

Trump budget plans double FDA review costs



[Jonathan Gardner](#)

US FDA drug reviews would be funded entirely from increased pharma sector user fees under a detailed White House budget blueprint released today.

The plan also confirms President Donald Trump's intent to chop funding from the National Institutes of Health, an agency with many defenders in Congress and biopharma as a source of medical innovation. But it is not all bad news – much-feared caps on drug price increases do not appear here, although repeated threats from administration officials mean the issue is still very much alive.

Taxing biopharma

The budget would add a \$1.2bn burden on the life sciences industry in fiscal year 2018 to pay for review of new medical technologies. The biggest chunk would be from innovative pharma, which would see its FDA user fees rise \$508m to \$1.3bn in 2018. For medical devices, the increase would be \$313m to \$439m – a massive tripling of the burden on medtech. Generic drug fees would rise \$293m to \$616m and biosimilars \$65m to \$87m.

This increase was hinted at in an earlier budget document ([White House budget undoes hard-won deals, March 17, 2017](#)). The risk is twofold: first, reauthorisation of all the FDA user fee programmes is a carefully negotiated process that is currently moving on Capitol Hill, and a proposal to massively increase the levies could disrupt it; and second, funding the entirety of the review process increases the chances that the FDA could be seen as a captive agency of biopharma with less regard for patient needs.

The administration justifies the increase by stating that “industries that directly benefit from FDA's administrative actions can and should pay to support FDA's capacity.”

Cures

The NIH cuts, likewise, run counter to congressional desires and specifically additional funding provided under the 21st Century Cures Act enacted last year. As with the FDA user fees, 21st Century Cures was a carefully negotiated bipartisan measure, and announcing a plan to reverse that law will not be taken well on Capitol Hill – indeed, in its final fiscal 2017 spending bill signed by Mr Trump, Congress added \$2bn to the NIH ([NIH breathes easier with budget boost, May 3, 2017](#)).

The 2018 White House plan trims \$5.7bn from the NIH in the 12 months starting October 1, taking its budget to \$26.9bn – in nominal terms, the least the agency has received since 2002. This proposal, first outlined in March, has been opposed by physician groups such as the American Society of Hematology and American Society of Clinical Oncology.

The proposed cuts fall most heavily on the best-funded centre, the National Cancer Institute, which would see \$1bn trimmed from the \$5.5bn it is to receive in 2017. The National Institute of Allergy and Infectious Diseases would see an \$838m decline and the National Heart Lung and Blood Institute \$575m, taking their respective budgets to \$3.8bn and \$2.5bn, respectively.

The advocacy group Research America criticised the NIH budget plans: "Surveys show how highly Americans rank securing better health and quality of life," said the group's chief executive, Mary Woolley, said in a statement. "The President's blueprint is tone-deaf to that reality."

Congress, of course, controls the federal government's pursestrings, and will thus have much to say about Mr Trump's proposals. But they remain in active discussion, meaning the sector must remain vigilant.

To contact the writer of this story email Jonathan Gardner in Virginia at jonathang-us@epvantage.com or follow [@ByJonGardner](#) on Twitter

