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

The Honorable Diana DeGette
United States House of
Representatives
Washington, DC 20515

Dear Chairman Upton and Representative DeGette:

The Association of American Medical Colleges (AAMC) is pleased to provide our preliminary thoughts on the 21st Century Cures discussion document released on January 27. 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 thanks and commends you and the Committee for convening the extensive series of hearings and roundtables, both in Washington and across the country, to explore the opportunities for and obstacles to accelerating the pace of discovery and translating this knowledge into novel therapeutics and prevention strategies for the benefit of all Americans. As you heard from the representatives of academic medicine, patient groups, industry, and the federal agencies who participated in the roundtables and hearings, this is a time of unprecedented opportunity to employ the fruits of scientific discovery to transform health care both in the United States and globally.

We recognize that the discussion draft reflects the Committee's initial attempts to address a wide range of research-related issues that emerged during the hearings and roundtables, and we applaud the transparent and inclusive approach to this process. We are concerned, however, that the lack of a unifying vision for re-energizing the nation's medical research enterprise weakens this document. Instead, the draft presents a collection of ideas and proposals that address perceived deficiencies of varying magnitude. This piecemeal approach is at odds

with the stated needs for addressing the research enterprise as a whole and for a more strategic approach to research funding and oversight.

As the next draft is developed, we urge the Committee to ensure that:

1) **the bill presents a comprehensive vision for the funding and regulation of medical research and is internally consistent;**
2) **any revised oversight or regulation of research serves to facilitate the research enterprise, not tie the hands of the agencies, institutions, or researchers;**
3) **current ongoing efforts to improve and harmonize the regulatory environment for research are encouraged and supported, not hampered;**
4) **federal agencies working to realize the vision of 21st Century Cures are provided with sufficient funding to accomplish their goals, appropriated in a predictable and timely manner that allows for strategic planning by the agencies, institutions, and researchers;**
5) **patients are more engaged in all aspects of the biomedical research enterprise; and**
6) **federal policies enhance the preparation of the 21st Century biomedical research workforce.**

In this spirit, we hope the following preliminary observations are useful to you as the Committee works to revise and update the current discussion draft.

Legislative and regulatory provisions governing medical research should facilitate a 21st Century research enterprise, not hinder scientific progress or duplicate current efforts

The AAMC wholeheartedly agrees that planning, oversight, and accountability are necessary, particularly in dealing with the fiscal constraints of the past decade, but must be done in a way to incentivize innovation, not stifle scientific serendipity. Section 4001 requires the NIH to issue "a "5-year biomedical research strategic investment plan" to make funding allocation decisions, including strategic investment for each institute; have a common format; and identify strategic focus areas.

The AAMC is unconvinced that an overarching NIH strategic plan will enhance fiscal or scientific efficiency, transparency, or accountability sufficiently to merit the considerable time, effort, and resources NIH and the community would need to devote. Currently, each NIH Institute and Center produces its own 5-year strategic plan, based on extensive input from the scientific and patient communities, the groups best suited to identify and prioritize emerging scientific opportunities and compelling health needs. Because Congress appropriates annual funding to each Institute and Center, it is incumbent on each Institute and Center to identify visionary, but attainable, goals and make strategic investments to achieve these objectives. Furthermore, the Institutes and Centers vary significantly in terms of

the health needs they must address, the state of science in their relevant areas, and the range of funding mechanisms used to support their scientific mission, and the variability in individual plans appropriately reflects these differing factors.

Moreover, NIH already engages in extensive trans-institute planning, as demonstrated by its commitment to activities such as the BRAIN Initiative and the administration's initiatives on precision medicine, antimicrobial resistance, and Alzheimer's disease; this planning reflects a balance between emergent priorities and longer-term strategic objectives.

Among broader concerns about the proposed approach, the AAMC specifically objects to the discussion draft's provision 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. While the AAMC agrees with the critical importance of the NIH's mission in the support of basic research, we believe that mandating in statute a specific percentage of funding to any type of research is counter-productive and unnecessarily limits NIH's ability to respond to emerging scientific opportunities or health needs.

The draft's provisions regarding federal funding of research by NIH demonstrate the document's fragmentary approach. In some cases, the draft's proposals are internally inconsistent. For example, section 4005 of the draft calls for the Government Accountability Office (GAO) to conduct a study on NIH's Common Fund, including an analysis of how the funds "have been used and the impact of that funding on each of the areas that received funding." On the very next page, section 4007 proposes to authorize additional money for the Common Fund.

The bill should mitigate regulatory burden on researchers and institutions, rather than increasing burden through potentially duplicative provisions or efforts.

As noted by NIH Director Francis Collins, M.D., Ph.D., and various representatives from academic medicine, the regulatory burdens that are imposed on institutions and faculty continue to grow, and in many cases different agencies have different regulations on the same issue. A March 2014 report from the National Science Board on *Reducing Investigators' Administrative Workload for Federally Funded Research* stated, "The past two decades have witnessed increasing recognition that the administrative workload placed on federally funded researchers at U.S. institutions is interfering with the conduct of science in a form and to an extent substantially out of proportion to the well-justified need to ensure accountability, transparency and safety." The report also noted, "Failure to address these issues has resulted in wasted Federal research dollars. At a time of fiscal challenges and with low funding rates at many Federal agencies, it is imperative that these issues

are addressed so that researchers can refocus their efforts on scientific discovery and translation."

The AAMC notes that in 2013, Congress charged the National Academy of Sciences (NAS) with conducting "a study on the impacts of Federal regulations and reporting requirements on institutions of higher education" (Senate Report 113-71 to accompany the FY 2014 Labor HHS Appropriation), and a designated committee was appointed to carry out this charge. The AAMC has already provided the NAS committee with information about the high cost and burden of certain regulations, including the Public Health Service regulations on financial conflicts of interest in federally funded research. The results of AAMC's research indicate that the time and resources institutions and faculty must devote to keeping up with and maintaining compliance with such regulations is a growing burden without demonstrated value added. The AAMC urges the Committee to use the upcoming results of the NAS committee's work to better frame any regulatory changes and to adapt the framework they suggest for addressing regulatory burden.

With regard to the proposal for clinical trials modification (sections 3001-2), the AAMC has long supported efforts to provide all human subjects with consistent and adequate protections. For example, the AAMC is working with the NIH and the research community to ensure a single Institutional Review Board (IRB) of record that ensures the protection of human research subjects while streamlining regulatory requirements and decreasing unnecessary burden on the institutions and investigators. In addition, the long-awaited proposed revision to the "Common Rule" on the oversight of federally funded research with human subjects has been drafted and is at the Office of Management and Budget (OMB) awaiting regulatory review. Given these productive efforts, we support a legislative approach that facilitates the harmonization of requirements through collaborative efforts; we worry that legislation that requires a specific approach is unnecessary and could hamper rather than encourage these ongoing efforts.

The AAMC welcomes the Committee's interest in removing unnecessary restrictions on activities that facilitate research. The AAMC urges lifting or easing the restrictions on travel by federal employees to scientific meetings, which are essential to help build and maintain the connections within and across disciplines that do help drive research innovation. We appreciate that the discussion draft appears to recognize this need, and we look forward to reviewing the text when section 4003 is updated.

The AAMC commends the Committee's inclusion of language in section 2221 to amend the HITECH Act to remove many of the current barriers imposed by the Health Insurance Portability and Accountability Act (HIPAA) for conducting research. The most beneficial proposed changes would maintain HIPAA's privacy

protections, but would also: allow using health care data to be considered health care operations; let 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 allow an individual to authorize future research (currently prohibited). All of the proposed revisions would be beneficial and remove barriers to research that have no potential of protecting or benefitting patients or research subjects.

Scientific Progress Requires Sustained, Predictable Funding Growth

The AAMC is disappointed that the current draft does not include authorization levels for NIH that reflect the unprecedented scientific opportunities and pressing health needs. If we are to achieve the full potential of advances in areas such as precision medicine, neuroscience, digital health technologies, and the other emerging opportunities discussed by the Committee, it will require sustained, predictable real growth in the budget for National Institutes of Health (NIH). As you know, the NIH budget has lost nearly 25 percent of its purchasing power after adjusting for inflation since 2003.

As NIH Director Collins noted during the initial roundtable discussion last May, "Certainly from NIH's perspective what we most desperately need in order to continue what has been the most successful story on biomedical research that the world has ever seen is a steady, predictable trajectory of support."

The AAMC urges Congress and the Administration to work together to support sustained predictable real growth in the NIH budget. In particular, the AAMC supports the recommendation of the Ad Hoc Group for Medical Research that Congress provide at least $32 billion for NIH in FY 2016.

In addition, while it is beyond the purview of this document and jurisdiction of the Committee, the failure to complete the annual appropriations process in a timely fashion unnecessarily impedes both planning and administering the research enterprise, both for NIH and for the institutions and scientists supported by federal funding. However, the Committee could mitigate the impact of this shortened timeframe for NIH decision making by granting NIH multi-year budget authority. Allowing NIH to carry over funding into the next fiscal year would enable more strategic management of grant funding, particularly in years when appropriations are not finalized until late in the fiscal year.

Patients should be more fully engaged in all aspects of the biomedical research enterprise

The AAMC agrees with the critical need to engage patients more fully in all aspects of the research enterprise. For example, the Committee is working on a proposal

[Title I, Subtitle H] to clarify and rationalize the rules to facilitate the responsible communication of scientific and medical developments. While the current rules are confusing and could use some clarification, the AAMC strongly encourages the Committee to develop a process that involves patients and physicians and other health providers in the formulation of these new rules, and to ensure that the new framework emphasizes the communication of evidence-based information.

The AAMC applauds and supports efforts to address the availability of educational information regarding medical products and to ensure the equitable diffusion of such information. The convening of an internal, agency-wide working group to strategize around traditional and electronic communication efforts and to identify subpopulations of import is an essential first step in ensuring equitable access to medical information and safety alerts. Additionally, the specific opportunities identified by the working group, including targeted outreach to traditionally underserved subpopulations and increasing their representation in the Food and Drug Administration (FDA) Patient Network, addressing the needs of Limited English Proficiency (LEP) populations, and leveraging the communication power of social media are all promising strategies.

We encourage federal agencies to work with hospitals, medical centers and electronic health record (EHR) developers to explore the possibility of enhancing or testing the use of automatic prompts via EHRs to alert providers, and therefore patients, to important safety and medical product information at the point of care. This or a similar strategy would assure the broadest possible dissemination of crucial information via practitioners well suited to interpret and deliver medical product alerts and updates.

Federal policies should enhance the preparation of the 21st Century biomedical research workforce

The AAMC thanks the Committee for recognizing the importance of early career scientists, and encourages Congress to keep in mind the complexity of the continuum of activities necessary to educate and train the next generation of biomedical scientists. The AAMC has been working with the NIH and other federal agencies on issues related to the biomedical research workforce, and we urge Congress to afford the agencies with the necessary flexibility to modify existing and add new training programs to meet the evolving needs of the 21st Century biomedical research workforce.

For example, the AAMC believes that NIH and other federal agencies are on the right track to recognize that a broad diversity of careers in academia, industry, and other sectors is a legitimate, valuable outcome of agency training and career development programs. AAMC also supports NIH's efforts to build a diverse research workforce. NIH's efforts to collect more data on the biomedical workforce needs will inform efforts to better understand the careers that trainees are

entering, align training with those needs, and educate trainees about these career options.

The challenge is to accelerate training and transition of these trainees to fully functional careers in science. NIH has developed several programs to help this career development and to recognize outstanding research by early career scientists. However, age at time of first award is not alone a determinative measure for how well the research system engages new scientists; increasingly, scientists train to work in teams and in collaborations on cross-disciplinary research. Training programs with team-based focus encourage interdisciplinary training and collaborations, which are necessary for the science of today and the future. The ages of "principal" investigators become less pertinent in multi-faceted team environments. Yet, other efforts are needed to continue to catalyze career transitions. Congress should allow federal agencies to continue monitoring these efforts without mandating specific data reporting. Research program leaders and their institutions are focusing strategically on how best to invest in and sustain research and research training programs, and to ensure that we are preparing the workforce for the needs of society - as a partner to federal funding agencies, private organizations, and industry in such investments.

Again, the AAMC thanks you and the Committee for the dedicated and diligent efforts to date 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,

Ann Bonham, Ph.D.
Chief Scientific Officer