Portfolio Media. Inc. | 860 Broadway, 6th Floor | New York, NY 10003 | www.law360.com
Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

Sequester Could Gum Up FDA Drug, Device Reviews

By **Rachel Slajda**

Law360, New York (August 10, 2012, 5:51 PM ET) -- A federal sequester slashing 8 percent of the U.S. Food and Drug Administration's budget could be devastating for the agency and the industry that relies on it, potentially forcing layoffs and slowing down drug and device reviews as the FDA tries to reach its user fee goals.

Unless Congress moves to avert the federal sequester before January by finding $1.2 trillion in deficit reduction or, more likely, by pushing the deadline back, each federal agency will have to cut its budget by an estimated 7.8 percent, including the FDA.

The cuts have an enormous potential to upset the FDA's review process, and especially the goals for speed, predictability and communication with sponsors laid out in its new user fee agreements.

"The food's going to be less safe, drugs are going to be approved slower, the degree of surveillance is going to be lower and the FDA is constantly going to be struggling to have the manpower to do the job," said Steven Grossman, deputy executive director of the Alliance for a Stronger FDA. His group is a coalition of pharmaceutical companies, industry groups and patient advocates that lobbies for more funding for the agency.

One major question is how user fees will factor into the sequester. User fees make up about 65 percent of the funding for drug reviews and 35 percent for device reviews, as well as nearly all of the FDA's requested budget increase for the 2013 fiscal year.

Grossman and others believe that the FDA's authority to collect and spend user fees cannot be touched by the sequester, since they are paid by the industry and not taxpayers.

"User fees, as we see it, are exempted," said Stephen Mahinka, head of the life sciences and health care practice at Morgan Lewis & Bockius LLP. "The collection and use of user fees would appear, at least the way see it, not to be part of the total amount ... you would be cutting. I think the user fee collections and the activities they fund would be insulated. Those activities would go forward."

If true, that could protect user-fee-financed activities like reviews — or, for biosimilars, development meetings — from being hit too hard. But John Cooney, a budget expert who worked in the Office of Management and Budget in 1985 and 1986, during the first sequester, says that's far from certain.

Because user fees go into the federal budget, they'd be subject to cuts like everything else, argues Cooney, who is now a partner at Venable LLP.

That's unless the FDA can successfully argue that user fees fall into one of the exemptions in the new sequester bill, signed in 2011. In particular, the bill exempts "activities financed by voluntary payments to the government for goods or services to be provided for such payments," which could conceivably include user fees.

It is the OMB — likely in consultation with the U.S. Department of Justice — that would make that call, Cooney said. The decision would likely be governmentwide, encompassing other user fees such as premerger notification filing fees paid to the Federal Trade Commission. But what exactly the White House will decide is tough to predict, according to Cooney.

"What would the OMB's conclusion be?" he questioned. Recalling his time during the 1986 sequester, he said agencies were constantly calling for interpretations of the law and which expenditures were exempt. "That's what drove us crazy. ... It was the most intense career experience I've ever had."

A spokeswoman for the FDA said the agency could not immediately comment on the issue.

Still, even if user fees are exempt from the sequester, they only account for part of the financing of product reviews. Much of the funding still comes from regular appropriations and could be vulnerable to cuts.

It's worth noting that the FDA must maintain appropriations for drug and device reviews at a certain level; if funding dips below that level, the agency must forfeit its user fees. That could give the FDA the incentive to direct as many of its appropriations toward reviews as possible in order to hang onto its user fees, said Lynn Mehler, a partner at Hogan Lovells.

In that case, the agency's other programs, such as food safety, could see a disproportionate hit.

"Say the FDA does see a big cut in their budget, what do they do? They can't use their user fees. Other programs that are not funded by user fees will be short-shrifted," said Mehler, who worked in the FDA's chief counsel office for 12 years. "The concern will be that some things that are not user fee funded, but still important to the public health, will see their budgets shrink because the FDA has to spend money on human drug applications. Where can we steal the money to put over here to keep our user fees?"

The Alliance for a Stronger FDA, however, doesn't believe even an 8 percent cut would bring down review appropriations far enough to trigger the forfeiture of user fees.

"It is our understanding that the proposed sequester would not lower FDA’s [budget authority] funding ... to a level at which the trigger would come into play. Even after a sequester, FDA would still be well above these minimums," Grossman said in a June blog post.

It's also unclear just how much discretion agencies will have to decide how to spread the cuts around, perhaps cutting more from lower-priority programs in order to keep high-priority programs mostly intact.

The cuts must be uniform, not only among agencies, but also among each "program, project, activity or account" within the agency. What qualifies as a program, project or activity is still unclear, Cooney said. At the FDA, the agency might have to make equal cuts to its food, drug, biologics, animal drugs, devices and other broad programs, allowing it discretion within those programs — or it might have to make equal cuts to smaller initiatives within those programs, limiting how much it could prioritize one activity over another.

No one wants the sequester to actually go into effect — especially now that the Congressional Budget Office has said the sequester combined with the expiration of the Bush tax cuts could sink the economy into another recession — and few think it will really happen.

Congress will, however, undoubtedly go until the last minute before it acts to stop the cuts, and the industry, in particular the Alliance for a Safer FDA, is preparing by lobbying lawmakers to find a way to avoid the sequester.

"It's long been our position that if Congress needs to make cuts, they should not be across-the-board cuts — that Congress should exercise its judgment about what the nation's priorities are," Grossman told Law360. "We're satisfied that if that's done, the FDA will be much better off than under across-the-board cuts. We know it's a priority and we think most of Congress recognizes that."

--Editing by Elizabeth Bowen and Katherine Rautenberg.