

March 5, 2025

VIA ELECTRONIC TRANSMISSION

Dr. Matthew J. Memoli
Acting Director
US National Institutes of Health
9000 Rockville Pike
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Dear Dr. Memoli:

We write to express our appreciation for the National Institutes of Health's (NIH) longstanding commitment to funding scientific research that advances medical breakthroughs. NIH's support has been instrumental in fostering innovation, improving patient outcomes, and sustaining the biomedical research enterprise, making the US the global powerhouse in medical innovation. We recognize the importance of ensuring that federal research dollars are used efficiently and effectively to maximize their impact. However, we are deeply concerned about the recently announced policy imposing a 15% cap on indirect cost recovery for NIH grants.¹ Given the far-reaching implications of this change, we respectfully urge NIH to rescind this directive and instead work collaboratively with us, our colleagues, and the US Office of Management and Budget (OMB) to develop a solution that balances transparency, efficiency, and sustainability.

The collateral damage of this policy, if implemented, will be profound and generational, reshaping the future of scientific progress in ways that cannot be easily undone. Beyond its immediate financial strain, the policy introduces significant procedural and structural issues that undermine the integrity of federal research funding. Below, we outline the specific concerns with the supplemental guidance and its broader implications.

Risk Tolerant Ecosystem

A defining strength of the US research enterprise is its risk tolerance—the ability to pursue bold, high-risk, high-reward scientific discoveries that push the boundaries of innovation and our understanding of the human body. This capacity to absorb uncertainty has been the foundation of American leadership in biomedical research and technological advancement, setting the US apart from other nations. Many of the most significant commercial, technological, and biomedical breakthroughs can be traced back to the federally supported research pipeline—one that thrives because of its ability to swing for the fences.

A critical component of NIH's success is its investment in basic research—the study of fundamental biological processes without immediate commercial objectives. These discoveries often lead to pivotal advancements in medicine. For example, research into the immune system's molecular workings laid the foundation for cancer immunotherapy, which harnesses the body's immune system to fight cancer. Such innovations stem from a research pipeline that would not exist without stable federal investment.²

¹ National Institutes of Health (NIH) (2025), NOT-OD-25-068: NIH Implementation of a Uniform 15% Indirect Cost Rate, <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-25-068.html>.

² NIH, Basic research digital media kit, <https://www.nih.gov/news-events/basic-research-digital-media-kit#funding>.

There are around 10,000 known diseases, 7,000 of which are rare, and treatments for around 500 of them. Neurological diseases and disorders have become a major priority for federal investment due to their devastating impact on the US healthcare system and global health. Six of the ten leading causes of death and disability are linked to neurological conditions, with stroke being the nation's leading cause of long-term disability.^{3, 4} The BRAIN Initiative recognized the foundational contributions of neuroscience to potential therapies.⁵ Physicians' progress to groundbreaking discoveries drives commercial innovation, preventive strategies, and evidence-based medical advancements that improve patient outcomes and long-term neurological health.

Funding from private foundations, while valuable, serves as an amplifier. The university research ecosystem is fundamentally built on federal research funding, with indirect cost rates intended to reflect expenses required to sustain groundbreaking scientific work. Appropriate indirect cost recovery is not limited to NIH grants; it is essential across all federal research funding mechanisms, whether through grants, cooperative agreements, or contracts. The necessity of federal support for research infrastructure is not unique to NIH. A parallel example can be found in the US National Aeronautics and Space Administration (NASA), where federally funded research has catalyzed transformative advancements in aerospace technology. The success of SpaceX as a dominant force in commercial spaceflight would have been improbable, if not impossible, without NASA's foundational investments in space exploration, infrastructure, and technology. Just as NIH leverages external partners to advance medical research and develop revolutionary treatments, NASA invests in external research partnerships with appropriate cost recovery to maintain US leadership in space exploration and technology.

The proposed 15% cap on indirect cost recovery would disrupt this well-established research ecosystem, forcing institutions to absorb critical infrastructure costs. No major research university could sustain its operations under this funding model, which would dismantle the very framework that has enabled US institutions to lead in global research and innovation. For researchers engaged in high-impact, transformative science, the financial strain would be untenable, leading many to leave academia for industry positions where they can pursue commercially viable products with fewer financial constraints.

In the broader context of federal spending, the cost of sustaining a strong research enterprise is minimal. However, the consequences of this policy shift will be anything but. Once dismantled, these funding structures will not be easily restored. The very research that drives medical advancements, fuels economic growth, and sustains America's competitive edge will suffer—not because of a lack of talent or opportunity but because of an arbitrary policy that undermines the financial sustainability of research institutions.

Global Competitiveness and National Security

The US remains at the global forefront of life-saving treatment, breakthrough technologies, and state-of-the-art facilities thanks, in part, to sustained NIH funding. The US accounts for over 40% of the global medical technology market, leading in the development and export of advanced medical devices over time with demonstrated growth over the years.^{6, 7} The US maintains most of the world's best-specialized

³ Feigin, V. L., Vos, T., Nichols, E., et al. (2024), Global burden of neurological disorders: A systematic analysis for the Global Burden of Disease Study 2021, *The Lancet Neurology*, [https://www.thelancet.com/journals/lanneur/article/PIIS1474-4422\(24\)00023-4/fulltext](https://www.thelancet.com/journals/lanneur/article/PIIS1474-4422(24)00023-4/fulltext)

⁴ US Centers for Disease Control and Prevention, Stroke facts and statistics, <https://www.cdc.gov/stroke/data-research/facts-stats/index.html>.

⁵ NIH, Blog Post: A look back at the BRAIN Initiative in 2023 and what's coming in 2024. January 31, 2024, <https://braininitiative.nih.gov/news-events/blog/brain-initiative-alliance-look-back-brain-initiative-2023-and-whats-coming-2024>.

⁶ Advanced Medical Technology Association, Medical device industry facts, <https://www.advamed.org/medical-device-industry-facts/>.

⁷ US Department of Commerce, Medical technologies, <https://www.trade.gov/medical-technologies-0>.

hospitals in oncology, cardiac surgery, neurosurgery, gastroenterology, urology, and other critical fields, attracting patients from around the world and reinforcing its status as the leading destination for medical tourism.^{8, 9} These specialized hospitals are also recipients of NIH funding, supporting multidisciplinary research teams that foster new investigators, physician-scientists, and research assistants who form the backbone of the next generation of medical innovation. Moreover, NIH-funded researchers are recognized on the global stage for paramount discoveries and advancements in the medical field – with more Nobel Prize winners in Physiology or Medicine than any other country.¹⁰

Like the US, many countries have career development and talent recruitment programs to attract and retain researchers in key scientific fields. They offer fellowships, international exchanges, and grant funding to incentivize collaboration not just domestically but also with global partners. However, countries of concern have increased state-sponsored initiatives designed to undermine US research innovation. For example, the Chinese Communist Party (CCP) has aggressively expanded its biomedical research enterprise as a part of the 14th Five-Year Plan for Bioeconomy Development.¹¹ Biomedicine and biosecurity are two of the four major fields with an outline of three powering pathways to success, including biotechnology innovation (i.e., new medicine development, synthetic biology), industrial development (i.e., workforce), and government policies designed to accelerate research output. Their goals are measured in two stages. From 2021 – 2025, the CCP seeks to increase the total scale of its bioeconomy, promote comprehensive strength in biotechnology, and develop industrial integration. In 2022, China surpassed the US in the Nature Index for natural sciences, reflecting its research output and quality.¹² By the end of this year, Chinese universities are expected to produce nearly twice as many PhD graduates in science and technology as their US counterparts.¹³ Moreover, the CCP's expansion strategy is not limited to domestic investments. Since 2008, the CCP has targeted US-funded researchers, institutions, and intellectual property critical to economic and national security. Congressional committees and government agencies have extensively documented these efforts, highlighting cases where NIH-funded research has been replicated or transferred to China for strategic advantage.^{14, 15} In response, Congress has taken bipartisan steps to minimize undue foreign influence, but the risk remains urgent and ongoing.¹⁶

If NIH reduces stable, long-term funding for high-risk, high-reward science, the US research pipeline will weaken, driving researchers to seek opportunities abroad. This policy shift would undermine America's biomedical leadership, erode its workforce competitiveness, and threaten national security, ultimately ceding scientific and technological dominance to global competitors.

⁸ Newsweek, The World's Best Specialized Hospitals 2024, <https://www.newsweek.com/rankings/worlds-best-specialized-hospitals-2024>.

⁹ Medical Tourism Magazine, (2023), What are the best countries for cancer treatment?, <https://www.magazine.medicaltourism.com/article/what-are-the-best-countries-for-cancer-treatment>.

¹⁰ Statista, (2023), Nobel Prize laureates in Physiology or Medicine by nationality, <https://www.statista.com/statistics/262896/nobel-prize-laureates-in-medicine-by-nationality/>.

¹¹ Government of China, (2022), 14th Five-Year Plan for Bioeconomy Development, <https://leap.unep.org/en/countries/cn/national-legislation/14th-five-year-plan-bioeconomy-development>.

¹² Cyranoski, D., (2023), China overtakes United States on key research impact measure, *Nature*, <https://www.nature.com/articles/d41586-023-02159-7>.

¹³ The Economist, (2024), China has become a scientific superpower, <https://www.economist.com/science-and-technology/2024/06/12/china-has-become-a-scientific-superpower>.

¹⁴ US Senate Permanent Subcommittee on Investigations, (2019), China's talent recruitment plans: How China's government is paying scientists inside the United States to transfer US taxpayer-funded research and innovation to China, <https://www.hsgac.senate.gov/wp-content/uploads/imo/media/doc/2019-11-18%20PSI%20Staff%20Report%20-%20China's%20Talent%20Recruitment%20Plans%20Updated2.pdf>.

¹⁵ US Senate Health Education, Labor & Pensions Committee, Full Committee Hearing: Protecting US Biomedical Research: Efforts to Prevent Undue Foreign Influence, Thursday, April 22, 2021, <https://www.help.senate.gov/hearings/protecting-us-biomedical-research-efforts-to-prevent-undue-foreign-influence>.

¹⁶ Consolidated Appropriations Act, 2023, Pub. L. No. 117-328, div. FF, §§ 2311-2315, 136 Stat. 4459 (2022).

Administrative Procedure

Federal agencies must adhere to established procedures when making changes to existing policies. Changes to indirect cost agreements, federal acquisition regulations allow all federal agencies to accept approved rates from cognizant agencies to ensure uniformity in indirect cost application.¹⁷ Agencies must notify the OMB of any deviations, and recipients (or subawardees) may dispute the application of their negotiated rates. Additionally, agencies must publicly disclose their procedures for deviating from negotiated rates and include relevant policies in funding opportunity announcements. With respect to changes in policy, federal agencies are generally required to provide public notice and an opportunity for comment before implementing significant policy changes.¹⁸ If a rule or regulation has a substantial economic impact exceeding \$100 million, agencies must conduct a regulatory impact analysis on various government levels and the private sector and should seek to minimize the burden on affected parties.^{19, 20} Additionally, they must assess how new regulations affect small institutions and ensure that any mandates do not create excessive financial burdens without proper consideration.²¹ Agencies generally do not use guidance documents to impose new binding requirements that were not already established in law or regulation. In addition, they are not subject to these requirements if they clarify existing policies or interpret regulations, offer non-binding recommendations, or state that entities retain discretion to comply. Federal courts ruled that agencies cannot impose substantive requirements through guidance documents without undergoing proper administrative procedures.^{22, 23}

The supplemental guidance circumvents these established administrative procedures, imposing a significant policy shift without public notice, opportunity for comment, or regulatory impact analysis. By issuing a binding directive under the guise of guidance, NIH has effectively enacted a substantive policy change without following federal rulemaking requirements. This lack of procedural transparency deprives research institutions of the opportunity to assess, adapt to, or challenge the policy, creating unnecessary disruption and regulatory uncertainty.

Indirect Cost Policy

NIH has long operated under a predictable and structured grant funding framework, ensuring compliance with federal regulations while fostering trust and collaboration between the federal government and research institutions. In general, institutions receiving federal awards are subject to stringent rules and regulations from the US Office of Management and Budget, the awarding federal agency, and other relevant agencies to ensure financial accountability.²⁴ As such, organizations must adhere to extensive eligibility requirements, be subject to annual audits, and follow federally approved indirect cost structures as negotiated with their cognizant agency.²⁵ Cognizant agencies were established to review, negotiate,

¹⁷ OMB, Indirect (F&A) Costs, 2 C.F.R. § 200.414(c).

¹⁸ Administrative Procedure Act, 5 U.S.C. §§ 551-559, 701-706.

¹⁹ Executive Order No. 12866, 3 C.F.R. 638 (1993), as amended by Executive Order No. 14094, 88 Fed. Reg. 21879 (2023).

²⁰ Unfunded Mandates Reform Act of 1995, 2 U.S.C. §§ 1501-1571.

²¹ Regulatory Flexibility Act, 5 U.S.C. §§ 601-612.

²² *Azar v. Allina Health Services*, 587 US 150 (2019), <https://supreme.justia.com/cases/federal/us/587/150/>.

²³ *Appalachian Power Co. v. EPA*, 208 F.3d 1015 (D.C. Cir. 2000), <https://casetext.com/case/appalachian-power-co-v-epa>.

²⁴ US Office of Management and Budget (OMB), Uniform Guidance, 2 C.F.R. § 200.

²⁵ US Department of Health and Human Services, Final Indirect Cost Rates, 48 C.F.R. § 342.705.

and approve cost allocation plans and indirect cost proposals on behalf of all federal agencies.²⁶ Once approved, the federally approved indirect cost rate is generally accepted across many federal agencies.²⁷

The supplemental guidance would create administrative burdens and insert financial instability in a system designed for transparency and efficiency. This abrupt policy shift disrupts longstanding cost negotiation processes, bypasses cognizant agencies, and imposes unilateral restrictions that conflict with existing federal financial management systems, undermining regulatory continuity and consistency in federal grant policies. Research institutions will have to respond to maintain some recovery costs. First, research institutions would have to completely restructure their institutional budgets and financial planning, which would be an extensive, expensive, and multi-year process. Reclassifying costs and shifting previously covered indirect costs, where feasible, will lead to increased compliance and justification requirements. Ultimately, this creates a more complex grant application and budgeting process NIH has historically sought to streamline.

The supplemental guidance uses a one-size approach using private foundations as an example, but it does not consider varying policies that allow appropriate cost recovery. Private foundations vary in their indirect cost agreements, ranging from allowable indirect, shared, and direct costs to sliding scales to better align funding with the diverse needs of grantees.²⁸ For example, the MacArthur Foundation adopts policy “in recognition of nonprofit organizations having indirect costs that are not directly attributable to the Foundation’s funded work but are necessary to support grant-funded projects or activities.”²⁹ As such, this foundation allows shared project costs to include occupancy, utilities, telephone/internet access, etc. The Robert Wood Johnson Foundation also allows occupancy as well as computing services for project or program staff, grants management or administrative staff, and other administrative costs that are incrementally incurred to support the project or program directly.³⁰ To be eligible, awardees must meet specific reporting requirements and disclosures, including federal tax forms. On sliding scales, the Packard Foundation and the Annie E. Casey Foundation structure their indirect cost rates based on an organization’s annual budget.^{31, 32} By contrast, OMB and the NIH generally classify occupancy costs (i.e., rent, utilities, maintenance, and depreciation) as recoverable through an institution’s indirect cost rate. The NIH does allow occupancy to apply to direct cost, but only if the cost is exclusively attributed to the grant-funded activity, is fieldwork, and meets special environmental conditions required for the research.³³

²⁶ Note: The HHS Division of Cost Allocation Program Support Center serves as the cognizant agency responsible for negotiating and establishing indirect cost rates for various organizations, including state and local governments, colleges and universities, hospitals, and other nonprofit entities. For commercial organizations, the NIH Division of Financial Advisory Services acts as the cognizant federal agency for negotiating indirect cost rates.

²⁷ Note: Fiscal Year 2008, the DoD Appropriations Act (Public Law 110-116) imposed a cap on indirect costs for certain DoD contracts, grants, and cooperative agreements, limiting them to 35% of the total cost. It applied to awards funded by the DoD's Basic Research appropriations, with report language stated it was to ensure federal funds would be directed toward direct research activities. The cap was specific to that fiscal year and certain funding allocations.

²⁸ Council on Governmental Relations, (2017), Comparing foundations to federal government research support, <https://www.cogr.edu/sites/default/files/6.30.17%20Comparing%20Foundations%20to%20Federal%20Government%20Research%20Support.pdf>.

²⁹ MacArthur Foundation, Cost-sharing and in-kind contribution policy, <https://www.macfound.org/about/our-policies/indirect-cost-policy/>.

³⁰ Robert Wood Johnson Foundation, Indirect cost rate policy, https://www.rwjf.org/content/granteeresources/legal-and-policy/Indirect_Cost_Rate.html.

³¹ David & Lucile Packard Foundation (2024), CFI Open Call FAQ, <https://www.packard.org/wp-content/uploads/2024/03/CFI-Open-Call-FAQ-2.pdf>.

³² Annie E. Casey Foundation, (2023), The Casey Foundation’s journey toward equitable grant making, <https://www.aecf.org/blog/the-casey-foundations-journey-toward-equitable-grant-making>.

³³ National Institutes of Health, (2023), NIH Grants Policy Statement, <https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf>.

Assessing private foundations' indirect cost policies requires a comprehensive review of their full funding guidelines rather than isolating a single aspect. The supplemental guidance does not consider their guidelines' broader financial structure, eligibility requirements, and allowable expenses, thus presenting an incomplete picture. Therefore, making direct comparisons to federal funding policies is inappropriate without a thorough evaluation of all contributing factors.

In addition, the supplemental guidance unequally burdens institutions with fewer alternative funding sources. Larger research institutions with private endowments, unrestricted funding, or industry partnerships may be able to absorb the funding gap. Smaller institutions and community-based research centers lack financial flexibility.

Cost Sharing Policy

Similar to indirect cost guidelines, private foundations often have specific policies regarding cost-sharing and in-kind contributions to ensure the effective use of their funds and alignment with their philanthropic objectives. In fact, many recognize this and have placed it in their guidelines. The Gates Foundation, for example, has stated in its historical guidelines that it does not match indirect cost rates approved by federal cognizant agencies and recognizes that “applicants may need to engage in cost-sharing between projects, tap into unrestricted funds, or conduct other fundraising to cover operations costs.”³⁴

By contrast, federal research funding policies generally prohibit cost-sharing and in-kind contributions. The OMB has a policy that federal agencies cannot require cost-sharing unless it is explicitly mandated by law or regulation or outlined in a specific funding announcement. If an institution voluntarily includes cost-sharing in a proposal, it must not be used as a factor in funding decisions. This is to ensure that awards are based on scientific merit and project feasibility rather than an institution's financial capacity. When cost-sharing is included, it must be verifiable in institutional records, necessary for achieving project objectives, and allowable under federal cost principles. Additionally, federal agencies are required to apply these rules consistently, ensuring uniform treatment across all applicants. In-kind contributions, such as donated equipment or waived indirect costs, can only count toward cost-sharing obligations if they are explicitly approved, documented, and properly valued. These regulations exist to prevent funding inequities, reduce administrative burdens, and promote transparency, ensuring that institutions with greater financial resources do not gain an unfair advantage over those reliant solely on federal support.³⁵ Institutions' abilities to supplement federal support with private resources can be highly variable. This policy aims to ensure transparency and a level playing field in the distribution of federal grants by ensuring they are based on scientific merit and project feasibility rather than an institution's ability to contribute additional resources.

The supplemental guidance does not consider the varying cost-sharing policies between private foundations and federal government requirements and the reasoning that allows or prohibits its use.

Clinical Studies

Clinical studies are the backbone of medical advancements that offer patients access to cutting-edge, life-saving, and quality-of-life-improving therapies. In fiscal year 2023, NIH allocated \$34.9 billion of its \$47.7 billion budget to competing and non-competing grant awards. This funding supported 58,951

³⁴ Bill & Melinda Gates Foundation (2015). Indirect Cost Policy, https://docs.gatesfoundation.org/documents/historical_indirect_cost_policy.pdf.

³⁵ OMB, Cost sharing or matching, 2 C.F.R. § 200.306.

extramural grants across 2,743 institutions, including universities, hospitals, and research organizations, many of which conduct human and animal clinical trials to advance medical innovation.³⁶

Conducting clinical trials is resource-intensive, with costs extending far beyond patient care and treatment. While much of the funding is allocated to specific research activities—such as data collection, drug administration, and patient monitoring—institutions must also cover regulatory compliance, infrastructure, and administrative expenses that support multiple projects.^{37, 38} One of the most significant financial burdens is regulatory compliance and oversight, which requires dedicated staff, legal review, extensive documentation, and ongoing safety monitoring to meet federal standards for human research. Additionally, maintaining research infrastructure—including specialized laboratory facilities, biostatistical support, and IT systems for secure data storage and patient record management—represents a significant, ongoing expense essential to trial execution. Private foundations benefit from this federal and state regulatory structure.

While these resources are shared across multiple projects, they remain essential for any trial to function. A 15% cap on indirect costs creates a financial gap that disproportionately affects the institutions conducting trials, particularly those without unrestricted funding sources to absorb administrative and infrastructure expenses.

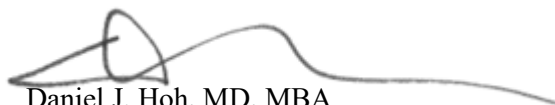
Conclusion

As physicians, we are committed to finding treatments and cures. While we recognize the importance of directing more funding toward direct research costs, this policy carries unintended consequences that threaten the sustainability of US biomedical research. Thank you for considering these concerns. If you have any questions or would like to follow up, please contact Dr. Alex Khalessi, the AANS and CNS Washington Committee Chair, at akhalessi@health.ucsd.edu, and Charlotte Pineda, the AANS and CNS Vice President of Health Policy and Advocacy, at cpineda@neurosurgery.org. We look forward to collaborating with you and other federal agencies to advance solutions that ensure transparency, fairness, and our continued excellence on the global stage.

Respectfully submitted,



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³⁶ NIH, FY 2024 by the numbers: Extramural grant investments in research, February 21, 2024, <https://nexus.od.nih.gov/all/2024/02/21/fy-2023-by-the-numbers-extramural-grant-investments-in-research/>.

³⁷ HHS, Institutional Review Board (IRB) approval process, <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/institutional-review-boards/index.html>.

³⁸ US Food and Drug Administration, Good Clinical Practice (GCP) standards, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/e6-r2-good-clinical-practice-integrated-addendum-ich-e6r1>.



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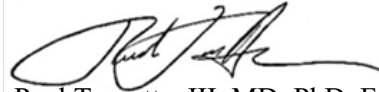
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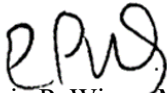
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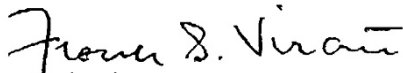
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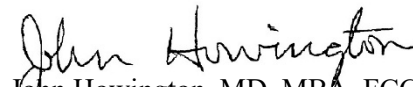
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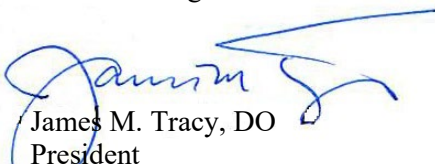
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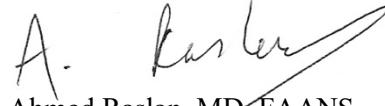
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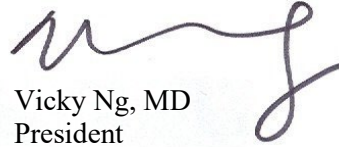
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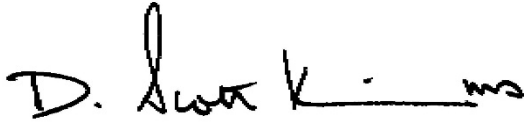
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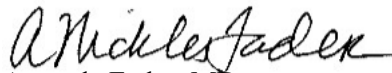
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The Honorable Tom Cole, US Representative
The Honorable Rosa DeLauro, US Representative