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The Honorable Bill Cassidy, MD
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate
Washington, DC 20510

Dear Ranking Member Cassidy:

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 Sept. 29 request for information (RFI) related to 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 and some preliminary conversations with experts across the AAMC's membership. While we are prepared to discuss each of the questions outlined in the RFI, in the interest of brevity, we have opted here to provide high level ideas responding to the themes embedded throughout the RFI. 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 the initial feedback 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.

Increasing the Pace of Science

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. Among other strategies, two that have promise are: 1) meaningful data sharing and data reuse; and 2) promoting commercialization of the products of NIH-funded research, including through public-private partnerships.

Meaningful data sharing of NIH-funded research advances biomedical research by enabling further validation of scientific results, facilitating reuse of hard to-generate data, catalyzing new research, and generally promoting more responsible stewardship of federal resources. The AAMC is strongly supportive of the recent strides the NIH has made in expediting this goal, including implementing a new agency-wide data management and sharing policy after a process that included several years of community engagement and feedback. Ensuring the success of this new policy will require NIH to undertake ongoing evaluation that focuses on determining which types of data provide value and are important to share and providing the appropriate guidance to grantees to share research data that follows community standards of being findable, accessible, interoperable, and reusable. That evaluation process is essential to understand the new policy's impact, effectiveness, and burden on grantee institutions.

Efforts to promote academic-industry collaborations should recognize that the 1980 Bayh-Dole Act has been exceptionally successful in incentivizing private investment in university-based inventions from federally sponsored research. Further, the Act helped catalyze the development of a community of academic tech transfer and licensing professionals. The Bayh-Dole Act included safeguards, such as march-in rights, to protect public interests in unusual or unforeseen situations. The AAMC does not believe that exercising march-in rights would be an effective way of addressing systemic concerns, such as around the affordability of pharmaceuticals, and that such problems should be addressed through other measures, not Bayh-Dole.

Extramural Research Program

The NIH's extramural research program is fundamental to the mission of academic medical centers, and those institutions, which receive the majority of NIH funding, are as fundamental to the NIH. 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. 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.

Our nation must invest in predictable funding for medical research to continue our progress in advancing health. The unpredictability of funds discourages individuals, especially early-stage researchers, from pursuing academic research careers, as the lack of predictable funding may hamper the ability to sustain their research programs. The NIH Maximizing Investigators Research Award (MIRA) provides investigators with more stable funding as the grants are generally longer and more flexible than other research grants. We commend this model and suggest that Congress could facilitate the use of such models as a complement to existing funding mechanisms to reduce year to year uncertainty on any particular grant.

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 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 trainee and early career scientists. 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. As an example, the National Research Service Award (NRSA)-funded programs serve as a model for providing mentorship and career development to early-career researchers. It is essential for highly skilled researchers, including postdoctoral scholars, to be compensated at a level commensurate with those skills regardless of funding source. However, institutions are prohibited from supplementing NRSA stipends with other federal funds, which has long been a challenge for some institutions in trying to provide early-career scientists with the support they need to advance their careers. NRSA-funded postdoctoral scholars should also have the same access to benefits as employee-classified postdoctoral researchers, but institutions are unable to provide them with those same benefits, as they are not classified as employees. This causes significant financial hardship and uncertainty for these scholars. In addition, staff scientists increasingly provide much needed expertise to advance large and complex research projects.

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 the newly established 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.

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. 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.

One 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.

Intramural Research Program

The AAMC recognizes and supports the critical role of the NIH Clinical Center in providing a unique national resource for very rare diseases and cutting-edge research. Disruptions in the funding and sustainability plans for the Clinical Center not only jeopardize clinical research projects but also put patients' and their families' lives at risk. We urge Congress to find mechanisms to ensure the continuity and sustainability of the Clinical Center, especially in ensuring its continued operation through times of interruption and fiscal uncertainty.

Organizing NIH for Success

Statutory Structure and Functions

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, multidisciplinary projects, or areas of specific need, the addition of the Advanced Projects Research Agency for Health (ARPA-H) to the tools available to fund research provides an encouraging avenue for exploration.

Success in biomedical research involves a wide variety of approaches and perspectives, and the addition of the ARPA model to an already robust federal biomedical research enterprise presents exciting potential. We have long held that ARPA-H should complement, and not replace, the research portfolio that NIH currently conducts, and that funding for ARPA-H should be supplemental to the budget for NIH. Additionally, the NIH supports a modest high risk, high-reward research program, managed under the Common Fund within the Office of the Director, comprised of four awards that are innovative in focus, review, and structure, and subject to a

comprehensive evaluation process. We support the continuation of this program at NIH as well. We recognize that these approaches to funding medical research and advancing discovery are novel. ARPA-H itself is promising but at an early stage and should be allowed to progress and be evaluated prior to making any assumptions about its long-term value or major changes to its structure.

Administrative Opportunities and Challenges

The AAMC is keenly attuned to the difficult balance between necessary oversight for the agency stewardship of federal funds and regulatory burden that diverts institutional resources from the conduct of research. Prior bipartisan Congressional action to identify and remedy specific sources of excessive regulatory burden through the 21st Century Cures Act held great promise but to date have not been fully implemented to optimize their potential impact. The legislation identified a number of specific areas where improvements were warranted and reduced some burdens and barriers, but there is more that can be done to alleviate regulatory burden from the research community. In some cases, as with the required re-evaluation of the regulations on research with animals, implementation of the requirements from 21st Century Cures was uneven and perhaps less comprehensive than it could have been. In other cases, areas for improvement were not identified in the legislation or have not achieved the gains envisioned by the drafters.

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. We have seen promising activities to harmonize standards around research security efforts, for example, in which the NIH, in concert with the National Science Foundation and the White House Office of Science and Technology Policy have been working for several years to release common standards and requirements for the community. While we have seen progress in these areas and continue to support these efforts, we note that in many cases variations in authority and agency-specific requirements prevent implementation of identical (rather than harmonized or aligned) requirements for grantee institutions. When federal agencies continue to have similar but not identical requirements, institutions remain forced to have complex internal policies to address every possible federal funding source. This is particularly evident in the requirements surrounding conflict of interest disclosures.

Improving Transparency and Oversight

The AAMC understands the critical responsibility that NIH has in its stewardship of the federal funds it has been tasked with allocating, and our experience consistently has been that the agency takes this responsibility seriously. Its actions with respect to research security and its internal oversight procedures have demonstrated this commitment. We understand as well 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.

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 currently only is 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 2024 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 this thoughtful RFI. 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,



David J. Skorton, MD
President and CEO