U.S. POLICY

Research in academic medical centers: Two threats to sustainable support

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Reductions in federal support and clinical revenue jeopardize biomedical research and, in turn, clinical medicine.

Unstable funding for biomedical research has created a hostile working environment that erodes the time available for investigators to conduct their research, discourages innovative high-risk science, threatens to drive established investigators out of U.S. academic biomedical research, and creates uncertainty for trainees and early-career investigators (1). However, executive directors at academic medical centers wrestle with another concern—one at the systemic level: At any amount of public investment, the cost of the biomedical research enterprise is growing inexorably beyond what available resources can reasonably support (1).

As leaders of U.S. academic medical centers, we are committed to providing high-quality patient care while using our limited resources effectively and efficiently. But we cannot achieve these goals nor meet the health care challenges of an aging and increasingly diverse population without acquiring new knowledge about human health and disease to support the development of creative therapeutic strategies (http:// medresearch.tumblr.com). Moreover, our nation's economy has depended on discovery and invention, the ultimate products of scientific research. Thus, biomedical research is crucial to the U.S. national agenda, and academic medical centers—the provenance for much of this research—are at particular risk. Persistent constraints on federal funding for biomedical research, including that from the U.S. National Institutes of Health (NIH), threaten to undermine the biomedical research enterprise, and decreasing clinical revenue compounds this threat. Support for the research ecosystem must be predictable and sustainable both for institutions and individual investigators. The U.S. Congress is currently developing the 21st Century Cures Act with the intent of addressing some of these concerns (see http://energycommerce.house.gov/cures).

DIMINISHING RESOURCES FOR SERVING SOCIETY

The remarkable collaboration between the federal government and academic institutions that shares the burden of scientific research and training began after the second World War and was built on the philosophy that new knowledge is a public good. These institutions dedicate resources to grow and sustain research programs (2). However, for the partnership to work effectively, the public's investment should be commensurate with the expansion of expensive taxpayerdriven research and development priorities in the areas of cancer, diabetes, cardiovascular and neurodegenerative diseases, clinical depression, emerging infectious diseases, and precision medicine as well as with the growth in federal regulation and oversight of research, which has increased substantially over the past half-century.

Aside from federal support, the major sources of funding available to academic medical centers are state governments, technology transfer (significant for only a few institutions) (3), philanthropy, tuition, and clinical income. According to the National Science Foundation (NSF), institutionprovided funding for faculty-conducted scientific research has grown faster than any other source of support over the past two decades (4, 5). We estimate that, on average, our respective institutions contribute 53 cents for each dollar (direct and indirect) of all sponsored-research support expended (6).

Some have asserted (1) that federal \aleph grants and contracts, by reimbursing indirect (facilities and administrative) costs and faculty salaries, "encourage grantee institutions to grow without making sufficient investments in their own faculty and facilities." In this context, the term "sufficient" is key. Indirect cost reimbursements compensate for costs already incurred by institutions, although many large researchand education-related expenditures are unallowable for reimbursement under federal cost policies, including the expense of both starting up laboratories and sustaining existing labs (4). Furthermore, the federal reimbursement rate for administrative costs for academic institutions has been capped at 26%, whereas administrative requirements for oversight of sponsored research, protection of human subjects, biosecurity and safety, humane use of animals in research, training in responsible conduct of research, pre- and post-award review and submission, and many other compliance obligations have increased significantly (www.nsf.gov/ pubs/2014/nsb1418/nsb1418.pdf). Indeed, the Association of American Medical Col-

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leges (AAMC) reports that 70 of its member institutions expended a total of \$22.6 million to comply with the 2011 regulations just for managing potential financial conflicts of interest (7). To help address some of these costs, the current draft of the 21st Century Cures Act calls for the creation of a Biomedical Research Working Group to provide recommendations for reducing administrative burdens on NIH grantees and applicants.

Academic institutions also must pay faculty salaries. A survey of AAMC-member institutions in 2009 found that physicians who conduct sponsored research received, on average, 29% of their salaries from sponsored programs, whereas nonphysician investigators received 49% (www. aamc.org/download/170836/data/ aibvol11 no1.pdf). Similar 2013 data for 72 academic medical cen-

ters (AMCs) (Fig. 1) show an overall median of 32% salary support from sponsored programs across full-time faculty who conducted sponsored research, with a median of 22% for M.D. faculty and 47% for non-M.D. faculty. We acknowledge that many research faculty are under extraordinary pressure to cover substantial portions of their salaries with grant funding, which is why we and others from academic medical centers are eager to participate in data-driven discussions with other stakeholders about how to reduce this pressure so that faculty members can focus more on the conduct of research than on securing funds for its support.

THE SECOND THREAT

Past growth in the biomedical research enterprise has depended substantially on clinical revenues generated at academic medical centers. Such revenues—which support capital infrastructure, employ medical faculty with research programs, and improve delivery of care through education, innovation, and discovery—are now shrinking as efforts to control the growth of health care costs are implemented. Reduced clinical revenues decrease the leverage that is critical to the overall support of research in academic medical centers—leverage needed to position such centers to compete for sponsored research funds. Moreover, amidst increasingly constrained clinical-

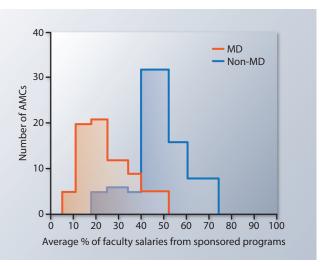


Fig. 1. Showing the money. Distribution of average salary coverage from sponsored programs at 72 academic medical centers in 2013. Because these data were obtained by dividing the total amount of sponsored support for faculty salaries by the total faculty-salary support from all sources at each institution, distributions across investigators at individual institutions are not available. [Data provided by the Association of American Medical Colleges, April 2015]

reimbursement levels, academic medical centers remain both the major care site and the option of last resort for the most complex and challenging patients. Bearing the cost of outlier patients and of clinical care provided as part of clinical research represents another contribution to the public good. Moreover, academic medical centers treat a disproportionately large share of individuals without adequate health insurance or sufficient means to pay for care. In 2012, the median charitable health care provided by AAMC-member teaching hospitals was \$65 million (8), which may or may not decline, depending on how the new landscape associated with the Affordable Care Act and other policy developments evolves.

UNCERTAINTY HINDERS STRATEGIC PLANNING

Loss of funding from all sectors inevitably means that the biomedical research enterprise must decrease in size. A smaller enterprise might be more sustainable, but the size of the biomedical research enterprise is not the appropriate end point. Improving the health of our patients and communities is our objective, and a smaller biomedical research enterprise will slow progress in our ability to address the health of our patients and lessen our contribution, through new knowledge and technology development, to the growth of the nation's economy.

Recommendations to stabilize the biomedical research enterprise must identify new resources, policies, and business models for sustaining such research, not simply shuffle financial responsibilities within the current model. We must reinvigorate the federal-academic partnership for research across all sciences. The convergence of many essential fields around biology, as highlighted in the recent report entitled A New Biology for the 21st Century, offers opportunities for academic partners to serve social objectives (www.nap.edu/ catalog/12764/a-new-biology-forthe-21st-century).

With regard to sustainability, both the federal government and our institutions must recognize on that we have made a huge investment in developing young scientists so that they can launch independent research careers, and if we

pendent research careers, and if we are to recoup our investment, these careers must be sustained at least until failure is evident. The draft 21st Century Cures Act includes a section devoted to emerging scientists, in order to promote increased support of investigators at the early stages of their independent careers. Academic medical centers must join with NIH to strengthen support for the training and early-stage research of for the training and early-stage research of physician-scientists, who carry out a singular mission in biomedical research (9); promote stable careers for our most creative principal investigators; and provide more stable support mechanisms for staff scientists (10). Furthermore, we must create career paths that at least partially decouple research activity from the trainee enrollment and develop training models that recognize that many trainees go on to a variety of important nonacademic careers, in addition to academic ones.

A sustainable business model with predictable growth in appropriations to NIH and other research sponsors, indexed to the relevant rate of inflation and projected over 3 to 5 years, would allow both federal and academic institutions to plan their investments in human and physical capital and manage expenditures more strategically than is possible in the face of annual funding uncertainty. The 21st Century Cures Act draft authorizes (but does not appropriate) increases of ~4.6% for fiscal years 2016 to 2018. In addition, the draft proposes the appropriation of an additional \$2 billion per

year for fiscal years 2016 to 2020 through the creation of an "Innovation Fund," the uses for which are still under discussion. This fund would be in addition to the regular NIH appropriation.

Academic medical centers are committed to leading the national effort to provide high-quality care to all Americans. But achievement of this goal requires a stable economic platform that supports the full spectrum of biomedical and engineering research, from the investigation of fundamental mechanisms of human biology and behavior to the translation of such discoveries to patients, communities, and populations. In short, to provide next-generation health care solutions, we require 21st-century policies that support modern scientific research and development. Because research in academic medical centers requires both federal and

institutional support—the latter of which depends on clinical revenue—scientists, administrators, and policy-makers must collaborate effectively to address both threats.

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