AAMC

Association of
American Medical Colleges
655 K Street, N.W., Suite 100, Washington, D.C. 20001-2399
T 202 828 0400 F 202 828 1125
www.aamc.org

May 19, 2015

The Honorable Fred Upton
Chair
Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Joe Pitts
Chair
Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

The Honorable Diana DeGette
Ranking Member
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

The Honorable Frank Pallone, Jr.
Ranking Member
Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

The Honorable Gene Green
Ranking Member
Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

Dear Chairmen Upton and Pitts and Representatives DeGette, Pallone, and Green:

The Association of American Medical Colleges (AAMC) is pleased to provide some preliminary thoughts on the amendment in the nature of a substitute to the 21st Century Cures Act released on May 19. The AAMC represents all 141 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 nearly 90 academic and scientific societies. Through these institutions and organizations, the AAMC represents 148,000 faculty members, 83,000 medical students, 115,000 resident physicians, and thousands of graduate students and postdoctoral scientists. More than 50 percent of the extramural funding awarded by the National Institutes of Health (NIH) supports groundbreaking medical research at AAMC-member medical schools and teaching hospitals.

The AAMC applauds you for producing legislation that continues the bipartisan and open manner in which the 21st Century Cures initiative has been conducted, and that addresses many of the issues we raised with the earlier draft.

We commend you especially for including language that would reauthorize the National Institutes of Health (NIH) for three years at funding levels that represent an increase of $1.5 billion per year, and for proposing $10 billion over the next five years in mandatory funding through an NIH Innovation Fund. This is a most welcome infusion of funding that will help revitalize our nation's biomedical research effort, and demonstrates an opportunity to facilitate sustainable, predictable, long-term growth for the agency. We are deeply grateful for this recognition of the critical importance of maintaining NIH as a national priority.

In addition, we renew our recommendation that NIH be granted multi-year budget authority to carry over funding into the next fiscal year and enable more strategic management of grant funding, particularly in years when appropriations are not finalized until late in the fiscal year.

At the same time, we note the current proposal mandates a number of new responsibilities and activities to the Food and Drug Administration (FDA) without a concomitant increase in funding, and we encourage you to consider the need for additional resources to enhance the agency's capacity for regulatory science and to address the additional mandates included in the legislation.

In our comments of March 18 on the earlier discussion draft, we urged the committee to ensure that the bill presents a comprehensive vision for the funding and regulation of medical research and is internally consistent. We are heartened by the bill in its current form, which organizes its proposals into the three broad categories of Discovery, Development, and Delivery.

In particular, we concur with NIH's support for the proposals in the proposed legislation to enhance accountability, and we believe that these proposals will assist the agency's efforts to invest in the highest research priorities, foster creative collaborations, and sustain the biomedical research workforce.

The AAMC believes the revisions proposed for the NIH Strategic Plan required in section 1021 are appropriate and will better coordinate the overall NIH plan with the strategic planning that is already occurring within the Institutes and Centers.

We acknowledge and thank you for deleting the provision in the initial discussion draft within the NIH Research Strategic Investment Plan (Section 4001) requiring the Director of NIH to ensure at least 55 percent of extramural research funding goes to support basic biomedical research.

The AAMC welcomes the proposal to ease the administrative burden on NIH, and supports section 1024, which would exempt certain NIH research activities from the requirements of the Paperwork Reduction Act.

We acknowledge the "sense of Congress" expressed in section 1025 "that participation in or sponsorship of scientific conferences and meetings is essential to the mission of the National Institutes of Health." We encourage the committee to exempt NIH from OMB Memo 12-12 to help build and maintain the connections within and across disciplines that do help drive research innovation.

The AAMC commends and supports section 1124, which mandates the Secretary to review or clarify regulations under the Health Insurance Portability and Accountability Act (HIPAA) for conducting research. In particular, we appreciate that the legislation allows the use and disclosure of protected health information (PHI) by a covered entity for research purposes to be treated as health care operations; lets researchers access data remotely for "reviews preparatory to research" without authorization (currently, they must be physically on site to look at medical records to determine if research is feasible); and allows a one-time authorization of use and disclosure for future research (currently prohibited). All of the proposed revisions would be beneficial and remove barriers to research without jeopardizing or disadvantaging patients or research subjects.

The AAMC appreciates the language in section 3041 to exempt certain transfers for educational purposes from the manufacturers' transparency requirements. This language appears to address concerns that have been raised with the chilling effect the current reporting requirements might have on legitimate continuing medical education (CME) programs.

We also appreciate that the legislation does not include language regarding the 340B Drug Pricing Program at this time. As you know, the Health Resources and Services Administration (HRSA) is expected to release comprehensive guidance that would address many components of the program and would provide the full stakeholder community an opportunity for public comment. We believe it would be premature to issue legislation on an administratively complex program like 340B in advance of this opportunity, particularly as part of the Cures initiative that has demonstrated a commitment to an open, collaborative, and transparent process.

We continue to review other provisions of the legislation with our members, and look forward to working with you as this legislation moves forward.

Again, the AAMC thanks you and your staff for your tireless efforts to identify opportunities to accelerate scientific discovery in the service of improved health, and we look forward to working with you as this legislation moves forward. Should you or your staff wish to discuss any of these points, please contact David Moore, AAMC Senior Director for Governmental Relations, at 202-828-0559 or dbmoore@aamc.org.

Sincerely,

Atul Grover, M.D., Ph.D.
Chief Public Policy Officer

cc: House Energy and Commerce Members