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October 22, 2019

Office of Science and Technology Policy  
Executive Office of the President  
Eisenhower Executive Office Building  
1650 Pennsylvania Avenue  
Washington, DC 20504

**Re: Office of Science and Technology Policy Request for Information on the Bioeconomy  
(84 FR 47561)**

The Association of American Medical Colleges (AAMC) appreciates the opportunity to comment on the White House Office of Science and Technology Policy (OSTP) request for information on promoting the bioeconomy. The AAMC is a not-for-profit association representing all 152 accredited U.S. medical schools, nearly 400 major teaching hospitals and health systems, and more than 80 academic and scientific societies. Through these institutions and organizations, the AAMC represents nearly 173,000 faculty members, 89,000 medical students, 129,000 resident physicians, and more than 60,000 graduate students and postdoctoral researchers in the biomedical sciences.

The AAMC recognizes the potential of a robust bioeconomy in contributing to scientific progress and advances in health and medicine. We are pleased to offer comments on the following questions:

**What specific actions could the U.S. Government take to reinforce a values-based ecosystem that will guide the transformation and expansion of the U.S. bioeconomy, in both the short- and long-term?**

The AAMC agrees that “departments and agencies should prioritize evidence-based standards and research” in the policymaking process, as stated in the Fiscal Year 2021 Administration Research and Development Budget Priorities. The government should also be aware of the regulatory burden created by compliance with varying requirements across federal science agencies and the detrimental effect that this can have on the research enterprise. To the extent that OSTP is able to assist with streamlining and harmonizing research requirements and ensuring that regulations are effective in achieving their intended outcome, reducing regulatory burden is an area of significant opportunity for reform. We also support the recommendations outlined in the 2012 National Bioeconomy Blueprint, that “attention should be given to application review times, sequential reviews by multiple agencies should be coordinated to allow parallel reviews, and specific guidance should be issued in response to stakeholder needs.”

As an organization supporting the full spectrum of research performed at medical schools and teaching hospitals, the AAMC appreciates the emphasis on applied science but notes the critical need

for early-stage discovery in establishing the translational pipeline and accelerating the development of treatments and cures. It is imperative that federal agencies continue to fund basic scientific inquiry, including the infrastructure needed to conduct fundamental research. This targeted investment in basic research is necessary to form the foundation for further product development and commercialization and contribution to the bioeconomy.

**In what ways can the U.S. Government partner with the private sector, industry, professional organizations, and academia to ensure the training and continued development of a skilled workforce to support the growth of the bioeconomy?**

A robust research and development ecosystem, and the development of the necessary workforce to support it, is bolstered by effective and principled partnerships between government, academia, and industry. The federal government should focus its efforts on establishing and expanding government-wide technology entrepreneurship programs, such as the highly successful NSF I-Corps program; streamlining partnership agreements for collaborations with federal laboratories; and expanding the metrics that are used to evaluate success of federal R&D investments and their resulting social and economic impacts.

The skillsets that are needed to promote the bioeconomy and future research workforce will likely continue to include quantitative and data science skills, and increased emphasis on leadership, team science, and communication. PhD and MD-PhD programs should encourage cross-disciplinary training and research and facilitate experiential learning for students in industry and other non-academic settings. Federal agencies can support these activities through training grants and designated funding, and by facilitating information sharing and dissemination of new training modules that focus on emerging areas of science and technology relevant to the bioeconomy.

Finally, it is essential to acknowledge the critical role of international collaboration and the contribution of foreign scientists to the U.S. research workforce, at all levels. The AAMC strongly supports the development of federal policies that balance national and economic security concerns with an open scientific environment and ensure that the U.S. continues to be a place where researchers from other countries can productively engage in education and research.

**In what ways can the U.S. Government partner with the private sector, industry, professional organizations, and academia to establish a more robust and efficient bioeconomy infrastructure?**

In order to truly catalyze the translation of research, we need to create more extensive networks and increase interactions across government, academia, and industry. Establishing the necessary infrastructure for the bioeconomy will require the federal government to fund regional research consortia and promote information and infrastructure sharing, including core facilities and instrumentation. It is also critical that agencies continue the necessary support provided to institutions via facilities & administrative costs, which offset a portion of the costs needed to develop and maintain the infrastructure for ongoing research programs.

Effective translation at the institutional level requires predictable, sustainable funding across the spectrum of biomedical research, from basic and preclinical to clinical research. There are a number of federal policies AAMC supports to facilitate translation of basic science discoveries to application

and/or entry into the marketplace, as detailed in a recent multi-association comment on federal technology transfer authorities and processes<sup>1</sup>.

**Across the spectrum, from basic discovery to practical application, what data policies, information-sharing mechanisms, and safeguards will be necessary for a prosperous U.S. bioeconomy?**

With increased data sharing comes a necessary focus on data quality, privacy, and security, particularly when dealing with sensitive or proprietary information. To facilitate effective data sharing and the development of the bioeconomy, the government should provide clear and harmonized policies across agencies as to how different types of data are expected to be shared, and adopt and recommend data standards so that datasets will be well curated, protected, accessible and reusable to enable research and allow for future interoperability. Federal agencies should also create secure data storage solutions whenever possible, as well as fund institutions to develop and maintain resources for data management and storage. We refer OSTP to recent comments<sup>2</sup> by the AAMC in response to proposed provisions for a draft NIH data management and sharing policy for further details on biomedical research data sharing.

Finally, we would like to reiterate the importance of continued, sustained investment in fundamental, investigator-initiated research to the development of the bioeconomy. Federal funding for basic research is a necessary step in building a foundation for the research enterprise and leading the way to applied and patentable discoveries for innovations in health and medicine.

The AAMC appreciates OSTP's efforts to engage the relevant stakeholders to inform federal decision-making on the bioeconomy and would be happy to work with the office as it moves forward on this issue. Please feel free to contact me or my colleagues Anurupa Dev, PhD, Lead Specialist for Science Policy ([adev@aamc.org](mailto:adev@aamc.org)) and Heather Pierce, JD, MPH, Senior Director for Science Policy and Regulatory Counsel ([hpierce@aamc.org](mailto:hpierce@aamc.org)) with any questions about these comments.

Sincerely,

A handwritten signature in blue ink, appearing to read "Ross E. McKinney, Jr., MD". The signature is stylized and includes a small circular mark at the end.

Ross E. McKinney, Jr., MD  
Chief Scientific Officer

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<sup>1</sup> <https://www.aamc.org/system/files/c/1/494656-highereducationassociationroifeedbackresponse.pdf>

<sup>2</sup> [https://www.aamc.org/system/files/c/1/493914\\_aamcsubmitscommentstonihonproposedprovisionsforadatamanagementa.pdf](https://www.aamc.org/system/files/c/1/493914_aamcsubmitscommentstonihonproposedprovisionsforadatamanagementa.pdf)