MEDTECH INSIGHT
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US Regulatory Roundup, January 2020: Recalled Surgical Gowns; Coronavirus News; FDA Inspection Tips; And More

by Shawn M. Schmitt

News that device giant Cardinal Health recalled millions of potentially unsafe, unsterile surgical gowns – and a message out of the US FDA for customers to "immediately discontinue" using the gowns – was of most interest to our online readers last month. Meanwhile, the FDA's plans to hasten emergency-use approvals of coronavirus test kits and a set of 10 tips for dealing with agency investigators also garnered significant attention. Here are January's 10 most popular US policy and regulation stories from *Medtech Insight*.

Recalled Surgical Gowns

News that *Cardinal Health Inc. recalled millions of potentially unsafe, unsterile surgical gowns* – and a message out of the US Food and Drug Administration for customers to *"immediately discontinue" using the gowns* – was of most interest to *Medtech Insight*'s online readers last month.

The device giant said in a late January recall notice to customers that the affected Level 3 gowns – non-reinforced, fabric-reinforced and RoyalSilk non-reinforced – were distributed between 1 September 2018 and 10 January 2020. Gowns are rated on a scale that measures barrier protection; Level 3 gowns offer moderate-risk protection.

The company recalled more than 9 million of gowns because it couldn't guarantee their sterility after a Chinese supplier, Siyang HolyMed, made them in what Cardinal Health called "unapproved locations that did not maintain proper environmental conditions."

On 30 January, *Cardinal Health admitted that Siyang HolyMed was a repeat quality control offender*, noting that there had been "supply chain issues" with the vendor in early 2018. Also on that day,

the device maker announced a second recall, this time for its PreSource Kits that include the recalled gowns. More than 2.5 million of the procedure packs were recalled.

Cardinal Health, which terminated its relationship with Siyang HolyMed this year, expects to lose $96m in the second quarter of fiscal year 2020 because of the recalls.

Other Safety Issues

As Cardinal Health tackled its troubles with gown sterility, other safety-themed articles were top reads in January.

In our No. 5 story, *three patients filed lawsuits claiming they were injured by Medtronic's surgical staplers*. The suits allege that the company knowingly sold defective devices and intentionally kept patients and physicians from being aware of the staplers' full safety records.

All three patients had gastrointestinal surgery that required stapler placement in late 2017. The staplers allegedly malfunctioned by leaving behind extra holes in internal tissues or not properly closing, leading to adverse events such as infections, cardiac problems and the need for additional revision surgery.

And our No. 7 story detailed how a *Medline Industries ethylene oxide (EtO) plant in Illinois that sterilizes medical devices temporarily closed* so it can make upgrades that conform to new state regulations that went into effect this year.

The closings of several EtO facilities over the past several months (the FDA says six plants have either shuttered temporarily or permanently) has industry safety experts concerned. They say the plant shutdowns could lead to a shortage of medical devices.

Coronavirus News

Meanwhile, readers were strongly interested last month in the *FDA's plans to hasten emergency-use approvals of coronavirus test kits*. News has moved swiftly since that story ran on 23 January; in fact, *the agency on 4 February gave its stamp of approval* to a 2019-novel coronavirus test that was developed and already in use by Centers for Disease Control and Prevention (CDC) laboratories.

Also on 4 February, an industry expert in Shanghai told *Medtech Insight* that *exports of components and finished medical devices coming from China will continue to flow* to the US and other countries for now, but there could be trouble soon if government quarantines and international travel bans remain in place. L.E.K. Consulting partner Stephen Sunderland explained that many Chinese device makers probably stockpiled inventory before the weeks-long Chinese New Year festivities began, alleviating short-term shortage fears.

FDA Inspection Advice

Garnering a lot of reader attention last month was our *10-part Compliance Corner series* on best practices for manufacturers when dealing with FDA investigators during a facility inspection. *Click here to read the entire series*, which offers tips from longtime industry experts David Elder, Steve Niedelman, John McKay and Susan Schniepp.

Hahn Takes The Wheel At FDA

Immediately following an all-hands staff meeting on 30 January, new FDA commissioner Stephen Hahn sent out an agency-wide email that outlined his key agenda items, including the use of data and patient input to guide regulatory decisions, and feedback from staff on how to improve the agency. *These action items were highlighted in our No. 10 story*.

Much of what's on Hahn's priorities list align with what FDA legal experts expected of him during a 24 January webinar hosted by consulting firm Kinexum and law firm Hogan Lovells. *Our story on what those experts said* was the eighth most-read *Medtech Insight* article last month.

Premarket Exemptions; FDA's Surveillance System

Stories on FDA premarket exemptions and the agency's device surveillance system rounded out our Top 10 list in January:

- *No. 3 story*: A final order issued in late December codified a move by the FDA to drop premarket notification requirements on some 200 class I and II device types. The 21st Century Cures Act required the agency to identify devices that could be made exempt from premarket notification requirements as part of a push to reduce regulatory burdens on industry. Class II devices are eligible for exemption if a 510(k) is not required to ensure safety and effectiveness, the FDA says.

- *No. 9 story*: An ineffective medical device surveillance system could put patients at risk, researchers argued in a set of three articles published in the *Journal of the American Medical Association* (*JAMA*) *Internal Medicine*. According to the articles, an ideal device surveillance system would comprehensively collect data on adverse events throughout a device's life span, would be integrated into electronic health records, and would analyze data to detect safety signals and underperforming devices. The US system falls short of that benchmark, the researchers say.

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

Rank	Story
1	*'Immediately Discontinue' Using Potentially Nonsterile Surgical Gowns, Packs From Cardinal Health, FDA Warns; Company Assessing Quality Issues*

2	*Compliance Corner: The 10 Best – And 10 Worst – Things You Can Do When FDA Inspects Your Firm (Part 1)*
3	*US FDA Exempts 200 Device Types From Premarket Notification*
4	*9.1 Million Surgical Gowns Recalled By Cardinal Health; Firm Pins Sterility Woes On Contract Manufacturer*
5	*Medtronic Faces Surgical Stapler Lawsuits In Minnesota, Texas*
6	*FDA 'Stands Ready' To Fight Coronavirus Via Emergency-Use Test Kits While WHO Mulls Virus Spread, Gets Out Guidance*
7	*Another Sterilization Plant Closes For Upgrades; FDA Monitoring Situation For Device Shortage*
8	*FDA Commissioner Hahn's Priorities Include Workplace Development Issues, Data Collection*
9	*Researchers Question Efficacy Of FDA's Device Surveillance System*
10	*In Letter To FDA Staff, Hahn Lays Out His Cards*