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US Regulatory Roundup, March 2019: FDA, FDA, And More FDA

by Shawn M. Schmitt

The US agency was particularly active last month, beginning with FDA chief Scott Gottlieb's surprising March 5 announcement that he would leave his post in April, and ending with an announcement by FDA on March 27 that it would roll out the biggest change to its mammography regulations in more than two decades. These issues and more made up the 10 most popular US regulatory and policy articles in March.

If there were three letters to best describe the US medical device regulatory and policy arena in March 2019, they would be "F" "D" and "A."

The agency was particularly active last month, beginning with FDA chief Scott Gottlieb's surprising March 5 announcement that he would leave his post on April 5. Our *breaking news story* about it piqued the interest of many online readers of *Medtech Insight*, making it the most-read article of the month.

One of the more popular agency officials in the Trump administration, Gottlieb instituted some significant reorganizations in his 22 months at the agency. And one week after Gottlieb's announcement, on March 12, it was announced that National Cancer Institute Director Norman "Ned" Sharpless would *step in as acting commissioner* when Gottlieb leaves.

In a March 20 farewell talk at the Brookings Institution, the current FDA commissioner said a *top piece of unfinished business* that he hopes is handled after his April departure is legislation to regulate laboratory developed tests, or LDTs. Our report on that garnered significant reader interest, as well.

Another topic of interest to *Medtech Insight* readers last month was the agency's warning that the *market could see device shortages*, after two facilities that use ethylene oxide to sterilize products

were shuttered because they exceeded the limits for how much EtO is acceptable to release into the environment. FDA chief Gottlieb noted that the agency has begun exploring other sterilization processes to minimize the reliance on ethylene oxide.

And on March 27, FDA rolled out the biggest change to its mammography regulations in more than two decades, requiring mammographers to give patients more information on the limitations of mammography tests, especially for patients with denser breast tissue. Mammographers will also have to adhere to new standards, *according to our report*, which was the third most-read article of the month.

Meanwhile, readers were also interested in the reorganization of FDA's Center for Devices and Radiological Health, which began in earnest on March 19. *The ambitious plan*, in the works since 2017, will see device center staff grouped more closely by the products they work on, rather than by the stage in the review process. The agency aims to finish the reorg by Sept. 30.

Rounding out the top 10 *Medtech Insight* articles of the month was news out of a March 25-26 FDA advisory committee *meeting on breast implants*. Despite pleas from implant patients for the agency to take off the market silicone and saline breast implants that have caused a serious range of symptoms in some women, the panel instead recommended FDA issue stronger public advisories warning of the risks of breast implants and a lymphoma associated with the products.

The 10 most popular US regulation and policy stories in March are listed in the table below.

Rank	Title
1	Scott Gottlieb Calls It Quits After An Active Tenure At US FDA
2	Sterilization Facility Shutdowns Could Spell Medical Device Shortage; FDA Urges Firms To Assess 'Downstream Impacts'
3	US FDA Proposes Biggest Mammography Rule Change In 20 Years
4	FDA Device Center Reorg Set To Roll Out This Week
5	FDA Says It's Approving Change Notices 3 Weeks Faster For Firms In CMMI Maturity Model Program; 40+ Inspections Waived
6	Heartburn: Yet Another Device-Maker Is Facing Cardiac Device Cybersecurity Worries – This Time, It's Medtronic
7	Unfinished Business: LDT Legislation A Top Priority For Departing FDA Chief Gottlieb
8	President Calls For Almost $100M More In Funding For FDA Device Activities In 2020
9	VA Medical Supply Purchasing Reform Could Open New Doors
10	'Do Your Job': To The Dismay Of Patients, FDA Panelists On Breast Implants Advise Better Risk Warnings, Not Recalls