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April 4, 2016

Darrell G. Kirch, M.D. President and Chief Executive Officer

The Honorable Lamar Alexander Chair Committee on Health, Education, Labor, and Pensions United States Senate Washington, DC 20510

The Honorable Patty Murray Ranking Member Committee on Health, Education, Labor and Pensions United States Senate Washington, DC 20510

Dear Chairman Alexander and Ranking Member Murray:

The Association of American Medical Colleges (AAMC) commends you for your leadership and vision in undertaking the bipartisan biomedical innovation initiative to enhance the process for getting safe treatments, devices, and cures to patients and to support the critical role of the National Institutes of Health (NIH) in that process. The AAMC shares your concern that the regulatory burden on institutions and individual scientists takes valuable time away from research, and is pleased to endorse the Promoting Biomedical Research and Public Health for Patients Act as an important proposal to help reduce this burden.

This legislation appropriately incorporates many of the recommendations of the National Academies' report *Optimizing the Nation's Investment in Academic Research*. The myriad regulations, policies, guidance documents, and funding requirements have increased and complicated the regulatory oversight of federally funded research and we agree with the National Academies' assertion that this system should be "critically examined and recalibrated." The AAMC is supportive of the approach in your bill, which provides some direction and clearly sets forth the objectives of the review and revision of specific rules and the regulatory framework overall, but is not so prescriptive that it prevents the NIH from identifying alternative solutions that could accomplish the same goals. Key provisions that have significant promise in decreasing regulatory burden include: the review of the rules related to the review of financial interests and reporting of financial conflicts of interest; the provision to reduce the administrative burden related to

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subrecipient monitoring by primary awardees of NIH grants; and the requirement for systematic review of similar regulations or policies issued by different funders, including for laboratory animal research.

The AAMC is a not-for-profit association dedicated to transforming health care through innovative medical education, cutting-edge patient care, and groundbreaking medical research. Its members comprise all 145 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 51 Department of Veterans Affairs medical centers; and more than 80 academic societies. Through these institutions and organizations, the AAMC serves the leaders of America's medical schools and teaching hospitals and their 148,000 faculty members, 83,000 medical students, and 115,000 resident physicians. More than half of NIH's extramural research funding is awarded to AAMC member medical schools and teaching hospitals.

Again, the AAMC thanks you for your leadership in sustaining NIH as a national priority, and we look forward to working with you and your committee as you move this legislation forward.

Sincerely,

Danell G. Kinch

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