

### **Hamburg: Agency Will Be Slowed, Likely Miss FDASIA Targets If Sequestration Occurs**

All of the FDA's programs will be compromised if across the board spending cuts, known as sequestration, take effect March 1, FDA Commissioner Margaret Hamburg said Tuesday.

Though she did not reveal specifics, Hamburg said the FDA is preparing to narrow its focus to what it considers to be its core functions. "There is a lot to be concerned about," she said.

As the debate over sequestration continues, Hamburg anticipates some of the program expansions and new activities anticipated with the passage of the FDA Safety and Innovation Act (FDASIA) will be put in a "stall mode" as the FDA awaits resolution of the sequestration issue. The agency will move forward with implementing FDASIA, but it will likely miss deadlines as its pace and efficiency is slowed, Hamburg said Tuesday at a meeting of the Alliance for a Stronger FDA.

Even if Congress agrees to a deficit reduction plan to avoid sequestration, the uncertainty has already created a "demoralizing environment" as the agency is trying to start up key new programs such as the generic drug and biosimilar user fee programs, Hamburg said. This has made it hard to recruit and retain high quality staffers.

To reduce spending, the agency has already started using less building space and encouraging telework. The FDA "will find every way to protect against the damage," but it doesn't "have a lot of fat in the system as a starting point" to help absorb the cut, she said.

Hamburg's comments came about an hour after President Barack Obama urged Congress to pass a smaller package of spending cuts and tax reforms that would delay the sequester for a few more months, until a larger deficit reduction deal can be reached.

Congress last pushed the sequestration deadline back at beginning of the year ([DID, Jan. 3, 2013](#)). — Sarah Karlin