critical role in the delivery and improvement of medical care in the United States and across the world. It is the leading funder of medical research in the world. That funding is critical for scientific innovation that improves health outcomes across the country, including clinical trials and the development of new treatment techniques and therapies. It has been the driving force for countless medical breakthroughs, including in cancer prevention and treatment and improvements in the quality of life for cancer patients and survivors, mental health treatment, reproductive healthcare and in vitro fertilization, and genetic testing that leads to timely treatment and risk-reduction measures, including during pregnancy. Together, NIH institutes and centers have made significant contributions to extending the health span of the public.

Research funded by the NIH is critical for professional associations to support the development of clinical practice guidelines and other clinical

resources that improve patient care. Organizations like *amici* develop clinical practice guidelines and other clinical resources so that healthcare professionals can provide the most effective, evidence-based, and scientifically current care to patients. Clinical practice guidelines and other clinical resources incorporate the latest scientific evidence and findings into recommendations that clinicians use to diagnose disease, assess potential treatment and diagnostic options for their patients, and measure treatment outcomes. *Amici* also develop other practical guidance and training materials that medical professionals use to treat their patients and to improve their skills.

NIH-funded research is integral to the care that people receive, because NIH-funded studies often serve as the basis for determining the best course of treatment for a particular patient. *Amici* routinely rely on NIH-funded research to create and update their clinical practice guidelines and other guidance materials in light of new and updated research.

A disruption in NIH funding of medical research and clinical trials will profoundly set back the advancement of medical care. Not only will a disruption in NIH funding destroy critical ongoing clinical trials and medical studies, it will impair the development of clinical practice protocols and guidelines and therefore will harm patients. Those protocols and

guidelines will be based on less reliable and fewer up-to-date studies. Moreover, guidelines and treatment protocols will be updated less frequently, thereby reducing health care professionals' access to the latest insights into patient care. This will dramatically slow the pace of medical advancements – advancements that previously have made it possible to reduce the morbidity and mortality rates associated with the conditions that *amici*'s members treat. The ultimate result will be to set back innovation and clinical care by years.

Given the exceptional public importance of NIH-funded research to the practice of medicine, *amici* respectfully urge the Court to affirm the district court's permanent injunction.

ARGUMENT

A. NIH Funding Is Critical To The Advancement Of Medical Care

NIH funding is critical to health sciences research in the United States. The NIH is the “largest single public funder of biomedical and behavioral research in the world.”² In 2024, over 80% of the NIH's nearly

² See NIH, *Impact of NIH Research, Direct Economic Contributions* (June 5, 2025), <https://perma.cc/NK7C-GG4E>.

\$50 billion budget was used to support research at over 2,500 institutions.³ These investments of taxpayer dollars are critical to developing the health science research that improves health outcomes for people across the country and around the world.⁴

NIH-funded projects are particularly valued in the medical community because of the high standards that the NIH sets for the projects it funds. Indeed, one category of NIH grants – R01 grants – is widely considered “the gold standard” for medical research⁵; these grants are awarded only for projects that are “discrete, specified, [and] circumscribed” and supported by “strong preliminary data.”⁶ As a result, NIH funding has an outsized effect on medical research, because NIH funding can spur additional private funding: “[E]very \$1 increase in publicly funded research

³ See Patrick Boyle, Am. Ass’n of Med. Colls., *What’s at Stake When Clinical Trials Research Gets Cut* (Apr. 24, 2025), <https://perma.cc/AHA9-NP3K> (AAMC, *What’s at Stake*).

⁴ Press Release, Am. Heart Ass’n, *A Strong National Institutes of Health Is Critical for the Future of Biomedical Research and Innovation* (Feb. 19, 2025), <https://perma.cc/4CVD-2UKL> (Am. Heart Ass’n Press Release).

⁵ See, e.g., Anna Kaatz et al., *A Quantitative Linguistic Analysis of National Institutes of Health R01 Application Critiques from Investigators at One Institution*, 90 Acad. Med. 69, 69 (2015), <https://perma.cc/2653-4C6K>.

⁶ NIH, *Comparing Popular Research Project Grants – R01, R03, and R21* (Apr. 9, 2024), <https://perma.cc/6CUV-GWP9> (NIH, *Comparing Popular Research*).

from the NIH leads to an additional \$8.38 of industry research and development investment.”⁷

As an example, research funded by the NIH at its National Cancer Institute (NCI) has played a role in every major advancement related to cancer prevention, detection, and treatment in the past 40 years. The clinical trials performed within the NCI’s National Clinical Trials Network over that time have prolonged the lives of cancer patients by at least 14.2 million life-years, at a cost of just \$326 in federal investment per life-year.⁸ Given this track record, the ongoing research funded by the NIH has the potential to lead to transformative breakthroughs for cancer care.

Similarly, the National Institute of Mental Health has been funding and making progress in identifying biomarkers for depression and other mental health disorders.⁹ Biomarkers serve as measurable indicators for diseases, so research in identifying biomarkers for mental health disorders has helped clinicians more precisely diagnose patients with mental health

⁷ Am. Heart Ass’n Press Release, *supra* n.4.

⁸ Joseph M. Unger et al., *Population, Clinical, and Scientific Impact of Nat’l Cancer Inst.’s Nat’l Clinical Trials Network Treatment Studies*, 41 J. Clin. Oncology No. 11 (Dec. 8, 2022), <https://perma.cc/WJ9X-YBYH>.

⁹ See, e.g., NIH, *Funding Opportunity Title – Precision Mental Health: Develop Tools to Inform Treatment Selection in Depression (UG3/UH3 Clinical Trial Optional)* (last visited June 13, 2025), <https://perma.cc/E7G3-Y95R>.

disorders. It is critical for that funding to continue, to prevent both the loss of momentum and the loss of previous investments.

Many other life-saving medical breakthroughs have resulted from NIH funding. One recent example is the development of vaccines against human papillomavirus (HPV), which is a leading cause of cervical cancer and other tumors.¹⁰ The NIH has provided the “vast majority” of the funding for the development of the vaccines.¹¹ The vaccines are incredibly effective – one study, by the Centers for Disease Control and Prevention, concluded that HPV vaccines can prevent 92% of cancers caused by HPV.¹² As a result, HPV vaccines have saved thousands of lives in the United States: Among teenage girls, infections that cause most HPV cancers have dropped 88%, and among young adult women, infections that cause most HPV cancers have dropped 81%.¹³

NIH funding also has been critical to developing new prescription drugs. Over 99% of the prescription drugs approved by the Food and Drug

¹⁰ Lasker Found., *2017 Lasker-DeBakey Clinical Medical Research Award* (last visited June 11, 2025), <https://perma.cc/PL8P-YB2P>.

¹¹ *Id.*

¹² Press Release, Ctrs. for Disease Control, *An Estimated 92% of Cancers Caused by HPV Could be Prevented by Vaccine* (Aug. 22, 2019), <https://perma.cc/WJ7B-5MBQ>.

¹³ Ctrs. for Disease Control, *HPV Vaccination* (Aug. 20, 2024), <https://perma.cc/T5RK-38PT>.

Administration between 2010 and 2019 were developed in part using NIH funding, including 100% of the drugs approved between 2010 and 2016.¹⁴ Among those are drugs that treat cancer, including drugs that directly target cancerous cells and drugs that help with managing the side effects of chemotherapy.¹⁵

Indeed, the list of NIH-funded medical innovations is nearly endless. They include development of the first artificial heart valves; identification of BRCA gene mutations that increase the risk of multiple cancers (including breast and prostate cancer); development of specialized printers for bioprinting of human tissue and lab-grown organs for transplants; discovery of biomarkers that allow the diagnosis of dementia in still-living persons; development of naloxone to reverse the effects of opioid overdose; development of early stage therapeutics and work to identify biomarkers for depression; implementation of nationwide testing for phenylketonuria (PKU), a genetic disease that can cause seizures, deafness, and intellectual disabilities; development and approval of the first medication for

¹⁴ Ekaterina Galkina Cleary et al., *Comparison of Research Spending on New Drug Approvals by the National Institutes of Health vs the Pharmaceutical Industry, 2010-2019*, 4 JAMA Health Forum 1, 1 (2023), <https://perma.cc/A5VJ-JEL6>.

¹⁵ Ekaterina Galkina Cleary & Fred D. Ledley, *NIH Funding for Research Underlying New Cancer Therapies*, 21 Lancet Oncology 755, 755 (2020).

postpartum depression; and development of cochlear implants – among much, much else.¹⁶ In short, NIH funding has been a key driver of advances in treatment in every field of medicine, benefiting nearly every patient in the United States and beyond.

B. NIH Funding Also Is Critical For The Development Of Clinical Practice Protocols And Guidelines

In addition to driving medical breakthroughs and new medical treatment options, NIH funding also is critical to the development of clinical practice guidelines and other guidance documents. Those guidance documents transform medical research into clinical practices and treatment by providing protocols on which clinicians rely to treat patients.

Amici's guidelines are written resources that medical professionals across the United States use to make informed decisions about patient care.¹⁷ The guidelines provide recommendations for how to treat patients based on the latest research in the field: They “move scientific findings into practice” by setting out clinical recommendations and “describing and appraising the scientific evidence and reasoning (the likely benefits and

¹⁶ NIH, *Impact of NIH Research – Improving Health* (May 2025), <https://perma.cc/NC82-2LEL>.

¹⁷ Robin Graham et al., Inst. of Med., *Clinical Practice Guidelines We Can Trust* 123 (2011).

harms)” behind those recommendations.¹⁸ By helping to bridge the gap between research and practice, the guidelines play a critical role in ensuring that patients receive the best care possible in light of the latest medical research.¹⁹

Amici and other medical specialty and healthcare professional organizations develop clinical practice guidelines and treatment protocols after reviewing the medical studies that assess possible courses of treatment.²⁰ For example:

- *Amicus* ACOG has published clinical practice guidelines on a number of key topics in the field of obstetrics and gynecology based on NIH-funded research, including on managing first and second stage labor,²¹ predicting and preventing spontaneous pre-term

¹⁸ *Id.* at 1, 12.

¹⁹ Mihaela C. Munteanu & Julie Choi Jordan, *A View into Clinical Practice Guidelines: Who Uses Them, Who Doesn't and Possibly, Why*, 1 *Qualitative Rsrch. Med. & Healthcare* 44, 48 (2017), <https://perma.cc/S8DD-Q2B7>.

²⁰ See ACOG, *List of Titles* (June 2025), <https://perma.cc/2VA4-Y8FM>.

²¹ ACOG, *Clinical Practice Guideline: First and Second Stage Labor Management*, 143 *Obstetrics & Gynecology* 144 (2024) (ACOG, *First and Second Stage Labor*).

birth,²² managing twin and triplet pregnancies,²³ osteoporosis,²⁴ menopause,²⁵ and breast cancer screening.²⁶

- *Amicus* APA has published clinical guidance on the prevention and treatment of delirium,²⁷ treatment of patients with borderline personality disorder,²⁸ and treatment of patients with eating disorders.²⁹ APA also publishes the Diagnostic and Statistical Manual of Mental Disorders (DSM), which is the most comprehensive, current, and valuable resource to guide mental health clinicians to diagnose and classify mental disorders. APA updates the DSM “on a rolling basis as warranted by advances in the science of mental disorders.”³⁰
- *Amicus* ACEP has published clinical policies on the use of thrombolytics (clot-busting medication) to manage acute ischemic

²² ACOG, *Practice Bulletin 234: Prediction and Prevention of Spontaneous Preterm Birth*, 138 *Obstetrics & Gynecology* 2 (2021).

²³ ACOG, *Practice Bulletin 231: Multifetal Gestations: Twin, Triplet, and Higher-Order Multifetal Pregnancies*, 137 *Obstetrics & Gynecology* 6 (2021).

²⁴ ACOG, *Clinical Practice Guideline: Osteoporosis Prevention, Screening, and Diagnosis*, 138 *Obstetrics & Gynecology* 494 (2021) (ACOG, *Osteoporosis Prevention*).

²⁵ ACOG, *Clinical Practice Guideline: Management of Postmenopausal Osteoporosis*, 139 *Obstetrics & Gynecology* 4 (2022) (ACOG, *Management of Postmenopausal Osteoporosis*).

²⁶ ACOG, *Committee Opinion 625: Management of Women with Dense Breasts Diagnosed by Mammography*, 125 *Obstetrics & Gynecology* 3 (2015).

²⁷ APA, *The American Psychiatric Association Practice Guideline for the Prevention and Treatment of Delirium* (manuscript 2025), <https://perma.cc/Q3AL-PXR3> (APA, *Delirium*).

²⁸ APA, *Practice Guideline for the Treatment of Patients With Borderline Personality Disorder* (2d ed. 2025) (APA, *Borderline Personality Disorder*).

²⁹ APA, *Practice Guideline for the Treatment of Patients with Eating Disorders* (4th ed. 2023) (APA, *Eating Disorders*).

³⁰ APA, *Submit Proposals for Making Changes to DSM-5-TR* (last visited June 13, 2025), <https://perma.cc/K9KZ-F3Z8>.

strokes,³¹ and emergency department management of patients suffering from myocardial infarctions (heart attacks).³²

- *Amicus* ACR publishes appropriateness criteria, which are guidelines developed to assist referring physicians and other providers in their selection of the most appropriate imaging studies for a wide range of clinical conditions, including breast, cardiac, gastrointestinal, gynecologic and obstetric, pediatric and thoracic, urologic, vascular, interventional radiology.³³
- *Amicus* AGS has published guidance on potentially inappropriate medication use in older adults.³⁴
- *Amicus* AUA has published clinical guidance on screening for men at risk for prostate cancer,³⁵ including specific guidance for those at high risk of prostate cancer.³⁶

³¹ ACEP, *Clinical Policy: Use of Thrombolytics for the Management of Acute Ischemic Stroke in the Emergency Department*, 84 *Annals Emergency Med.* e57 (2024) (ACEP, *Use of Thrombolytics*).

³² ACEP, *Clinical Policy: Emergency Department Management of Patients Needing Reperfusion Therapy for Acute ST-Segment Elevation Myocardial Infarction*, 70 *Annals Emergency Med.* 724 (2017) (ACEP, *Emergency Department Management*).

³³ See, e.g., ACR, *ACR Appropriateness Criteria: Renal Failure* (2020), <https://perma.cc/NU6A-44PD>; ACR, *ACR Appropriateness Criteria: Second and Third Trimester Vaginal Bleeding* (2020), <https://perma.cc/TW9F-EN76>; ACR, *ACR Appropriateness Criteria: Second and Third Trimester Screening for Fetal Anomaly* (2020), <https://perma.cc/55LX-DXW4> (collectively, *ACR Appropriateness Criteria*).

³⁴ AGS, *American Geriatrics Society 2023 Updated AGS Beers Criteria for Potentially Inappropriate Medication Use in Older Adults*, 71 *J. Am. Geriatrics Soc'y* 2052 (2023) (AGS, *Potentially Inappropriate Medication Use*).

³⁵ AUA, *Early Detection of Prostate Cancer: AUA/SUO Guideline Part I: Prostate Cancer Screening*, 210 *J. Urology* 46 (2023).

³⁶ *Id.*

- *Amicus* SMFM has published clinical guidance on preventing preterm birth in clinical practice,³⁷ as well as guidance on reducing infant morbidity after preterm premature ruptures of membranes.³⁸

Amici follow a rigorous and systematic process for developing clinical guidelines. For example, *amici* start by selecting topics for developing guidelines that are “clinically important to the practice of” a particular medical specialty often based on “new or conflicting evidence” or the “prevalence of a condition or procedure.”³⁹ Then, a document-writing team comprised of subject-matter experts performs a comprehensive literature search to identify relevant evidence to review.⁴⁰ During the search for new literature, “[p]riority is given to high-quality systematic reviews, published evidence-based guidelines by clinical or public health organizations, randomized controlled trials . . . , and analytical observational studies.”⁴¹

³⁷ SMFM, *SMFM Statement: The Role of Cervical Pessary Placement to Prevent Preterm Birth in Clinical Practice*, 216 Am. J. Obstetrics & Gynecology BP8 (2017).

³⁸ SMFM, *SMFM Consult Series 71: Management of Previa and Periviable Preterm Prelabor Rupture of Membranes*, 231 Am. J. of Obstetrics & Gynecology PB2 (2024).

³⁹ ACOG, *Clinical Practice Guideline Methodology: Methodology*, 138 Obstetrics & Gynecology 518, 519 (2021) (ACOG, *Methodology*).

⁴⁰ *Id.* at 520.

⁴¹ *Id.*

These are precisely the types of studies that frequently receive and depend on NIH funding.⁴²

Amici monitor medical advances and their guidelines to ensure that the guidelines remain up to date. For example, *amicus* ACOG reviews its published clinical guidance documents for accuracy and continued relevance over time, and updates or reaffirms them to ensure they reflect the most up-to-date research.⁴³ Other *amici* do the same.

Unsurprisingly, NIH-funded studies are critical to developing and updating clinical practice guidelines. For example, ACOG's clinical practice guideline on first and second stage labor relies on an NIH-funded study on active pushing during labor to support several of its recommendations.⁴⁴ Both of ACOG's clinical practice guidelines on osteoporosis – *Osteoporosis Prevention, Screening, and Diagnosis*,⁴⁵ and *Management of Postmenopausal Osteoporosis*⁴⁶ – rely on an NIH study on osteoporosis

⁴² See, e.g., NIH, *Comparing Popular Research*, *supra* n.6.

⁴³ ACOG, *Methodology*, *supra* n.39, at 521.

⁴⁴ ACOG, *First and Second Stage Labor*, *supra* n.21, at 150-51 (citing William A. Grobman et al., *Association of the Duration of Active Pushing with Obstetric Outcomes*, 127 *Obstetrics & Gynecology* 667 (2016)).

⁴⁵ ACOG, *Osteoporosis Prevention*, *supra* n.24.

⁴⁶ ACOG, *Management of Postmenopausal Osteoporosis*, *supra* n.25.

prevention, diagnosis, and therapy.⁴⁷ Likewise, a variety of the criteria for imaging guidelines prepared by *amicus* ACR grew out of NIH-funded research.⁴⁸ *Amicus* APA also relies extensively on NIH-funded research to publish its guidance on prevention and treatment of delirium,⁴⁹ borderline personality disorder,⁵⁰ and eating disorders,⁵¹ and to regularly update the DSM. And *amicus* AUA's clinical guidance on screening for men at risk of prostate cancer relies on a nomogram (a type of model) developed to assist in clinical decision-making that was the result of NIH funding.⁵²

Similarly, the NIH funded a national lung cancer screening trial, which led to the discovery that screening with the use of low doses of

⁴⁷ ACOG, *Osteoporosis Prevention*, *supra* n.24, at 700-01 (citing NIH Consensus Development Panel on Osteoporosis Prevention, Diagnosis, and Therapy, *Osteoporosis Prevention, Diagnosis, and Therapy*, 285 J. Am. Med. Ass'n 785 (2001)).

⁴⁸ See ACR *Appropriateness Criteria*, *supra* n.33.

⁴⁹ *E.g.*, APA, *Delirium*, *supra* n.27 (citing Patricia S. Andrews et al., *Relationship Between Intensive Care Unit Delirium Severity and 2-Year Mortality and Health Care Utilization*, 29 Am. J. Critical Care 311 (2020)).

⁵⁰ *E.g.*, APA, *Borderline Personality Disorder*, *supra* n.28 (citing Anees Bahji et al., *Pharmacotherapies for Adults With Alcohol Use Disorders: A Systematic Review and Network Meta-Analysis*, 16 J. Addiction Med. 630 (2022)).

⁵¹ *E.g.*, APA, *Eating Disorders*, *supra* n.29 (citing Julian Baudinet et al., *Multi-Family Therapy for Eating Disorders: A Systematic Scoping Review of the Quantitative and Qualitative Findings*, 54 Int'l J. Eating Disorders 2095 (2021)).

⁵² AUA, *Early Detection of Prostate Cancer: AUA/SUO Guideline Part II: Considerations for a Prostate Biopsy*, 210 J. Urology 54, 55 (2024).

computed tomography reduced the mortality rate from lung cancer.⁵³ Based on the results of that NIH-funded trial, ACR developed its Lung Reporting and Data Systems, which is the standardized framework for characterizing and reporting imaging findings.⁵⁴

NIH funding also has revolutionized patient care for strokes. Funding from the National Institute of Neurological Disorders and Stroke has led to faster diagnoses of strokes, improved treatment decisions, and better recovery outcomes for stroke patients. To take one example, ACEP's clinical policies on the use of thrombolytics for acute ischemic strokes owe their very existence to NIH-funded research and regularly rely on NIH-funded studies to improve those policies.⁵⁵

Likewise, NIH-funded research has improved the treatment of myocardial infarctions. NIH-funded research has led to the development of

⁵³ Nat'l Lung Cancer Screening Trial Research Team, *Reduced Lung-Cancer Mortality with Low-Dose Computed Tomographic Screening*, 365 N. England J. Med. 395 (2011), <https://perma.cc/H4NX-43U6>.

⁵⁴ ACR, *Lung-RADS v2022: Assessment Categories and Management Recommendations*, 21 J. Am. College Radiology 473 (2024), <https://perma.cc/N3HV-N74G>.

⁵⁵ *E.g.*, ACEP, *Use of Thrombolytics*, *supra* n.31 (citing Amrou Sarraj et al., *Endovascular Thrombectomy for Acute Ischemic Strokes: Current US Access Paradigms and Optimization Methodology*, 51 Stroke 1207 (2020)).

thrombolytic agents that have been critical tools in unblocking clots.⁵⁶ NIH-funded research also has advanced the development of stenting and angioplasty to restore blood circulation following a heart attack.⁵⁷ Thus, NIH-funded research continues to inform ACEP's clinical policies on myocardial infarctions.

NIH-funded research also has advanced knowledge on all aspects of aging, including Alzheimer's disease and related dementias. NIH-funded research also informed *amicus* AGS's guidance on potentially inappropriate medication use in older adults.⁵⁸

As these examples demonstrate, NIH-funded studies play a crucial role in ensuring that medical professionals are able to make the best and most up-to-date decisions about what course of treatment to recommend to patients.

⁵⁶ *E.g.*, J.H. Chesebro et al., *Thrombolysis in Myocardial Infarction (TIMI) Trial, Phase I: A Comparison Between Intravenous Tissue Plasminogen Activator and Intravenous Streptokinase*, 76 *Circulation* 142 (1987).

⁵⁷ *E.g.*, ACEP, *Emergency Department Management*, *supra* n.32 (citing Michael J. Ward, *Incidence of Emergency Department Visits for ST-Elevation Myocardial Infarction in a Recent Six-Year Period in the United States*, 115 *Am. J. Cardiology* 167 (2015)).

⁵⁸ *E.g.*, AGS, *Potentially Inappropriate Medication Use*, *supra* n.34 (citing Laura N. Gitlin et al., *Targeting and Managing Behavioral Symptoms in Individuals with Dementia: A Randomized Trial of a Nonpharmacologic Intervention*, 58 *J. Am. Geriatric Soc'y* 1465 (2010)).

C. Disrupting NIH Funding Will Set Back The Advancement Of Medical Care

A disruption in NIH funding will lead to a pause – if not a complete cancellation – of many scientific studies. Funding for indirect costs is critical to medical research; it pays for building construction and maintenance, utilities, laboratory equipment maintenance, and for the faculty and staff who work on multiple studies. 45 C.F.R. § 75.414(a). As the district court concluded, the only “reasonable outcome” of a 15% cap to indirect costs “will be the discontinuing of research supported by” these funds. Memo. and Order on Mot. for Prelim. Inj. 35-36, *Ass’n of Am. Med. Colls.*, No. 25-10340 (D. Mass. Mar. 5, 2025), ECF No. 51 (Mem. Op.).

As the district court explained in its preliminary injunction opinion, researchers across the country have conclusively demonstrated that many studies will be immediately suspended if the Rate Change Notice goes into effect. Mem. Op. 58-60. The researchers provided declarations giving examples of the critical medical research likely to be affected, including:

- Research on the use of immunotherapy as a pathway for a cure to brain cancer in both adults and children⁵⁹;

⁵⁹ Declaration of David Paul Norton ¶ 4, *Ass’n of Am. Univs. v. Dep’t of Health & Human Servs.*, No. 25-cv-10346 (D. Mass. Feb. 10, 2025), ECF No. 2-13.

- Research aimed at providing for better outcomes for those with Parkinson’s disease⁶⁰;
- Genetic research in search of the root cause and potential treatments for Amyotrophic Lateral Sclerosis (also known as Lou Gehrig’s disease)⁶¹;
- Clinical trials aimed to accelerate improvements to dementia care⁶²;
- Research aimed at improving nutrition and healthy eating habits of preschool-aged children⁶³;
- Research focused on studying the early identification and prevention of coronary heart disease⁶⁴;
- Research focused on the pathophysiology of Alzheimer’s disease and how to improve treatments for patients with Alzheimer’s disease⁶⁵;
- Research focused on engineering nanoparticles to more efficiently and safely deliver cancer immunotherapy for breast cancer and other cancers⁶⁶; and
- Research focused on fetal development during pregnancy.⁶⁷

⁶⁰ *Id.*

⁶¹ *Id.*

⁶² Declaration of Dr. Greg Hirth ¶ 5, *Ass’n of Am. Univs. v. Dep’t of Health & Human Servs.*, No. 25-cv-10346 (D. Mass. Feb. 10, 2025), ECF No. 2-5.

⁶³ *Id.*

⁶⁴ *Id.*

⁶⁵ *Id.*

⁶⁶ Declaration of C. Cybele Raver ¶ 4, *Ass’n of Am. Univs. v. Dep’t of Health & Human Servs.*, No. 25-cv-10346 (D. Mass. Feb. 10, 2025), ECF No. 2-29.

⁶⁷ *Id.* ¶ 6.

The researchers' predictions already have come to pass. *Amici's* members have reported that several ongoing studies have been paused or terminated due to the uncertainty around NIH funding.

A disruption to NIH funding will completely, and in many cases permanently, derail studies. Clinical trials “cannot be restarted like a car. Supplies of drugs and devices have to be restocked, participants drift away, and researchers move on to other projects that pay.”⁶⁸ Further, “clinical trials must generally be continuous to be effective, due to concerns for both patient care and trial validity.” Mem. Op. 60. If clinical trials are paused, they may no longer produce viable results, because trials often must be continuous to be effective. *Id.* That means that any pause in a study could quickly turn into a permanent cessation of that study, leading to massive waste of years of research and funding, and the loss of potential scientific advancements.

A pause in funding thus will undermine the long-term scope of medical research and innovation. There is a long lead time in medical research: Studies generally must begin many years before the publication of the research findings, and before those findings lead to any meaningful

⁶⁸ AAMC, *What's at Stake*, *supra* n.3.

health improvements.⁶⁹ For example, one study found that the time from the moment a clear intervention is defined and selected for testing, through various research phases, until the start of widespread implementation, ranged from 18 years to 54 years.⁷⁰ Such a long lead time means that there will be significant waste if a pause in funding results in cancellation of studies. Since many clinical research projects will be forced to stop mid-trial and may not be restarted, the taxpayer-funded resources that already have been expended will go to waste, and those projects will never reach the point of implementation, meaning that the public will not benefit from the research.

Given the importance of NIH-funded research to the development of clinical guidelines and to the everyday practice of medicine, any disruption in NIH-funded research will impair the development of clinical guidelines

⁶⁹ See, e.g., Stephen R. Hanney et al., *How Long Does Biomedical Research Take? Studying the Time Taken Between Biomedical and Health Research and Its Translation Into Productions, Policy, and Practice*, 13 *Health Rsrch. Pol’y & Sys.* 1 (2015).

⁷⁰ *Id.* at 11-12; see C. William Balke et al., “*Oh, the Places You’ll Go*”: *Transformation of the Nation’s Biomedical Research Enterprise in the 21st Century*, 19 *J. Sport Rehabilitation* 359, 362 (2010) (explaining that “[t]he average latency for discoveries to translate into advances in clinical practice is 25 years” and describing “the path from discovery to practical application” as “long”).

and impact patient care.⁷¹ Emerging techniques, approaches to care, and medicines that could be the basis of new or updated guidelines or treatment protocols will not exist.

The result will be to set back the advancement of medical care. Impeding future research or rendering unusable existing NIH-funded research will greatly damage the United States' role as the leader of medical research and innovation, to the detriment of *amici's* members, hundreds of thousands of clinicians, and to the countless patients they treat every day.

⁷¹ See ACOG, *First and Second Stage Labor*, *supra* n.21, at 145 (explaining that a “high” quality of evidence rating is the result of “[v]ery strong evidence” and that “[t]here is high confidence in the accuracy of the findings and further research is unlikely to change this”); see also *Clinical Practice Guidelines*, *supra* n.17, at 93 (explaining that “[t]he idea that trustworthy clinical practice guidelines should be based on a high-quality [systematic review] of the evidence is beyond dispute”).

CONCLUSION

The Court should affirm the decision of the district court.

Dated: June 16, 2025

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(g), undersigned counsel certifies that this brief:

(i) complies with the type-volume limitation of Rule 29(a)(5) because it contains 5,437 words, including footnotes and excluding the parts of the brief exempted by Rule 32(f); and

(ii) complies with the typeface requirements of Rule 32(a)(5) and the type style requirements of Rule 32(a)(6) because it has been prepared using Microsoft Word for Microsoft 365 and is set in Century Schoolbook font in a size equivalent to 14 points or larger.

Dated: June 16, 2025

/s/ Nicole A. Saharsky
Nicole A. Saharsky

CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the First Circuit by using the appellate CM/ECF system on June 16, 2025. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

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