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Is Biomedical Innovation Being Stifled?



PERSPECTIVES

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Knee-Capping Excellence

his past spring, the Trump administration's fiscal year 2018 budget had little good news for the nation's biomedical research enterprise. Prominent among areas targeted for deep cuts, the National Institutes of Health (NIH) faced a threatened 22% reduction in its funding—\$7.7 billion less in appropriations than the previous year.

Such a draconian action was dismissed upon arrival on Capitol Hill, and steps were taken to shore up overall NIH funding. But buried within the administration's accompanying budget documents, and receiving far less attention, was a seemingly arcane change in the way NIH supports extramural research, by capping grant funding for indirect costs—also known as facilities and administrative (F&A) costs—at 10% of total research costs.

Longtime supporters of biomedical research in the House and Senate understood the significance of the proposed cap and acted quickly to try to block it. A temporary measure to block the cap was enacted in September and may be extended for the balance of this fiscal year. But the potential remains for unilateral action by the administration to cap or cut indirect cost recovery over the longer term, and there are discussions in Washington about the parameters of federal funding for university-based biomedical research generally and indirect cost recovery in particular.

The sheer magnitude of the research funds at stake under the proposed 10% cap underscores the consequential nature of the issue and signals a misunderstanding of the ways in which indirect costs

are essential to the conduct of biomedical research. A 10% cap would reduce by almost two-thirds the amount of funding that research university sponsors would receive to offset indirect costs on federal research grants. In the absence of ready sources of alternative revenue to make up this shortfall, such a cut could not help but force universities to contract dramatically the overall level of research activity conducted on our campuses.

Here I explore the history, rationale, and criticism of the recovery of indirect costs. I focus on NIH funding because the Trump administration targeted that agency in its proposal. Yet, I recognize that similar effects could be felt across multiple federal granting agencies, such as the National Science Foundation (NSF) and Department of Energy, that rely on NIH-approved rates in funding comparable research. I find that the indirect cost reimbursement formula is an essential component of the biomedical research partnership between the federal government and universities. And I show that the proposed cut by the administration would have a severe impact on the financial capacity of universities to continue to support federally funded research activity.

A valuable partnership

The compact between the federal government and the nation's research universities in biomedical research is rooted in Vannevar Bush's seminal report on US scientific research—*Science, The Endless Frontier*. To support the nation's burgeoning post-World War II scientific needs, Bush urged the federal government to provide funds to research universities for basic research. Bush argued that these universities could best provide for the "free,

untrammeled study" and risk-taking critical to discovery, that it would be impractical for government to re-create the laboratories that already existed on campuses, and that the "traditional sources of support" for academic research would be insufficient without federal support.

Bush's recommendations led to the creation of a deep partnership between the federal government on one hand and universities (and other institutional sponsors) on the other in which the government would co-invest with these institutions in scientific research. (The federal government also distributes research funds to nonacademic research institutes, private industry, and other stakeholders, but the vast majority of funding goes to research universities, and so that is my focus here.) Universities would build and nurture the research ecosystem and contribute a portion of their own funds to support federally sponsored research, and the federal government would allocate research funds on a competitive and meritocratic basis to their scientists.

From the start, this partnership has been financed through the reimbursement of direct and indirect costs, both allocated from the same pool of appropriated research funding.

Direct costs refer to those research costs that are incurred by the principal investigator specifically for the research proposed in the grant application, such as the salaries and stipends of scientists, the cost of lab supplies and equipment, and travel for conducting the research or sharing the results.

Indirect or F&A costs refer to those research costs that are incurred by the university across multiple research projects, such as the construction and maintenance of laboratories; secure data storage and highspeed data processing; utilities such as ventilation, heat, and lighting; libraries and other research facilities; radiation and chemical safety and hazardous waste disposal; the administrative personnel to support the research and ensure compliance with safety and other rules; and advanced technology and lab equipment that can be optimized for repeated use across many grants. Because indirect costs compensate universities for facilities and services that support a number of different investigators, indirect costs are allocated on a proportionate basis across shared infrastructure and personnel.

For more than six decades, the federal government has been reimbursing universities for indirect costs alongside direct costs. In 1966, the federal government came to adopt the modern system of compensating those indirect costs, in which colleges and universities are reimbursed

through negotiated rates that are tailored to each institution and its particular expenses and type of research. From the outset, the government has underscored that it would calculate rates using a principle of "cost-sharing" rather than full cost reimbursement.

In practice, F&A rates are calculated as a percentage of the amount awarded for direct research costs (not as a percentage of the overall grant), and universities are expected to deploy their own funds to close the substantial remaining balance. Currently, the average amount paid to universities for indirect research costs on a federal grant is approximately 25%-33% of the total amount of the grant, and the underlying F&A rates vary by university (up to about 65% of direct costs). Research universities that conduct a great deal of biomedical research are generally at the upper end due to higher costs involved in providing and overseeing biomedical research facilities. To further complicate matters, these rates include within them a cap of 26% on allowable administrative (but not facilities) costs, which the Office of Management and Budget (OMB) imposed on universities in 1991 in response to incidents involving misuse of federal funds at several institutions.

As a result, unlike other funding arrangements between the federal government and private entities such as contracts or grants with industry partners that typically cover all related costs under a full reimbursement model—here the federal government reimburses universities for indirect costs only up to a prescribed maximum, and the sponsoring university is responsible for all research costs incurred above that level. In 2015 alone, universities contributed \$4.9 billion of their own funds to support the indirect costs of federally sponsored research, at the same time that the overall federal portion of research costs declined (from 61% in 2010 to 55% in 2015).

Flawed rationales

Supporters of the Trump administration's proposed cut to indirect cost recovery have offered a handful of arguments in its defense. Some have suggested that indirect cost reimbursement creates an incentive on the part of universities to overbuild new research facilities. Others have asserted that it leads to the over-hiring of administrators at universities. Still others have claimed that universities receive less in indirect cost recovery from foundations and other nonprofit funding partners than they demand from the federal government. Although the precise character of these arguments varies, their proponents generally see in current NIH grant funding a potential for misuse or overpayment.

In considering these concerns, it is necessary to acknowledge the elaborate oversight systems that have institutions in scientific research. (The federal government also distributes research funds to nonacademic research institutes, private industry, and other stakeholders, but the vast majority of funding goes to research universities, and so that is my focus here.)

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been developed over the years to temper the incentives for abuse. For instance, the federal government carefully defines what can and cannot be considered as an indirect cost, and how those costs are to be calculated by academic institutions. Every three to four years, each research university faces a comprehensive assessment led by either the Department of Defense's Office of Naval Research or the Department of Health and Human Services to evaluate and negotiate the indirect cost rate to be allowed on federal grants. The formal process for establishing each university's rate can include requests for additional data and campus site reviews for interviews and equipment audits.

Two types of accounting audits are also employed, one of a university's financial statements and the other of a specific grant or project. Should an audit, or other source, expose misuse, federal rules and processes provide for the imposition of sanctions and other punishments under state and federal law.

Moreover, since universities bear the full up-front costs of investment in the labs and research facilities that support scientific activities, and since universities are fully responsible for indirect costs incurred above the prescribed ceiling, they face clear incentives to refrain from wasteful spending and constrain costs. Specifically, if a university expands its infrastructure or organization beyond what is justified in light of its anticipated grant awards, the existing administrative cap and rate-setting process prevent that misplaced bet from being externalized to the federal government. It must be borne by the institution.

As the federal investment in biomedical research has declined in real dollars in recent years, the exposure of universities to unrecovered investments in research infrastructure has only increased. It is noteworthy in this regard that, according to a 1996 Arthur Andersen study, universities at least to that point incurred lower indirect costs in conducting federal research than did industry or federal laboratories.

Recently published studies challenge the arguments made in defense of the Trump administration's cut to indirect cost recovery. In *Issues* in 2015, Arthur Bienenstock, Ann Arvin, and David Korn analyzed public data on biomedical research facilities at academic institutions and called into question claims of overbuilding of biomedical research space. A 2015 Demos study by Robert Hiltonsmith found that the number of executives and administrative personnel per student at public research universities has actually declined since 1990. And although the American Institutes for Research found that the number of

"professional staff" (including research personnel) has increased slightly at public and private universities, so too has the amount of actual research occurring at universities; hence it is unclear how this increase in and of itself is evidence of bloat.

Finally, although the Trump administration's budget asserts that NIH is paying more to universities for indirect costs than do private foundations, and specifically references the Gates Foundation, this misses the fact that the federal government and NIH use different rules than private foundations to delineate direct from indirect costs. A 2017 applesto-apples comparison published by the American Association of Universities demonstrated that the federal government and philanthropic foundations compensate "a similar percentage of the total funding" for the expenses that constitute federal indirect costs. In any event, if philanthropy in fact does not pay adequate indirect cost rates for the research they support, that only enhances the importance of the federal government's role in supporting the infrastructure of research.

This discussion does not mean that there is no scope for increased efficiencies in the way in which the federally funded biomedical research system is conducted. That would be both naïve and disingenuous, and in fact a number of academic medical institutions have taken steps to reduce costs in recent years, in areas ranging from procurement to energy management to organizational efficiency. Rather, my argument is that the various critiques of indirect cost reimbursements have failed to provide any systematic evidence of abuse and waste on a scale that would justify the two-thirds reduction in cost reimbursements entailed by the adoption of the cap.

Devastating effect

According to the administration's own supporting budget materials, the proposed cap would have led to more than a \$4.6 billion reduction in funding in fiscal year 2018 alone. There is no credible evidence that universities would be able to cover a funding reduction of this magnitude through hitherto unrealized cost savings. (Recall that universities are already incented to adopt efficiencies in order to reduce their institutional support for funded research.) Further, given the remarkably tight financial margins under which most universities operate, it is quixotic to imagine that the large pools of undesignated funds required to make up for lost federal funding actually exist. Even if institutional leaders were willing to consider reallocating existing funds to cover the contraction in federal research funding, they would

still confront substantial legal, moral, and political constraints on using endowment or tuition revenues for this purpose.

Unavoidably then, universities would be forced to reduce the amount of federally funded research activity that is conducted on their campuses. As noted, institutions tend to have different indirect cost recovery rates to start, and so the precise level of the contraction in research would vary across institutions. But no matter the university, the scale of the reductions needed would not be trivial. A study recently conducted by the economic consulting firm Charles River Associates for Johns Hopkins University found that if the university were unable to reduce the portion of research expense attributed to indirect costs—and if it were not able to find alternate funding sources to compensate for the loss in federal funds—then the imposition of the cap would force a nearly three-fourths reduction in its federally funded research portfolio.

As a result, it is conceivable that if the proposed cap on reimbursement of indirect costs went into effect, pressure would be placed on OMB to allow expenses that are now considered administrative costs to be allocated to the direct cost line. Unless the overall appropriated funding were left entirely intact—which seems unlikely given the administration's proposed cuts to the NIH budget more broadly—a world in which the government cuts the recovery of indirect costs and then allows those cuts to come out of direct costs is of course no better than a world in which direct costs are cut themselves. If all of the \$4.6 billion in question came out of direct costs, the reduction in NIH direct research funding to scientists at universities and other institutions would be about 28%.

In all, the proposed cap would result in a staggering blow to the nation's vital interest. Universities would be forced to retrench by downscaling a research enterprise that has been a vital force in advancing discovery and human health. The impact might fall most heavily on early career investigators, who find themselves on fewer and smaller grants and are among the most vulnerable to funding contractions. The economic consequences of these cuts would also reverberate across the United States, confined not only to the biomedical and pharmaceutical sectors, but affecting the many upstream and downstream industries that are connected to them, and the jobs and communities they support. Simply, the proposal would amount to a deep and inextricable cut to the private-public partnership at the foundation of the nation's biomedical research enterprise.

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