

Sequestration to slash research grants and delay biosimilars

The impact of the massive US federal budget sequester, which met with dire warnings before March 1, is proving difficult to measure and slow to take full effect since that date. Nonetheless, in some quarters, anxiety levels remain high as to the eventual adverse impact on federally supported biotech research programs as well as regulatory agencies. Although special legislation is being written to spare medical research and contemplated, at least, for user fees, the mood among legislators makes such specific compromise rescue measures seem unlikely to move forward anytime soon.

"BIO is particularly concerned that the sequestration, as implemented, will not only shrink public funding for the National Institutes of Health (NIH) and the Food and Drug Administration (FDA), but also, more specifically, will deny FDA the ability to use a portion of the user fees provided to the FDA by private companies under the Prescription Drug User Fee Act (PDUFA)," says Jim Greenwood, president and CEO of the Biotechnology Industry Organization (BIO) in Washington, DC. "We are learning that under sequestration, companies' user fees must still be paid, but FDA will not be allowed to spend all of the funds. This is very concerning to BIO—and more importantly to all patients eagerly awaiting approval of new drugs and therapies to treat their diseases."

The budget sequester is "not the end of the world, but it's not good for FDA," says Peter Pitts, president of the Center for Medicine in the Public Interest in New York. For example, PDUFA dates may need recalibrating. US Department of Health and Human Services (HHS) secretary Kathleen Sebelius has warned that FDA cutbacks will heighten food safety risks from fewer inspections, but Pitts points to longer-term strategic effects arising from the sequester. "Anything having to do with policy development, such as dealing with biosimilar drugs, will grind to a halt," he says. "The sequester will delay regulatory innovation by pushing things that are important but not life-threatening off the agenda."

Richard Dolinar, who chairs the Alliance for Safe Biologic Medicines in Washington, DC, says his members are concerned about the effects sequestration could have on the FDA's ability to issue a final guidance on biosimilars and their approval. "The FDA must have access to the scientific and regulatory expertise needed to evaluate these complex products."

Although FDA officials say they will not furlough agency employees, other regulatory agencies, such as the US Environmental Protection Agency, with jurisdiction over some biotech products, are already notifying their employees as to how many days they will be forced to take off without pay.

Table 1 Sequestered funding at US agencies

Agency	Cuts in FY13 budget (\$ millions)
NIH	1,600 ^a
FDA	209 ^b
USDA ^c	60

^aApplies to funding for research and grants. ^b\$82 million will also be sequestered from PDUFA fees. ^cUSDA, US Department of Agriculture.

The overall impact of the budget sequester on federal research programs is proving difficult to gauge (Table 1). Furlough programs are likely to hit at least some federal researchers working in biotech. Also, estimates vary of how deeply forced cuts will affect extramural programs throughout the country. For example, funding for NIH grants will likely be reduced, and that could lead to the loss of "several thousand" jobs in research across the country, HHS secretary Sebelius says.

Other federal departments supporting research programs involving biotech have issued similar warnings. An anticipated \$60-million cutback in research funding at the US Department of Agriculture could mean a loss of about 100 grants, "disrupting critical progress being made in areas such as bioenergy production, animal and plant disease," says agriculture secretary Tom Vilsack. Officials at the Department of Energy project a similar scaling back, including programs investigating alternative energy production. Additionally, officials at the National Science Foundation expect cuts to lead to a reduction of nearly 1,000 grants and affecting 12,000 people, according to the agency's former director Subra Suresh, who stepped down in March.

Some outside organizations predict dire consequences. For instance, according to the Washington-based coalition called ScienceWorksForU.S., the sequestration will lead to "a minimum \$203-billion reduction in US GDP over the next nine years and 200,000 fewer jobs per year between 2013 and 2016" because of reduced federal R&D spending. "With sequestration, the prospects for new medicines will dip," says coalition member William Chin, executive dean for research at Harvard Medical School in Boston. "Basic research is funded largely by government sources and not by industry. Industry will need to continue to focus its funding in late-stage development."

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President Obama tried and failed to avert sequester cuts.