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

June 16, 2017

The Honorable Thomas Price, MD Secretary of Health and Human Services 200 Independence Avenue, SW Washington, DC 20201

The Honorable Mick Mulvaney Director, White House Office of Management & Budget 725 17th Street, NW Washington, DC 20503

Dear Secretary Price and Director Mulvaney:

I am writing on behalf of the Association of American Medical Colleges (AAMC) to express strong concerns over the Administration's proposed cut of \$7.2 billion – 21 percent below current levels – in the FY 2018 budget of the National Institutes of Health (NIH), primarily achieved through a limitation on reimbursement of Facilities and Administrative (F&A) expenses. This proposal, particularly when coupled with the Administration's proposal to lower the salary cap for NIH and other Department of Health and Human Services (HHS) grants to Executive Level V, would make it unaffordable for many institutions to continue supporting medical research and ultimately would lead to less research across the country. As a result, patients would be forced to wait longer for cures and innovative treatments, communities would lose high-paying jobs and other economic returns, and as a nation, we would lose ground against foreign competitors like China, who are rapidly increasing their investments in medical 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 147 accredited U.S. medical schools; nearly 400 major teaching hospitals and health systems, 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 nearly 160,000 faculty members, 83,000 medical students, 115,000 resident physicians, and thousands of graduate students and post-doctoral trainees.

The longstanding, bipartisan federal commitment to NIH has made the U.S. the world's preeminent leader in medical research and has yielded countless medical breakthroughs that affect every American. The AAMC stands with the hundreds of medical research organizations and patient advocates who seek \$36.2 billion for NIH in FY 2018, as a continuation of the steady and reliable increases in the federal biomedical research investment that are necessary to advance scientific progress toward new and improved medical treatments. A family of a patient who receives a diagnosis for which there is no known cure, or only moderately effective treatments, should not have to cope with the added burden of seeing their government retreat from a promising research frontier that may offer real hope. We should do all that we can to build consistently and predictably on prior investments in research, and pursue the Secretary Price and Director Mulvaney June 16, 2017 Page 2

scientific opportunities currently available. NIH-funded research has led to increased life expectancy and declines in deaths from cancer, heart disease, stroke, diabetes, and other devastating and debilitating diseases. NIH research also contributes to job creation and economic growth, and to the nation's health security.

F&A expenditures are related to and essential for medical research. A major portion of the proposed cut to NIH would come from reimbursement of facilities and administrative costs on NIH grants. Although also referred to as "indirect" costs, F&A expenditures are directly related to and necessary for support of biomedical research at our member institutions – they are expenses that institutions incur *because* of the federal research they conduct. For example, F&A reimbursement helps ensure support for research infrastructure and operating expenses, including maintenance of state-of-the-art laboratories and high-tech facilities, data processing and storage, energy and utility expenses associated with research, security for dangerous chemicals and biologics, and the administration of a grant throughout its lifecycle. For more than 70 years, F&A costs have been included in federal grants, recognizing that research institutions incur research-related expenses that may not be directly attributable project by project, but are nevertheless essential to conducting research. Please make no mistake, a cut to F&A reimbursement is a cut to biomedical research.

F&A charges are based on real costs and reimburse institutions for actual expenditures that are audited through a rigorous process on a regular basis. The first step in determining F&A charges occurs when each institution negotiates the amount it can be reimbursed for F&A expenses with its respective government auditing agency. The F&A rate is based on what the institution has previously expended for research facilities and operating expenses as determined by and outlined in Office of Management and Budget (OMB) rules to be necessary and reimbursable costs required to conduct research. The method is standardized across nine categories of expense, each of which must be well-documented and justified in the negotiation process. Once an F&A rate is established, that rate is multiplied against the allowable direct charges in the grant (referred to as the "modified total direct cost" or MTDC), and thus the F&A charge is determined. Federal support for F&A as a share of the NIH budget has not grown in more than a decade, as reported in the NIH's Congressional Justification accompanying the budget request.

Academic institutions substantially contribute to medical research from their internal resources. As partners in the U.S. biomedical research system, medical schools, teaching hospitals and universities invest substantially from their own resources to sustain research, over and above what NIH and other external sponsors provide. A 2015 AAMC study found that on average, each medical school invested \$111 million dollars or \$0.53 for every dollar received for sponsored research to support their research programs. According to the study, a substantial portion of the institutional contribution is to pay for unrecovered F&A expenses, as the current federal support for F&A does not fully cover an institution's research costs. All such expenditures serve to make the conduct of science – and the training and provision of new generations of scientists – possible. This research partnership, in which the federal government sponsors research at academic medical centers and universities through competitively awarded grants, has yielded the major medical advancements noted above. Under this system, research institutions themselves, and not the federal government or taxpayers, assume the long-term risk of investment in facilities and infrastructure.

Comparisons of federal grants policy with private philanthropy are misleading. Some – including the Administration's budget proposal – have observed that private foundations like the Gates Foundation treat expenses on grants differently. But comparing federal F&A reimbursement policies to foundation policies is misleading. Many foundations recognize and allow for certain facilities or administrative costs

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to be charged as direct line items on each grant, so their support for F&A expenses is greater than what the reported F&A rate may suggest. The foundation rate also may apply to a much larger base than the modified total direct cost used in federal grants. In other words, institutions incur many of the same costs, but foundations often use different methods for accounting and paying for them than the federal government. Thus, in their approaches to funding research, both private foundations and the federal government recognize the essential role F&A costs play in conducting advanced research. In this regard, the Gates Foundation itself has issued the following statement:

The administration's proposal does not reflect the Bill & Melinda Gates Foundation's process for determining direct or indirect costs. Our policy is based on our specific programmatic approach, which is tailored to meet needs across sectors and organizations. Research institutions such as the National Institutes of Health operate under a different set of costs and demands.

Overall, foundations make up only 6 percent of all research funding, and their research focus often differs from the federal government (e.g., the Gates Foundation has a strong international focus). Fundamentally, academic institutions receiving foundation funds accept a cost-share, to strategically advance a specific aspect of the research mission, not the research program overall. Additionally, OMB rules prohibit federal funds from subsidizing research costs of non-federally sponsored research activity.

A cap or cut in F&A recovery would have adverse and unintended consequences. A cap on F&A recovery such as the one the administration has proposed for NIH grants would result in cuts to highpriority research aimed at finding new cures, improving public health, and growing the economy. Without sufficient federal support for F&A, research institutions would be unable to sustain the scientific infrastructure necessary to conduct this cutting-edge research. F&A support is already limited by the rigorously negotiated rates at each institution – any further limitation would undercut the expenses institutions have incurred. As a result, many medical schools and teaching hospitals would no longer be able afford to operate extensive research programs, especially as costs rise and alternative funding sources, such as state support and clinical revenues, dwindle. A cap or flat rate could well have the unintended long-term consequences of consolidating remaining research programs into fewer institutions by making research costs prohibitive for smaller and geographically diverse academic medical centers. Even for those institutions who continue to conduct research, it is unrealistic to expect that they would be able to operate at the same capacity, much less absorb the lost opportunity from closing research programs. It could also discourage institutions from pursuing cutting-edge research requiring specialized facilities. Reduced F&A recovery would also result in layoffs and losses of skilled jobs, not because of gains in efficiency but from institutions cutting back on their research programs. For many states and counties, academic medical centers and universities are major employers of both blue and white collar jobs, and generate economic activity well beyond their campuses.

Lowering the salary cap would exacerbate efforts to recruit and retain physician scientists, an increasingly important component of the scientific workforce that ensures research both is translated from "bench to bedside," and reflects a "bedside to bench" approach. In addition to the proposal to limit F&A support, the FY 2018 budget request also proposes lowering the salary cap on NIH and other HHS research grants from Executive Level II to Executive Level V, a nearly 19 percent decline. Academic institutions must make up the difference between an investigator's actual salary and the annualized rate permitted by the cap. The lowered cap would further increase the disincentive of physician scientists to participate in research projects. These highly trained individuals are especially vital to research translating laboratory findings into patients and clinical applications. The difficulty in

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promoting and supporting physician scientists' careers is already a problem that has been of great concern to NIH and the research community. This apparently arbitrary proposal to lower the cap would significantly exacerbate these concerns.

The AAMC is deeply concerned that the FY 18 proposals related to NIH will destabilize the research enterprise that has only served to advance the nation's physical and fiscal health. While we welcome the opportunity to work with the Administration to identify opportunities to streamline the administrative and regulatory burden associated with medical research, we caution that these efforts will not obviate the F&A support necessary to produce high quality, life-changing science. A limitation on federal F&A reimbursement, reductions in the salary cap, and reduced federal funding for NIH would undermine the ability of medical schools and teaching hospitals to sustain their medical research missions at current levels. The subsequent ripple effect – slower scientific progress, longer waits for cures, fewer jobs, and forfeiture of America's global research leadership in an increasingly innovation-based world economy – would affect every American. We strongly urge you to reconsider this approach.

Thank you again for your attention to our concerns.

Sincerely,

Danell G. Kinch

Darrell G. Kirch, MD President and Chief Executive Officer