

FDA Budget To Plunge By \$319M If Sequester Takes Effect

By Rachel Slajda

Law360, New York (September 14, 2012, 8:14 PM ET) -- The governmentwide sequester set to take effect in January would slice \$319 million from the U.S. Food and Drug Administration's budget next year and billions more from other health departments, the White House announced Friday, but an expert says the agency may be able to insulate its drug and device reviews from the cuts.

The Office of Management and Budget released a report Friday detailing how much would come out of each agency under the Budget Control Act of 2011's mandated cuts. The sequester will go into effect at the start of 2013 unless Congress passes legislation cutting \$1.2 trillion from the federal deficit over the next 10 years.

The OMB said 8.2 percent would be cut from the FDA's salaries and expenditures, totaling \$318 million in cuts in the 2013 fiscal year. Another million would be cut from a revolving certification fund, it said.

The FDA and industry groups have expressed concern that the cuts would affect the industry-paid user fees that fund a large portion of the agency's drug and device reviews. User fees make up about 65 percent of the funding for drug reviews and 35 percent for device reviews, nearly all of the FDA's requested budget increase for the 2013 fiscal year, and 44 percent of the agency's overall budget.

In order to collect those user fees, the FDA must also keep taxpayer-funded spending on activities like drug and device reviews above a certain level. If funding dips below that level, the agency must forfeit its user fees. The report's baseline for the FDA budget that the cuts are based on — \$3.9 billion — appears to include the portion funded by user fees.

Steve Mahinka, chair of the life sciences and health care practice at Morgan Lewis & Bockius LLP, told Law360 that the FDA would do everything it could to protect that funding.

“You'd lose 44 percent instead of 8 percent. It would be insane to function like that,” Mahinka said. “It's relatively easy to protect user-fee programs by allocating your cuts within your agency, within the FDA, in a sufficient way so you don't trigger the loss of user fees.”

The OMB report, required by the Sequestration Transparency Act passed this summer, does not break down the cuts further among sections of the agency.

Elsewhere in health care discretionary spending, the National Institutes of Health would lose \$2.5 billion in 2013, sharply limiting the research grants it doles out. Grants to set up the Affordable Care Act's insurance exchanges would be cut by \$66 million, and funding for state grants and demonstration projects under Medicare and Medicaid would be cut by \$40 million.

The ACA's prevention fund, which funds preventive health measures like obesity prevention programs and vaccination drives, would see a \$76 million cut, and the Office of the National Coordinator for Health Information Technology would lose \$1 million.

The cuts would be devastating to public health, said Emily J. Holubowich, a senior vice president at the lobbying firm Cavarocchi Ruscio Dennis Associates LLC. Holubowich is also the executive director of the Coalition for Health Funding, which includes doctors' groups, patient advocacy groups and local public health officials.

Holubowich said that cutting research funding would have long-term effects, discouraging young people from going into biomedical research. Other cuts to training for health care professionals could discourage people from beginning careers as doctors or nurses, exacerbating current shortages.

"These cuts would be the knockout blow to public health," she said.

--Editing by Elizabeth Bowen.