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August 6, 2024

The Honorable Cathy McMorris Rodgers
Chair
Committee on Energy & Commerce
United States House of Representatives
Washington, DC 20515

Dear Chairwoman McMorris Rodgers:

On behalf of the Association of American Medical Colleges (AAMC), thank you for your longstanding support for medical research. I am pleased to provide this response to your June 14, 2024, request for stakeholder input on your discussion framework to strengthen the National Institutes of Health (NIH).

The AAMC is a nonprofit association dedicated to improving the health of people everywhere through medical education, health care, medical research, and community collaborations. Its members are all 158 U.S. medical schools accredited by the Liaison Committee on Medical Education; 13 accredited Canadian medical schools; approximately 400 academic health systems and teaching hospitals, including Department of Veterans Affairs medical centers; and more than 70 academic societies. Through these institutions and organizations, the AAMC leads and serves America's medical schools academic health systems and teaching hospitals, and the millions of individuals across academic medicine, including more than 193,000 full-time faculty members, 96,000 medical students, 153,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences. Following a 2022 merger, the Alliance of Academic Health Centers and the Alliance of Academic Health Centers International broadened participation in the AAMC by U.S. and international academic health centers.

As you know, the NIH plays a critical role in improving the health and well-being of families and communities through groundbreaking foundational discovery and life-saving medical research conducted by approximately 300,000 researchers at more than 2,500 universities, medical schools, and research institutions in every state in the nation, and serves as an important program of intramural research at the NIH campus. More than half of the external research that NIH supports occurs at AAMC-member institutions pursuing advances in disease prevention, treatment, and diagnosis, across the full spectrum of conditions facing patients everywhere.

In addition to their integral role in advancing discovery, our members provide the world's most advanced and expert patient care informed by the latest innovations in fundamental and clinical research. In other words, our member academic medical centers not only play a fundamental role in creating the breakthroughs of the future, they also are actively putting such innovations into

practice for a diverse array of patients. Their seat at this nexus of research and care delivery gives the experts internally at the AAMC and at our member medical schools, teaching hospitals, and health systems a unique perspective both on the urgency with which patients and their providers seek new and more effective treatments, as well as the challenges and opportunities to accelerate our progress. We have drafted our comments to your RFI through this lens.

The responses that follow primarily reflect input from AAMC staff, including information from conversations with experts across the AAMC's membership. Our community sincerely appreciates the approach that you have taken in actively seeking input from stakeholders on the discussion framework. The AAMC takes seriously the invitation you issued in your June 14 opinion piece to work with you and your colleagues, and while we may not agree with all of the elements of the proposal, we are prepared to engage in the discussion on opportunities to strengthen our medical research enterprise. Like our responses to Senator Cassidy's RFI last fall and to the RFI issued more recently by Representatives DeGette and Bucshon, we have opted here to provide you with suggestions and principles to respond to the themes you have highlighted. We welcome the opportunity to continue to serve as a resource to you and your staff as you undertake this process and to elaborate further on any of the feedback included in this letter.

Additionally, the AAMC strongly supports the talented leaders and dedicated scientists and staff at NIH who have dedicated their careers to public service. In many cases, the NIH itself has applied its unique expertise and taken initiative in addressing pervasive challenges, often by engaging and with support from the broader stakeholder community. Accordingly, we have focused many of our comments here on highlighting existing efforts of interest underway, clarifying the purpose of current policies and practices, and/or suggesting areas where we believe Congress, as opposed to NIH itself, is best positioned to take action to strengthen the research enterprise.

Overarching Principles

As you consider any potential legislation to enhance further the NIH's operations, we recommend the following considerations, which we address in greater detail throughout the remainder of the letter:

- Any structural or operational changes to NIH should only occur after a deliberative process that: includes a thorough, evidence-based assessment and evaluation of the current NIH structure with collection and analysis of relevant data; incorporates relevant expertise within NIH, the federal government, and the research and broader stakeholder communities; allows for stepwise changes or pilot programs as needed; and has a strong scientific rationale.

- Some federal policies for the conduct and oversight of research have gone through an extensive development process that incorporates input and expertise from the scientific community to ensure that the policies are effective in addressing the relevant issues and have a basis in scientific knowledge and understanding. As described further below, in some cases, those multi-year development and implementation processes are currently underway and represent significant investment of resources already by institutions and federal agencies. We recommend that Congress refrain from developing legislation that supersedes those identified policies before they even have had a chance to be fully

implemented. In addition to preventing delays in achieving optimal outcomes, allowing such carefully crafted policies to take effect would also support ongoing Congressional efforts to minimize ineffective regulatory burden.

- We agree that, ultimately, any legislation should serve to optimize the medical research and innovation enterprise. We encourage you to ensure that changes intended to strengthen the NIH do not inadvertently harm the processes that ensure academic medical centers and other U.S. research institutions are able to remain the global leaders in science and research and maintain the nation's international competitiveness in science and technology.

Structural, Mission, and Leadership Proposals

The AAMC shares the desire to position NIH to operate efficiently and effectively to drive discovery, capitalize on the ideas and successes of the nation's scientists, and improve health through research. Maximizing the impact of NIH-funded research is a priority for the entire research community. The structure of the NIH's components have provided grantee institutions and researchers a predictable framework for aligning funding priorities with disease process and fields of study. In addition to novel grant mechanisms that can support individual investigators, we provide the following recommendations for your consideration:

- The AAMC urges Congress to ensure that the NIH is able to support a wide breadth of scientific areas of inquiry, including fundamental/basic research, clinical, translational, and population health research. Any structural changes, especially those involving the rethinking of the organization of NIH institutes and centers, should take place through a deliberate, transparent, and rigorous process that includes public input, relevant stakeholder expertise, and is based on advancements in our understanding of science. The overall intent of any such changes should improve efficiency, collaboration, and scientific alignment.

- We agree that evaluation is important and understanding what could be improved or modernized at NIH is valuable. Any evaluation and assessment should be conducted by people with the appropriate organizational and scientific expertise.

- All structural changes to NIH should be developed and justified with a clear scientific rationale. While we agree that term limits can potentially bring in new ideas, we also note that science moves slowly, and leaders need time to institute plans and visions for individual institutes and centers. Implementing arbitrary limits would risk diminishing the appeal of such positions and negatively affect NIH's ability to recruit highest talent, particularly if the initial term is any less than 10 years.

- We agree with the importance of and support the existing NIH policies in the following areas: conflict of interest and transparency initiatives, misconduct including sexual harassment, and accessible reporting mechanisms. The agency and the grantee community have worked to implement these policy reforms over time, and they have substantial impact on improving the integrity of research and the research environment.

There may be existing structures, such as the Scientific Management Review Board, that could facilitate such a process and could serve as a starting point for any discussions around

reorganization or other structural changes.

Funding Proposals

Facilities and Administrative Costs

The AAMC and its member institutions have engaged for years in conversations about whether more funds should be allocated to specific grants rather than for Facilities and Administrative (F&A) costs (also referred to as "indirect costs" despite the direct impact that these resources have on an institution's ability to conduct research). These F&A funds reimburse institutions for real, actual costs related to performing federally sponsored research, including expenditures related to construction and maintenance of labs, energy and utility expenses, and safety and security measures. These costs are reimbursed according to a formula negotiated between the research institution and federal auditors, based on auditable expenditures and determination of which costs are allowable for federal reimbursement under OMB regulation. An institution's negotiated rate applies to sponsored research across federal agencies, including NIH, the Department of Defense, etc. Medical schools and universities also contribute substantially from their own internal resources in support of the research mission. Without support for F&A expenses, research as is conducted today simply would not be possible, and institutions would need to dramatically scale back their research programs, slowing scientific progress toward better treatments and cures.

The AAMC is very concerned that proposed changes to limit the F&A reimbursement structure would have a negative effect on research conducted across the country. The cost for institutions to conduct science are increasing, including substantial costs related to research and data processing, as well as compliance and regulatory activities that institutions are required to undertake. Continuing Congressional efforts to reduce regulatory burden could, over time, reduce the real and substantial costs that institutions face. This approach would help reduce F&A expenses without undermining the ability of research institutions nationwide to carry out NIH-funded research.

Another approach to addressing the role of F&A costs, which as currently reimbursed do not cover the full costs of conducting research, is represented in various NIH efforts to establish shared facilities, such as for sophisticated instrumentation or other research resources. Shared facilities costs can be offset through "user fees" charged as direct costs on research grants (many animal research facilities are supported in this way). Such facilities can also be shared across a region, among multiple institutions, and potentially increase efficiency by supporting a broader number of investigators. There is also evidence that shared facilities may encourage interactions among users, leading to collaborations and new insights. Congressional efforts could encourage and facilitate the increased use of shared resources.

Achieving Appropriate Balance Between Oversight and Regulatory Burden

The AAMC is keenly attuned to the difficult balance between necessary oversight for the agency's stewardship of federal funds and regulatory burden that diverts institutional resources from the conduct of research. One area in which the AAMC has seen both significant progress and avenues for continued work is in interagency collaboration across the federal government to streamline and standardize requirements for grantees of different agencies.

The AAMC understands the critical responsibility that NIH has in its stewardship of the federal funds it has been tasked with allocating, and history has shown that the agency takes this responsibility seriously. Among other examples, its actions with respect to research security and its internal oversight procedures have demonstrated this commitment. We also understand the role that Congress plays in its oversight function. The AAMC has long supported the development of a Research Policy Board to look across agencies at oversight and regulatory burden. This board was a key component of the 21st Century Cures Act and was enthusiastically supported by the biomedical research community. Unfortunately, despite the statutory requirement for the implementation of the board, to date the research policy board has not been created. The AAMC continues to see this board, which intentionally included membership from across the biomedical research community, as a powerful tool in transparency and in reducing regulatory burden. We encourage activities that would facilitate the creation and implementation of the board.

Proposals Regarding NIH Grants

The NIH's extramural research program is fundamental to the mission of academic medical centers, and those institutions, which receive the majority of NIH grant funding, are as fundamental to the NIH. That dynamic is the foundation for the cures, treatments, diagnostics, and preventive interventions that patients, families, and communities seek every day. The AAMC engages on virtually every aspect of the NIH extramural research program and is glad to provide insights or thoughts for your office on any of the topics discussed herein or any other topic related to the program.

Grant Recipients

The NIH's tested and rigorous peer review process for the assessment and evaluation of research proposals is an essential instrument for ensuring scientific merit of funded proposals. The AAMC has provided feedback to NIH as it assesses its own processes and appreciates the opportunity to speak to the impact of those efforts.

We do, however, recognize that the objective evaluation of research ideas, especially when bolstered by the resources available to the principal investigators, can concentrate federal funds in certain institution types, geographic regions, and more established investigators. The efforts that NIH has undertaken to address this concern have resulted in some impactful models of novel grant mechanisms. We provide below examples of some of these successful approaches.

NIH's peer review system utilizes scientists to rigorously evaluate the scientific and technical merit of grant applications proposed by their peer colleagues. Importantly, this transparent and fair review is done by experts – allowing NIH to identify the strongest, highest-impact research. Because research proposals are highly technical and field-specific, scientists – many whom have spent decades understanding the body systems and diseases specific to a particular NIH institute (sometimes even down to a molecule or protein) – are *uniquely poised* to provide the scoreable and objective analysis needed to identify promising, yet feasible, science. The NIH peer review system, overseen by the NIH Center for Scientific Review, is comprised of over 18,000 scientific reviewers and utilizes only 0.4% of the total NIH budget. Importantly, the NIH continues to collaborate with scientific communities to refine and improve the efficiency and quality of peer review.

An area of interest that observers have identified is in expanding the reach of NIH's resources to an even greater diversity of awardees. While we would like to emphasize the critical and necessary role of NIH's peer review process in identifying the most promising science to fund, we also recognize the opportunity for support across a wider range of potential grantees demographically, geographically, and institutionally.

The NIH's Institutional Development Award (IDeA) program provides funding for centers and for research networks within qualified states. As with other NIH research, the IdeA approach relies on rigorous peer review to determine excellence among competing programs. As such, the program has demonstrated that the NIH is able to help build research capacity within regions that traditionally have not been recognized as significant venues for medical research, and that more communities and institutions have potential to participate in and directly contribute to biomedical discovery and application. Exploring the feasibility of applying such a model to other areas of underinvestment could help reveal additional opportunities to broaden participation in NIH research, particularly if implemented as a supplement to the existing programs rather than at the expense of current investments.

The AAMC is very aware that the future of biomedical research depends on the successful development, retention, and support of research trainees and early career scientists. We agree with the importance of ensuring support to develop the career of early-stage investigators (ESI) and also emphasize the need to ensure that the biomedical research workforce represents includes individuals who can bring a broad set of experiences and perspectives to science and discovery. The AAMC appreciates the focus that NIH has placed on supporting scientists early in their careers and notes that NIH is limited in certain efforts as a result of the agency's authority, funding, or regulations from other agencies.

Our nation must invest in predictable funding for medical research to continue our progress in advancing health and also to bolster our research workforce. The unpredictability of funds discourages individuals, especially early-stage investigators, from pursuing academic research careers, as the lack of predictable funding may hamper the ability to sustain their research programs. There have been various proposals to counter these troubling trends. One model that has demonstrated some promise is the NIH Maximizing Investigators Research Award (MIRA), which provides investigators with more stable funding as the grants are generally longer and more flexible than other research grants. We believe this model could be one, among others, that Congress could explore; by facilitating the use and NIH's evaluation of such models as a complement to existing funding mechanisms, Congress can help support NIH's work to reduce year to year uncertainty on any particular grant and identify evidence-based ways to address some of the most pervasive and pressing challenges facing the science workforce. Importantly, this approach holds more promise in allowing NIH to remain flexible and nimble as such challenges emerge and change, compared to approaches that would set arbitrary limits in statute.

The AAMC recognizes and has commended the NIH for launching its agency-wide strategic plan for diversity, equity, inclusion, and accessibility (DEIA) in alignment with complementary initiatives, including the UNITE initiative to address structural racism and the strategic plan by the Chief Officer for Scientific Workforce Diversity to bolster inclusive excellence in the biomedical workforce. The AAMC also commends the NIH for developing the Maximizing Opportunities for Scientific and Academic Independent Careers (MOSAIC) program, for which AAMC is a grantee, and the Faculty Institutional Recruitment for Sustainable Transformation (FIRST) program. These programs are working to build cohorts to aid researchers in their

successful transition to research faculty positions and helping to keep them in those roles.

Oversight Responsibilities

We support NIH initiatives that promote robust, replicable, and ethical research, as well as scientific data sharing. As we have stressed in the public record, we agree that robust oversight of research with both human participants and animals, when focused on the ethics and conduct of the research from proposal to publication is an appropriate focus for the agency and for institutions. We note that the existing NIH grants policy contains sufficient oversight requirements, including through its specific policy on foreign subawardees, and agree that enforcement with established requirements should remain a focus of the agency.

As discussed in our overarching principles, we strongly recommend that Congress not supersede ongoing and developing government-wide efforts, including in two critical areas: research security and the oversight of dual use research. Following work in 2016 to develop comprehensive policies and safeguards related to the security of the nation's research results and data, an effort led by the National Science and Technology Council, involving 17 federal agencies involved in scientific research funding, demonstrates a commitment to establish a coordinated set of reporting and requirements to protect intellectual property and minimize security risks while avoiding detrimental impacts on international scientific collaboration. This substantial expansion of federal government oversight of research by every research funding agency, which has recently moved into implementation stages with significant involvement and investment from academic communities, should be allowed to move forward without the addition of new intervening requirements. We suggest that a focus on evaluating the impacts of this work, both on research security and research outputs, would be a productive next step.

Similarly, we urge Congress not to take action that would override the extensive, recently released *United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential*. Evaluation of the impact of this significant effort should be a focus of related oversight efforts, but we underscore that any additional requirements beyond what have already been proposed in this new policy should be based on identified gaps and should be developed with the scientific expertise of the NIH and other federal agencies with relevant subject matter expertise, along with academic community input. We are concerned that a parallel Congressional effort that overlays different requirements would be counterproductive because it would restart the process to address these issues without the benefit of understanding the impact of the current efforts.

Other Issues

Without question, the bipartisan, decades-long federal commitment to NIH and the U.S.'s global leadership in medical research have been instrumental in advancing science to combat nearly every health threat facing patients and their families nationwide. Even in the midst of the extraordinary investment Congress has made in NIH over the last decade, however, scientific opportunity continues to far outpace available resources. NIH is currently only able to support 1 in every 5 promising proposals, with some institutes forced to turn away even a far greater share of applications they receive. Moreover, recent appropriations have been key in assisting the agency to recover lost purchasing power after a decade and a half of flat or effectively flat funding, but still have not reached, in inflation-adjusted terms, our 2003 level of investment. "Boom and bust" cycles of funding, particularly when coupled with delayed completion of the

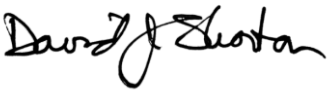
annual appropriations process, are counterproductive, given the long-term nature of discovery.

To fully optimize the nation's potential to advance new preventive interventions, diagnostics, therapeutics, and cures – and to lay the groundwork for the scientific "miracles" that will protect us against emerging threats and bolster our national security – it will be essential to ensure the nation sustains a commitment to predictable, robust growth for the NIH over the long term. We cannot afford to underinvest in medical research or to stifle lines of inquiry by drawing artificial boundaries on science. We hope to work with lawmakers to continue a trajectory of sustained, robust growth for NIH in FY 2025 and beyond, with as much stability and predictability of funding as possible.

Additionally, while we welcome the opportunity to explore the potential of structural changes in enhancing efficiencies, we caution that such efficiencies will be limited without the appropriate funding support. To the extent Congress chooses to pursue new programs, we urge lawmakers to ensure they are supplementing the essential ongoing work supported by the agency. Likewise, an approach that focuses on pilot projects and/or that empowers NIH to implement any potential changes through a phased process that allows collaboration with, deliberation among, and feedback from medical research stakeholders will have a greater chance of success than dramatic changes that risk upending the medical research enterprise. These principles will be important safeguards to ensure the U.S. continues to lead the world in medical research and does not jeopardize our potential to pursue cures, drive innovation, and maximize the economic returns that the federal investment yields.

Thank you again for the opportunity to provide feedback on the proposed discussion framework. The AAMC and its members take seriously the responsibility entrusted in awardees to ensure that NIH funds advance our understanding of medicine and health. As mentioned above, my colleagues and I hope to continue to serve as a resource to you and your team and look forward to continuing to discuss our mutual goal of improving the health of all. Please contact AAMC Chief Public Policy Officer Danielle Turnipseed, JD, MHSA, MPP (dturnipseed@aamc.org) or Senior Director of Public Policy & Strategic Outreach Tannaz Rasouli (trasouli@aamc.org) with any additional questions.

Sincerely,



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