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December 5, 2011

Office of Science and Technology Policy
Executive Office of the President
725 17th Street Room 5228
Washington, DC 20502

Submitted electronically to: bioeconomy@ostp.gov www.regulations.gov

**Re: Request for Information: Building A 21st Century Bioeconomy**, published in the October 11, 2011 *Federal Register* (76 FR 62869)

The Association of American Medical Colleges (AAMC) is pleased to have this opportunity to comment on the Request for Information entitled *Building a 21st Century Bioeconomy*, issued by the Office of Science and Technology Policy (OSTP).

The AAMC is a not-for-profit organization representing all 136 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, and nearly 90 academic and scientific societies. Through these institutions and organizations, the AAMC represents 128,000 faculty members, 75,000 medical students, and 110,000 resident physicians.

We are pleased to see the Executive Office address the critically important topic of translating the country's innovations in biological research to meet the challenges our nation faces. Below we address some of the questions posed by OSTP as it works to develop a National Bioeconomy Blueprint.

As a general comment, we note that the examples of new research opportunities provided by the RFI, and the general framing of the document, appear to imply that the 21st Century Bioeconomy will be mainly driven by laboratory-based research translated into largely commercial applications. The AAMC agrees that bench research will continue to be a major driver of the new economy. However, profound discoveries and implementation of research findings also take place in a variety of other places, including clinical delivery settings and in communities, ensuring fidelity with the social contract that the benefits of research will be used to improve health and develop sustainable health delivery systems for all Americans. The AAMC, which focuses on improving health for all, advocates for support of research across the full continuum of health sciences, from basic biological research to implementation science, health services research, etc. This continuum involves biomedical, social, behavioral and other sciences, and, as the RFI indicates, is increasingly transdisciplinary and team-oriented.

**Grand Challenges**

> **Description from OSTP:** President Obama has identified "grand challenges"' as an important element of his innovation strategy, such as "smart anti-cancer therapeutics that kill cancer cells and leave their normal neighbors untouched; early detection of dozens of diseases from a saliva sample; personalized medicine that enables the prescription of the right dose of the right drug for the right person; a universal vaccine for influenza that will protect against all future strains; and regenerative medicine that can end the agonizing wait for an organ transplant."'

The institutions represented by the AAMC perform more than half of all extramural research sponsored by the National Institutes of Health (NIH), and also conduct research supported by other federal agencies, industry and philanthropy. We note that major scientific challenges inevitably have implications for resources and infrastructure. In fact, many areas of biomedical science are becoming increasingly dependent on large scale instrumentation, facilities and infrastructure, similar to how the physical sciences came to rely on such infrastructure in the 20th Century. Major challenges should therefore include development of new resources that can support life sciences broadly. Two examples would be the development of new biomarkers for disease, and new disease models. Improvement in information systems and the broad use and integration of electronic medical records into research would be a substantial benefit to innovation in health care.

**Research and Development**

> **Description from OSTP:** R&D investments, particularly in platform technologies, can support advances in health, energy, the environment, and agriculture, and accelerate the pace of discovery in fundamental life sciences research.

The AAMC strongly agrees with the premise of this section, and the increasing opportunities for developing platform technologies. Moreover, such development often focuses on technologies that are "precompetitive" and would permit more extensive partnerships involving industry, academic institutions, governmental agencies and non-profit organizations.

A particularly ripe area for precompetitive collaboration is in the effort for establishing valid biomarkers for slow developing diseases. The current effort led by researchers from NIH's National Institute on Aging, industry and academia to develop quantitative disease models by sharing data from Alzheimer's Disease patients shows great promise. As an Institute of Medicine panel recently noted, "Collaboration on data, resources, and biological specimens could lead to significant advances in the development of genomic and genetic applications. However, intellectual property protections and other barriers can inhibit or outright prevent these collaborative efforts." To the extent possible, federal regulations and policies should promote these collaborations.

Federal policies should also promote the use of shared research facilities, instrumentation, and other resources, both regionally and remotely. Resource sharing helps promote efficiencies in construction, maintenance, and operation of, for example, expensive core facilities. As noted above, much biomedical research relies on advanced technologies, informatics, and emerging tools, as well as on shared research resources that often require dedicated professional staff. Growth in transdisciplinary research - and the increasing need for investigative teams with diverse and specialized skills and capabilities - also further complicates the management of science. The very process for using shared resources can help promote collaboration among investigators, and may help promote team science. The extraordinarily productive use of DOE-funded synchrotron radiation facilities to support biological structure investigations is a model in this regard. Other potential models of collaboration involving the use of shared infrastructure include the NIH Clinical and Translational Science Awards (CTSA) program, which is developing national consortia for clinical investigation. CTSAs also link with other established resources and programs, including for example pioneering programs in clinical effectiveness and health outcomes research in the Department of Veterans Affairs.

**Moving Life Sciences Breakthroughs From Lab To Market**

> **Description from OSTP:** It is a challenge to commercialize advances in the life sciences because of the risk, expense, and need for many years of sustained investment. The Administration is interested in steps that it can take directly, but is also interested in encouraging experimentation with new private-sector-led models for funding commercialization of life sciences research.

The AAMC believes that the Bayh-Dole Act and other federal policies promoting technology transfer already provide an excellent framework to facilitate transfer of technology from academic institutions into useful application. Recent joint comments by the AAMC, the Association of American Universities, and other higher education associations to the Department of Commerce, noted that a major limitation for university transfer of technology is faculty's lack of access to funding for proof-of-concept research, market analysis, or appropriate mentoring. To address this situation, the associations recommended the establishment of new "Translational Supplemental Awards."

> These awards would be made by the major federal research agencies to support proposals jointly submitted by an existing principal investigator and the university TTO or another appropriate institutional research or technology commercialization official. These awards would be made at the tail end of federally funded awards to support next stage research for projects that show strong clinical or market potential. We believe that providing such awards would both incentivize researchers to think about the potential commercial applications of their research and help to change the culture of the federal research agencies in ways that would help facilitate the commercialization goals of the Administration. (AAU et al, April 1, 2011)

**Workforce Development**

> **Description from OSTP:** Investment in education and training is essential to creating a technically-skilled 21st century American bioeconomy workforce.

Biomedical and health science training, both through training programs and research project grants, not only creates environments for trainees to develop in-depth discipline-based expertise, but should also help prepare trainees for a broad diversity of careers, including industry, public policy, and other areas, all of which potentially contribute to health and medicine. The AAMC supports high quality education and training for all research trainees and recognizes the need for early exposure to and training for a broad range of career options, including those outside of academic research. A successful graduate of a training program, along with acquiring scientific research skills, would acquire professional and career development skills, such as effective communication, collaboration, and leadership. In addition, training programs should include a team-based focus and encourage interdisciplinary training and collaborations, as increasingly, young scientists train to work in teams and in collaborations on cross-disciplinary research.

Although beyond the scope of AAMC's core constituency, AAMC recognizes the important role that community colleges play in training the science and engineering workforce. In addition, the AAMC recognizes that the science workforce goes beyond researchers to include all members of a team - the business advisors, core facility specialist, pharmacists, nurses, and physician assistants. Community colleges, undergraduate programs and graduate education all have critical roles to play in preparing students for the broad expertise that is needed in the research workforce of the 21st century.

Training future scientists and engineers also requires partnerships with the private sector. As noted above, many trainees will go into careers in the private sector. The AAMC proposes that prospective employers, including those from the private sector, inform academic training programs of the knowledge and skills that they value in trainees and recommend training needs so that trainees are better prepared to enter the workforce. In addition, AAMC recommends that the private sector develop more training opportunities, in the form of internships and fellowships, for students and postdocs. For example, the National Science Foundation's program for Integrative Graduate Education and Research Traineeship (IGERT) provides an excellent model for exposing trainees to opportunities for collaboration and application of research to social needs.

**Reducing Regulatory Barriers To The Bioeconomy**

> **Description from OSTP:** As President Obama has stated, our regulatory system must "identify and use the best, most innovative, and least burdensome tools for achieving

> regulatory ends" and "protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation."

The AAMC is supportive of this administration's efforts to review and reduce regulatory burden. In addition to looking at the overall burden of any regulatory process, we believe that it is essential to assess whether the regulatory burden at any level is supported or justified by the resulting benefit or success of the regulation in accomplishing an agency's stated goals. To accomplish this objective, the evaluation of existing regulations should include assessment of both the burden placed on researchers and institutions and clear metrics to evaluate success. More importantly, the text of new regulations should embed mechanisms and metrics to review their burdens and effectiveness.

Of primary concern in the highly-regulated environment of biomedical research is whether new regulations are based on solid evidence that the proposed change will adequately address regulatory concerns while allowing ethical, scientifically sound research to continue. This "evidence-based regulation" not only increases the chances that the agency goals will be achieved, but also promotes compliance and public trust that the regulations are the result of evidence that supports their adoption. For example, in the final rule on financial conflicts of interest (Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought, 42 CFR Part 50 Subpart F), the definition of a Significant Financial Interest that must be disclosed by an investigator to an institution includes certain remuneration or equity interests with a value of $5000 or more. The rules that have been in effect since 1995 set that same *de minimis* threshold at $10,000. The decreased threshold will substantially increase the number of disclosures institutions will have to collect and review, but was not supported by data that indicated the need for or likely effect of the change on the objectivity of research. It may be that the increased burden borne by institutions and researchers is justified by the effect of such disclosures on research objectivity, investigator behavior, or public trust, but we cannot know without setting both the expectation and the process for assessing the impact.

**Public-Private Partnerships**

> **Description from OSTP:** The Administration is interested in serving as a catalyst for public-private partnerships that build the bioeconomy and address important unmet needs in areas such as health, energy, agriculture, and environment.

AAMC recognizes that the realization of the promise of biomedical research requires the development and fostering of principled partnerships between academia, industry, government, and communities (for example, see our comments on precompetitive technology and biomarkers above). Particularly with regard to the translation of promising therapeutics from the bench to clinical practice, the facilitation of such partnerships is a critical role for the government. The bioeconomy needs the input from all stakeholders, including the academic medical centers and teaching hospitals to remain competitive on a global scale. By establishing roadmaps and support for the productive, ethical collaboration between the public and private sectors, the

Administration can both set expectations and increase public trust in the U.S. Research enterprise.

We would be pleased to offer OSTP further assistance in this important process. The AAMC has long been an advocate for the improvement of health of all through discovery and has provided federal agencies and administrations with specific comments on many of the topics summarized here and related comments about the development of a research workforce, the regulation of research, and the importance of preparing for the research needs of the future. I invite you to visit our website if you would like additional information on these topics [insert testimony and correspondence page here] and please do not hesitate to contact me with any questions.

Sincerely,

Ann Bonham, Ph.D.
Chief Scientific Officer