

nature biotechnology

Concerns over Cures

Provisions in the 21st Century Cures Act related to leadership at the US National Institutes of Health (NIH) may spell trouble ahead.

On December 13, in one of the last acts of his administration, President Barack Obama signed into law the landmark 21st Century Cures Act. This multifaceted and labyrinthine piece of legislation, which was hailed as a bipartisan triumph in both the US Senate and House of Representatives, contains a smorgasbord of funding initiatives for biomedical research, presents sensible reforms to US Food and Drug Administration pathways for approving new antibiotics and regenerative medicines, provides resources for combatting the US heroin and prescription opioid epidemic and reauthorizes several important mental health programs for suicide prevention (p. 6). But the legislation fails to address the ongoing crisis in NIH grant funding for rank and file US biomedical researchers. And the increasing centralization of power in the NIH director raises the specter of increasing political interference in scientific funding.

According to the hype, the Cures Act is a welcome fillip to NIH research funding. It allots an extra \$4.8 billion over the next decade to the outgoing administration's three signature initiatives: Precision Medicine, the Cancer Moonshot and the Brain Research Through Advancing Innovative Neurotechnologies (BRAIN). But the untold story is that these marquee projects represent the only remnants of a much more ambitious NIH funding proposal of \$8.75 billion in the original House bill. This proposal, which would have added \$2.5 billion in discretionary funding to support R01 grants and younger researchers, was axed by Republican fiscal hawks last September. Although the final act does include a "Next Generation of Researchers Initiative" to encourage NIH to promote and prioritize young faculty, no funding is earmarked to support such activities.

How existing NIH funding is allotted to each of the different institutes may also be affected. In a section entitled "Increasing Accountability at the National Institutes of Health," five-year terms have been introduced for directors of each of the NIH's 27 institutes and centers (except the US National Cancer Institute, which has a politically appointed director).

Increased accountability and transparency for NIH leadership sounds like a good idea. But the concern is that the law puts too much power into the hands of one person: the NIH director.

This is problematic for several reasons. First, the Cures Act fails to specify criteria or a process by which NIH institute directors will be assessed. Second, anyone familiar with the pace of research will recognize that five years is a very short period for any institute director to make a mark. The 5-year limit will likely further engender a management culture focused on short-term goals and lower enthusiasm for 'risky' research. Third, subordinate institute directors now have little incentive to challenge decision making from the Director's office. And the change in the perceived status of institute directors may also discourage recruitment of talent from the community.

But perhaps the most serious drawback could be how this opens up each of the NIH institutes to political interference. A correspondence on p. 20 details some of the questions swirling around the incoming Trump administration's attitude to human embryonic stem cell and fetal tissue research. There is no guarantee that the next NIH director, as a political appointee of the regime, won't be selected because their views on embryo research are in line with conservatives.

Greater politicization of NIH research funding would be a retrograde step, especially in an era where politicians are increasingly unmoored from the shackles of evidence. Short-termism and politics have no place in science funding decisions. The incoming administration should bear that in mind if they want to make American biomedical science great again.

Where are the data?

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These statements will report the availability of the 'minimal data set' necessary to interpret, replicate and build on the findings reported in the paper. Where applicable, they will include details about publicly archived data sets that have been analyzed or generated during the study. Where restrictions on access are in place—for example, in the case of privacy limitations or third-party control—authors will be expected to make this clear.

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Not only differences in the culture of data sharing and access between different disciplines, but also a lack of obvious, public, community repositories can pose a significant barrier to public data deposition. Nevertheless, even in disciplines that are not yet so able to embrace openness and sharing, there is increasing awareness and appreciation that data deposition can enhance the visibility and reuse of published research, and that data citation can increase the recognition of those who create and share data.

Our aim is that consistent information on data availability in our papers will promote data reuse by future researchers. Indeed, where public data archiving is a mandatory requirement of journals, increasing evidence suggests that the inclusion of data-availability statements with persistent links to data in published articles is an effective approach to ensuring public data availability and policy compliance (*FASEB J.* 27, 1304–1308, 2013).