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Hamburg Details Some Sequestration Impact On FDA

By Derrick Gingery / Email the Author / *Feb. 5, 2013*
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Executive Summary

Commissioner says allowing the sequester would slow implementation of FDASIA provisions and reduce some overseas inspections.

FDA Commissioner Margaret Hamburg warned against allowing the budget sequester to be implemented and hinted at some of the potential effects the cuts could have on the agency shortly after a similar pitch from President Obama.

Obama asked Congress Feb. 5 to pass a short-term sequester delay that included spending cuts and tax reform and allow more time for negotiations to replace the cuts and avoid damage to the economy.

Hamburg spoke about the sequester's anticipated effects on FDA about an hour after Obama's speech, although she did not reference his address. She told the Alliance for a Stronger FDA that the cuts could result in reduced facility inspections and slowed implementation of new user fee and other programs.

Hamburg also reminded the group that the agency relies on personnel more than other agencies to implement and run those programs.

"It's a lot of exciting and important work, but it requires that we have the depth on the bench, the expertise, of course scientifically, and the sheer people power to support these efforts," she said during remarks to the advocacy group.

Sequestration is expected to result in about $319 million in cuts to the FDA budget, including user fees, if not prevented ("FDA's 8.2% Solution: Sequestration Would Cut $319 Million" — *"The Pink Sheet" DAILY*, Sep. 14, 2012).

It has been suggested that hiring could be delayed or layoffs required if the sequester is in effect ("How Do You Solve A Problem Like Sequestration?" — *"The Pink Sheet,"* Sep. 3, 2012).

A congressional deal near the end of 2012 averted the cuts until March 1 ("Fiscal Cliff Legislation Adjusts ESRD Payment Bundle To Help Offset Doc Fix" — *"The Pink Sheet" DAILY*, Jan. 2, 2013).

FDA has been tight-lipped about its specific plans for dealing with sequestration. But Hamburg gave a small clue, saying the agency would perform about 2,100 fewer domestic and foreign inspections of food facilities.

Hamburg said she hoped a lot of personnel actions would not be necessary, but said certain activities would be limited, especially with international inspections because they are a significant cost. She said more emphasis could be placed on using systems that target the riskiest facilities to reduce the number of onsite inspections.

While the figure did not include medical product facilities, it would not be a dramatic leap to suspect that domestic and international drug facility inspections could also be reduced if the cuts are made.

They likely would hurt FDA efforts to deal with industry globalization and work with other trusted regulators to share the inspection workload.

FDA wants to use information from the European Medicines Agency and others, which would allow the agency to better focus its resources ("FDA Envisions Many Regulatory Coalitions Dealing With Globalization Issues" — *"The Pink Sheet,"* Sep. 26, 2011).

Agency Is "Lean," But In Good Health

The agency already has implemented initiatives intended to cut costs, such as increasing telework and reducing travel and other budgets.

FDA also now uses the office "hoteling" concept, in which employees do not have a permanent work space, Hamburg said. She also said the agency is looking at contracts to reduce service duplication.

"We're lean, but we're in robust good health," Hamburg said. "We need to really look for every opportunity that we can to streamline our activities and leverage our resources, but we cannot walk away from our critical roles and responsibilities."

Critical Programs Will Move Forward

Regardless of sequestration, implementation of the biosimilar and other critical programs will move forward, Hamburg said.

The new user fee program was enacted as part of the FDA Safety and Innovation Act and launched in October 2012 ("FDASIA Is Signed, Not That White House Wanted Anyone To Notice" — *"The Pink Sheet,"* Jul. 16, 2012).

But Hamburg said FDASIA implementation may not go as quickly as possible under sequestration, which may endanger commitments to industry made in the various user fee agreements.

“I am very concerned about our ability to engage as fully as we might otherwise,” she said. “We’re going to have to prioritize in some important ways, but we don’t see stopping elements. We will not make our targets. That’s almost a given.”