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Commission on Evidence-Based Policymaking

Commission on Evidence-Based Policymaking Comments
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The Association of American Medical Colleges (AAMC) appreciates the Commission on Evidence-Based Policymaking's commitment to explore the impact, feasibility, and necessity of using available and newly collected data to propose, implement, and evaluate government programs and policies and is pleased to provide this response to the request for comments to guide the Commission's future activities, findings, and potential recommendations. The AAMC is a not-for-profit association representing all 147 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 160,000 faculty members, 83,000 medical students, 115,000 resident physicians, and thousands of graduate students and postdoctoral trainees in the biomedical sciences.

The comments below provide the Commission with: examples of recent reports that support the need for evidence-based policymaking; a model the AAMC has used to evaluate the effect of a revised regulation and which could be applied to other policies and programs; and the Association's thoughts on when evidence-generation should be considered or required in the context of new policies. As an organization that works to support the tripartite mission of research, clinical care, and medical education at our member institutions, the AAMC supports the increased collection and use of evidence throughout the policymaking and implementation process, from the proposal of new policies and programs through the evaluation of the effectiveness of those policies and programs. Without data to understand the need for or likely impact of new initiatives, regulations or policies may be ineffective, inefficient, or unduly burdensome without achieving intended aims. One area that has received significant attention recently and for which there are limited but promising mechanisms and proposed frameworks for incorporating evidence into policies and programs is in biomedical research.

A well-documented increase in regulatory burden for biomedical research underscores the need for thoughtful, deliberative, evidence-based policymaking. Recent studies and reports

that have sought to catalogue the cumulative effect of this burden raise concerns that the failure to engage in systematic, evidence-based assessment of current, possibly outdated, and proposed

policies is potentially diminishing research productivity and advances. The 2012 Federal Demonstration Partnership Faculty Workload Survey of researchers found that on average, 42% of their research time was spent fulfilling administrative duties instead of conducting research.[1] Since that time, the number of new and proposed regulations and policies has only increased, placing significant stress on researchers and academic institutions. Recent reports from the National Academies of Sciences, Engineering, and Medicine (the Academies),[2] the Government Accountability Office (GAO),[3] and the AAMC[4] identify a need for federal agencies to harmonize regulations, reduce workload and costs, and consider evidence-based regulatory approaches.

Determining the effectiveness of government policies and programs is hindered by a lack of data to inform the rulemaking process and limited evidence-based mechanisms to evaluate whether agency goals are being met. The Academies' report on optimizing the nation's investment in academic research examined many regulations governing federally funded research, finding that the expansion of the regulatory system is diminishing the effectiveness of the U.S. research enterprise. Notably, the Academies' committee discovered there is "little rigorous analysis or supporting data precisely quantifying the total burden and cost to investigators and research institutions of complying with federal regulations specific to the conduct of federally funded research." The report also highlights the committee's "difficulty finding data calculating the opportunity costs associated with diverting time, expertise, resources, and potential away from the conduct of basic and applied research to meet regulatory demands."[5] The report cited the AAMC Conflict of Interest (COI) Metrics Project as an existing effort to quantify the impact and burden of research regulations on academic institutions.

The AAMC COI Metrics Project (www.aamc.org/metricsproject) was designed to measure the cost and outcomes of the 2011 revised regulations on financial conflicts of interest in Public Health Service funded research. The study, which collected data from AAMC member institutions over a course of three years (the year before the August 24, 2012 implementation date for the revised regulations and the first two years after implementation), concluded that academic institutions incurred significant costs beyond their ongoing program administration costs to fully implement the regulations. Notably, these regulations made discrete changes to an existing framework without changing the underlying structure of the rule, meaning that at the

[1] Federal Demonstration Partnership Faculty Workload Survey (2012). http://sites.nationalacademies.org/cs/groups/pgasite/documents/webpage/pga_087667.pdf
[2] "Optimizing the Nation's Investment in Academic Research, A New Regulatory Framework for the 21st Century," (2016). https://www.nap.edu/catalog/21824/optimizing-the-nations-investment-in-academic-research-a-new-regulatory.
[3] See "Federal Research Grants: Opportunities Remain for Agencies to Streamline Administrative Requirements," (2016) http://www.gao.gov/assets/680/677949.pdf.
[4] AAMC Analysis in Brief, "Implementing the Regulations on Financial Conflicts of Interest, Results from the AAMC Conflict of Interest Project", April 2015. https://www.aamc.org/download/429214/data/april2015implementingtheregulationsonfinancialconflictsofintere.pdf
[5] "Optimizing the Nation's Investment in Academic Research, A New Regulatory Framework for the 21st Century," (2016). p 2.

time that the new rule was issued *each of these institutions already had the infrastructure, policies, and personnel in place to comply with the existing regulations.* Nonetheless, to come into compliance with the revised requirements of the regulations, 71 institutions invested almost $23 million ($22,557,744) in total, and the average number of full time equivalent employees needed to administer the requirements of the rule increased from 1.9 to 2.7. The number of "significant financial interests" (not financial conflicts of interest) collected by institutions rose by 45% as a result of new thresholds and requirements, requiring additional resources to review them for potential financial conflicts of interest. This substantial investment of resources resulted in relatively modest increases in the identification of conflicts of interest that required further review and reporting, with less than half reporting any increase in the number of identified financial conflicts of interest and all but 5 institutions of those that did see increases reported identifying fewer than 20 more conflicts of interest the year after the rule was implemented than the year before.

Based on AAMC's findings in addition to data from surveys by the Council on Government Relations and the National Science Board's Task Force on Administrative Burden, the Academies' report concluded that these surveys "call into question whether the new COI rule is accomplishing its intended goal of protecting the integrity of the scientific process and the welfare of research subjects, especially given the documented increases in administrative burden to institutions and investigators in the year following implementation of the rule."[6]

Efforts like the AAMC COI Metrics Project not only demonstrate how objective, rigorous, and systematic evaluation can be used as a framework for evidenced-based review of government programs, policies, and regulations, but also suggest how such a model could be employed *prospectively* to assess the likely impact of proposed regulation and policy (Questions 1, 16, and 17). The key to effective evidence generation in this context is the early consideration of whether the type of policy being considered would benefit from a prospective pilot or data collection and identification of the types of data that will best demonstrate the impact and the effectiveness of the policy or program. Partnership with those served by or affected by the initiative can be an efficient and effective way to answer these threshold questions. Recognizing that the required evidence will not always come from existing government data, pilot programs or collaboration with institutions, associations, and communities can both increase engagement in the process and enhance the changes that the initiative will accomplish its desired goals.

A 2013 memorandum to federal agency and department heads from the Office of Management and Budget captured the desire to "deliver[] a smarter, more innovative, and more accountable government for citizens," one component of which is for government agencies to "continually improve program performance by applying existing evidence about what works, generating new knowledge, and using experimentation and innovation to test new approaches to program

[6] "Optimizing the Nation's Investment in Academic Research, A New Regulatory Framework for the 21st Century," (2016). p. 91.

delivery."[7] This call for applying evidence to program delivery can be seen as a welcome and logical extension of the 2011 mandate to streamline regulations through retrospective review by agencies and increase interagency coordination to harmonize regulations.[8] However, as the GAO report concludes, with respect to the administration of federal grants, "opportunities exist… to further reduce universities' administrative workload and costs," and "efforts to standardize requirements have not fully addressed variations in agency implementation of requirements."[9]

Agencies should integrate robust evidenced based evaluation mechanisms into the proposed rulemaking process to ensure that regulatory decisions are made using the best and most current evidence available (Question 17). The failure to gather and use data about impact, including burden and outcomes, can lead to protracted or ultimately unsuccessful policymaking processes where the stated objectives of the policy are poorly reflected in its issued form or not achieved in its implementation. A failure to determine in advance how that policy will be evaluated leaves agencies and the regulated communities equally uninformed about which policies are working as intended. As a current example, the Academies report discussed at length the Department of Health and Human Services' Notice of Proposed Rulemaking (NPRM) for the "Common Rule" which governs federally funded research with human subjects. The Academies made the recommendation to suspend the Common Rule NPRM, concluding that the proposed rule was "marred by omissions, the absence of essential elements, and a lack of clarity."[10] Among other concerns, the report highlights the committees' concern with the proposed revision prohibiting all research with deidentified biospecimens without written consent, a concern echoed which was also echoed in AAMC's comment letter to HHS, which stated that the revision as proposed would place "extraordinary stresses […] on the research community as a whole" and "without increasing meaningful understanding […] or protection of human subjects."[11] If the rule is implemented as proposed, it appears that there is no specific plan to evaluate its cost, impact, or success. Given the significant costs that would be needed to implement just this one aspect of the proposed rule and the potential chilling effect on essential research with biospecimens, the lack of a plan to gather evidence to evaluate the policy is problematic.

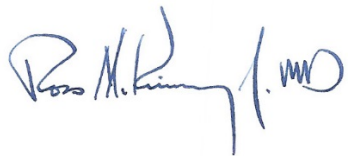
The Commission has asked if program or policy evaluation can or should be incorporated in program designs. If the evidence and criteria on which the success of a proposed policy would be measured were included as a routine and reviewable component of the policymaking process, agencies would have the benefit of stakeholder input on the evaluation process, best sources of

[7] "Next Steps in the Evidence and Innovation Agenda," Memorandum to the Heads of Departments and Agencies (July 26, 2013), https://www.whitehouse.gov/sites/default/files/omb/memoranda/2013/m-13-17.pdf.
[8] Executive Order 13563: "Improving Regulation and Regulatory Review," 76 Fed Reg. 3821 (Jan. 18, 2011).
[9] "Federal Research Grants: Opportunities Remain for Agencies to Streamline Administrative Requirements," (2016), pg. 3.
[10] "Optimizing the Nation's Investment in Academic Research, A New Regulatory Framework for the 21st Century," (2016) p.167, The Academies report also recommends the establishment of a new commission to reconsider the process for protecting and engaging human research subjects, p.168.
[11] AAMC Comment Letter, January 4, 2016 (available at https://www.aamc.org/download/451896/data/aamcsubmitscommentstohhsonthecommonrulenprm.pdf).

data to support the evaluation, and whether the proposed metrics are likely to provide the agency and the public with meaningful evidence about a program or policy's effectiveness. This would set a precedent for an unparalleled and productive level of engagement between agencies and stakeholders, demonstrating not only accountability, but a commitment to the shared goal of ensuring that federal policies are implemented for the right reasons and meet clear, articulated objectives.

AAMC is supportive of the Commission's interest in using data to build evidence to inform program and policy design. The AAMC would be happy to work with the Commission on any of the issues discussed in our letter, provide additional information about the methodology or findings from the AAMC COI Metrics Project, or discuss the evidence-based policymaking across any areas that affect the academic research community. For more information, please contact me or Heather Pierce, Senior Director, Science Policy and Regulatory Counsel (Association of American Medical Colleges, 655 K Street NW, Suite 100, Washington DC 20001, (202) 478-9926, hpierce@aamc.org).

Sincerely,



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