UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

ASSOCIATION OF AMERICAN UNIVERSITIES, AMERICAN COUNCIL ON EDUCATION, ASSOCIATION OF PUBLIC AND LAND-GRANT UNIVERSITIES, BRANDEIS UNIVERSITY, BROWN UNIVERSITY, THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, THE CALIFORNIA INSTITUTE OF TECHNOLOGY, CARNEGIE MELLON UNIVERSITY, 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, and TRUSTEES OF TUFTS COLLEGE,

Plaintiffs,

v.

DEPARTMENT OF HEALTH & HUMAN SERVICES,

NATIONAL INSTITUTES OF HEALTH,

DOROTHY A. FINK, M.D. in her official capacity as Acting Secretary, Department of Health and Human Services, and

MATTHEW J. MEMOLI, M.D., M.S. in his official capacity as Acting Director, National Institutes of Health,

Defendants.

Case No. 1:25-cv-10346-AK

Leave to File Granted
on February 19, 2025

MEMORANDUM OF LAW
OF *AMICUS CURIAE* MASSACHUSETTS BIOTECHNOLOGY COUNCIL, INC. IN SUPPORT OF PLAINTIFFS' MOTION FOR A TEMPORARY RESTRAINING ORDER

The Massachusetts Biotechnology Council ("MassBio") respectfully submits this Memorandum of Law as *Amicus Curiae* in support of Plaintiffs' Motion for a Temporary Restraining Order.

INTEREST OF *AMICUS CURIAE*

Founded in 1985, MassBio is a nonprofit association of more than 1,700 organizations involved in health care and life sciences, including about 1000 biopharmaceutical companies that are active in Massachusetts.

On February 7, 2025, the Office of the Director of the National Institutes of Health issued Supplemental Guidance to the 2024 NIH Grants Policy Statement: Indirect Cost Rates (NOT-OD-25-068) ("NIH Policy"), announcing that beginning February 10, 2025, "there will be a standard indirect rate of 15% across all NIH grants for indirect costs in lieu of a separately negotiated rate for indirect costs in every grant." NIH Policy. At the same time, NIH announced through social media that while $9 billion of the $35 billion in annual NIH research grants went to indirect costs last year, "[t]his change will save more than $4B a year effective immediately."[1]

MassBio is deeply concerned that this sudden, $4 billion annual cut in NIH research funding (with its corresponding cut of hundreds of millions of dollars in funding to Massachusetts institutions, in particular) would harm patients, research scientists, and the entire life sciences sector. If allowed to go into effect, the NIH Policy will immediately hobble the basic scientific research ongoing in Massachusetts to develop life-saving medicines for patients around the world, halt clinical trials, and threaten Massachusetts' (and the country's) standing as the leader in biopharmaceutical development.

[1] National Institutes of Health, "X" Post (Feb. 7, 2025 6:19 p.m.), https://x.com/NIH/status/1888004759396958263

MassBio is especially concerned with the suddenness of the funding cuts. The biopharmaceutical research and development system has been built around certain basic assumptions, including the indirect cost rates, which have been fixed in annual appropriations bills since 2018.

Despite billions of dollars in biopharmaceutical industry research and development investment each year, NIH basic research funding plays a vital role in drug development by supporting one of the three vital parties to the innovation ecosystem. This innovation ecosystem is crucial to developing new drugs, biologics, and vaccines and consists of three, interrelated parties that collaborate to move medicines from the scientist's laboratory to address patient needs. The three parties in this ecosystem include: (1) academia and small biotech companies that partner to pursue the underlying research; (2) venture capital firms that invest in the drug development process; and (3) pharmaceutical companies that work to bring new therapies to patients.

All three of these parties are essential components of the drug discovery, development, and commercialization process. MassBio and others have helped to create a thriving innovation ecosystem in Massachusetts due in large part to the close collaboration between academia—with their groundbreaking innovations—and biopharmaceutical companies. And their work has led Massachusetts to become one of the leading biopharmaceutical development hubs in the world. However, this ecosystem is fragile and will be disrupted if just one of the parties suffers a setback, as the NIH funding cuts set forth in the NIH Policy threaten to do. MassBio's deep industry knowledge and insights into how the NIH funding cuts will hamper drug development in Massachusetts will provide an important perspective as the Court considers the public interest in Plaintiffs' request for injunctive relief.

ARGUMENT

The public interest—one of the necessary elements of a claim for injunctive relief, *U.S. Ghost Adventures, LLC v. Miss Lizzie's Coffee LLC*, 121 F.4th 339, 347 (1st Cir. 2024)—weighs strongly in favor of enjoining the NIH Policy. First, the sudden, deep funding cuts announced in the NIH Policy will disrupt the basic scientific research that is vital to the innovation ecosystem and has led to the development of nearly every approved medicine in recent years. Second, the NIH funding cuts would immediately halt ongoing clinical trials, depriving patients of access to vital treatments and curative medicines. Third, the funding cuts would, in time, endanger Massachusetts' (and the country's) role as a world leader in drug development.

I. The Sudden NIH Funding Cuts Would Disrupt the Basic Scientific Research that is Vital to Biopharmaceutical Development in Massachusetts, Leading to Fewer Scientific Breakthroughs.

Massachusetts has created a world-class innovation ecosystem that has held to the development of dozens of life-altering treatments and cures for diseases. That ecosystem includes NIH-funded basic science, venture capital firms that invest in early-stage biopharmaceutical development, and mature biopharmaceutical companies that complete clinical trials and bring new drugs and vaccines to market. All parts of this ecosystem are critical to the continued development of life-saving medications in Massachusetts. While biotechnology and pharmaceutical companies invest billions in research and development each year, the NIH funding of basic science research is critical to successful drug development.[2] And that ecosystem has been based on long-term NIH funding of this basic research, including the indirect cost rates, which Congress has confirmed in its annual appropriations since 2018. *See* Consolidated

[2] *See* Congressional Budget Office, Research and Development in the Pharmaceutical Industry at 18-19, https://www.cbo.gov/publication/57126 (April 2021) ("Publicly funded basic science thus provided the foundation upon which complementary work on the applied science of drug development could be undertaken by the private sector.")

Appropriations Act, 2018, Pub. L. No. 115-141, 132 Stat 348, § 226. The sudden NIH funding cuts will fracture this innovative ecosystem.

Nearly every FDA-approved drug developed was based, at least in part, on NIH-funded basic research.[3] With less basic scientific research, there will be fewer scientific discoveries. With fewer scientific discoveries, there will be fewer innovations on which to develop life-saving medications and cures for disease.

One recent and prominent discovery provides a helpful example. The mRNA vaccine technology, which led to the development of two life-saving vaccines against COVID-19—including one that was developed in Massachusetts—followed decades of scientific research and development through collaborations across NIH researchers, NIH-funded academic research labs, and biopharmaceutical companies.[4] Indeed, "[f]or decades, NIH has supported the research that led to these vaccines."[5] This same mRNA technology is likely to lead to even more vaccines in the future with further private investment and biopharmaceutical research and development. There are already clinical trials ongoing that rely on mRNA technology for cancer vaccines, among others.[6] It will never be known what would have happened if NIH funding had been cut off—as the NIH Policy would do—for mRNA technology while it was still in the early stage of development.

---

[3] *See* 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*, JAMA Health Forum (Apr. 28, 2023) (finding that "[f]unding from the NIH was contributed to 354 of 356 drugs (99.4%) approved from 2010 to 2019 . . .").

[4] *See* National Institute of Allergy and Infectious Disease, *Decades in the Making: mRNA COVID-19 Vaccines*, https://www.niaid.nih.gov/diseases-conditions/decades-making-mrna-covid-19-vaccines (last viewed Feb. 18, 2025).

[5] *Id.*

[6] *See* Yu-Shiuan Wang et al. *mRNA-based vaccines and therapeutics: an in-depth survey of current and upcoming clinical applications*, 30 J. Biomed. Sci. 84 (Oct. 7, 2023).

Much of this promising NIH-funded research is ongoing in Massachusetts. The sudden $4 billion annual funding cuts resulting from the NIH Policy would be devastating to the delicate innovation ecosystem in the State, immediately holding back the discovery and development of life-savings medications.

II. The NIH Funding Cuts Would Likely Halt Ongoing NIH-funded Clinical Trials, Depriving Patients of Access to Vital Treatments and Curative Medicine.

In addition to funding basic scientific research, NIH funds thousands of clinical trials across the country, studying the safety and effectiveness of innovative medications on patients of all ages. The NIH clinical trial database shows 611 NIH-funded and 1622 industry-funded clinical trials currently enrolling patients at locations in Massachusetts.[7] While industry funds more clinical trials than NIH,[8] NIH provides financial support to the academic physicians who are primary investigators of industry-sponsored clinical trials, too.

If implemented, the NIH Policy puts funding for many clinical trials with NIH financial support—and the continuation of those trials themselves—in doubt. One MassBio member company is sponsoring a Phase II trial for an innovative rare disease treatment. On February 10, after NIH issued the new NIH Policy, but before the Court entered the Temporary Restraining Orders, the trial investigator reported that they had paused enrolling new patients in the study because of the NIH Policy. If patients cannot enroll in the study, the study cannot be completed. And if the Phase II study cannot be completed, the medication cannot move into Phase III, and the medication will not be approved for patient use.

---

[7] *See* National Library of Medicine, ClinicalTrials.gov, https://clinicaltrials.gov/search (filtered for "Location: Massachusetts"; "Study Status: Recruiting"; "Funder-Type: NIH" or "Funder-Type: "Industry") (accessed on Feb. 18, 2025).

[8] *See* Stephan Ehrhardt et al., *Trends in National Institutes of Health Funding for Clinical Trials Registered in ClinicalTrials.gov*, 314 J. Am. Med. Ass'n 2566-67 (Dec. 15, 2015) (finding in 2014, industry sponsored 35.6 of clinical trials and NIH 5.7%).

Even if the clinical trials could eventually resume, each day of delay in the clinical trial, results in a similar delay for patients to access the important new medicine. With more than two thousand clinical trials currently enrolling patients in Massachusetts, there would be substantial harm to the public interest should many of those trials be paused as a result of the new NIH Policy.

III. The NIH Funding Cuts Would Significantly Reduce Basic Scientific Research, Endangering Massachusetts' (and the Country's) Role as a World Leader in Drug Development.

As explained above, the NIH funding cuts would have catastrophic consequences for the innovation ecosystem for biopharmaceutical development in Massachusetts, leading to the discovery and development of fewer treatments and cures for patients. Over time, the NIH funding cuts will also endanger the role of Massachusetts and the United States as the world's leaders in drug development.[9]

Because the limited private funding for basic research is usually awarded to the most experienced researchers, the $4 billion in annual NIH funding cuts would lead to the loss of thousands of early career researchers across the country. Many of these research scientists who cannot get funding may move into other careers, and others may move to other countries where the government will commit to fully fund their research.[10] The U.S. leads the world in pharmaceutical development and Massachusetts has been the leader, among the States. But that status is not guaranteed and these sudden and drastic cuts to basic scientific research come at the

[9] *See* Yali Friedman, *Where are Drugs Invented, and Why Does it Matter?*, 16 ACS Med. Chem. Ltr. 589-91 (May 16, 2017) (concluding that "North America (largely the United States) accounts for more than half of the drug patent inventorship").

[10] *See* David J. Bier, *Abandoning the US, More Scientists Go to China*, Cato Institute (Apr. 11, 2023) (analyzing recent "data showing that the United States is losing the race for scientific talent to China and other countries"), https://www.cato.org/blog/abandoning-us-more-scientists-go-china.

same time as China (and other countries) are increasing their investments in basic research, providing ample opportunities in other countries for young scientists who hope to make breakthrough discoveries.[11] The likely result is that we—as a State and as a country—will lose our competitive advantage in biopharmaceutical research and development, with enormous consequences for public health, national security, and economic development.

CONCLUSION

For the forgoing reasons, the public interest weighs strongly in favor of enjoining implementation of the National Institutes of Health, Supplemental Guidance to the 2024 NIH Grants Policy Statement: Indirect Cost Rates (NOT-OD-25-068).

February 20, 2025

Respectfully submitted,

/s/ Eric M. Gold

Eric M. Gold, BBO #660393
MANATT, PHELPS, & PHILLIPS LLP
177 Huntington Avenue, Suite 2500
Boston, MA 02115
Tel: 617-646-1423
EGold@manatt.com

Counsel for
Massachusetts Biotechnology Council, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on February 20, 2025, I filed the forgoing document using the Court's ECF system and it will be sent electronically to all counsel of record identified on the Notice of Electronic Filing.

/s/ Eric M. Gold
Eric M. Gold

[11] Dennis Normile, *China announces major boost for R&D, but plan lacks ambitious climate targets*, Science (Mar. 4, 2021).