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FDA class I medical device recalls on track to break record in 2021

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Following the temporary lapse in FDA inspections of manufacturing sites amid the COVID-19 pandemic, this year has already seen more class I medical device recalls issued than in all of 2020. The agency is now working to remediate the interruptions resulting from the pandemic among certain manufacturers of high-risk medical devices in reporting these recalls to the FDA.

The impact of the pandemic across the medical device industry has varied from the start, with some companies benefiting from increased sales while others grappled with a disruption in manufacturing.

From Medtronic plc and Boston Scientific Corp. to Smisson-Cartledge Biomedical LLC and Combat Medical Systems LLC, class I recalls have this year have been issued by companies of varying sizes and backgrounds. Most are for cardiac devices, followed by SARS-CoV-2 assays.

The increase in class I recalls this year compared to last should not come as a surprise, experts told *BioWorld*. In any case, it serves as a testament to the system working to get back on track.

Fluctuations in class I recalls

Class I device recalls were down in 2020 in line with previous years, except for 2019 when there was a government shutdown that disrupted the FDA's work in a similar manner to the pandemic.

The FDA has issued 37 class I recalls for the 2021 calendar year to date. This compares to just 33 in total for the entire 2020 calendar year, underscoring the impact of the pandemic on these recalls. Totals stayed within a range of less than 40 between 2015 and 2019 when this spiked to 51, up from 32 in 2018. 2021 will likely surpass 2019 and is on track to break the current record.

The last record-breaking year for class I recalls was in 2013, with a total of 62. By this time in 2013, these had also totaled 37. Yet experts identified several COVID-19-related factors that indicate 2021 will far surpass 2013, including getting production back to pre-pandemic levels.

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The upward trend this year coincides with the FDA's postponing of both domestic and foreign surveillance inspections last March over growing concerns about the potential for widespread COVID-19. The FDA reverted to remote inspections and alternative tools during this time and set the goal of resuming domestic inspections using a new risk assessment system last July.

As part of the strategy to resume inspections, the plan was to do so in order of priority based on risk and other factors. The system involved pre-announcing prioritized domestic inspections to FDA-regulated facilities for the foreseeable future to help assure FDA and the firm's staff safety.

The impact of the lapse in FDA site inspections led to 52 domestic inspections conducted from March to September 2020, vs. about 400 in prior years, and only three foreign inspections.

Another area that COVID-19 had a major impact in terms of addressing class I recalls, among other corrective actions, relates to the dip in elective procedures. Delaying these procedures due to COVID-19 created a backlog that will take time for industry and the FDA to catch up on.

"We noticed last year a significant decrease in non-emergency care, elective procedures," head of public affairs at industry group AdvaMed, Jim Jeffries, told *BioWorld*. "Anything not related to COVID-19 was effectively shut down and this could probably explain why there were fewer recalls last year," Jeffries added. Now, what industry is seeing is the reverse effect of that.

Interruptions with notification and reporting

The FDA uses the term "recall" when a manufacturer takes a correction or removal action to address a problem with a medical device. Recalls can occur when a medical device is deemed defective, when it could be a risk to health or when it is both defective and a risk to health.

In most cases, a company, whether it be a manufacturer, distributor, or another responsible party, issues a voluntary recall of a medical device on its own. When it learns that it has a product with an issue warranting a recall, the company initiates a recall and notifies the FDA.

The FDA can legally require a company to recall a medical device, which could happen if the company refuses to recall the device and there is a reasonable probability that the device could cause serious adverse health consequences and/or death. "However, in practice, the FDA has rarely needed to order a medical device recall," FDA spokesperson Audra Harrison noted.

Class I medical device recalls are a priority for the agency as the highest risk category for recalls, typically involving devices that require premarket application approval from the FDA.

The 37 class I recalls the FDA has issued (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=&productdescriptiontxt=&productcode=&IVDProducts=&rootCauseText=&recallstatus=&centerclassificationtypetext=1&recallnumber=&postdatefrom=01%2F01%2F2021&postdateto=07%2F16%2F2021&productshortreasontxt=&firmlegalnam=&PMA_510K_Num=&pnumber=&knumber=&PAGENUM=100) so far this year include several devices regularly used in critical care settings. There are many factors that may lead a manufacturer to recall a device, including the FDA's ongoing surveillance of a device and analysis of its performance data, the manufacturer's ability to remediate issues, as well as the collaboration between the company and agency to ensure the benefits of the device outweigh risks for patients using it.

Harrison told *BioWorld* that "although the COVID-19 pandemic has not changed the FDA's critical oversight role to protect and promote public health by ensuring medical devices are safe and effective, we have seen some interruptions with notification and reporting to the FDA and implementation of mitigation efforts on behalf of some firms with active recalls." Harrison said that the agency "continues to actively work with these firms to address such recalls and implement mitigation efforts as soon as possible." The FDA is aware of a limited number of disruptions related to the pandemic, she said.

A delay in reporting recalls to the FDA because of the pandemic was almost to be expected, noted James Boiani, an attorney at Washington-based law firm Epstein Becker & Green PC, told *BioWorld*.

"There was an understanding that some of the submissions that the FDA would be getting might be delayed because the people who needed to do them couldn't get to work or had clients who had experienced COVID-19 outbreaks at their facilities that hampered their abilities," Boiani said. "There might have been some unwritten latitude" driving delays in reporting, also, Boiani added.

2021 likely to set a record

Within the context of the spike in 2019, 2021 has also surpassed the total number of class I recalls issued within the same time frame. There was a total of just 26 by this time in 2019.

"This seems to demonstrate that the system is working exactly as it should to protect patients," Jeffries said about the increase in recalls this year and the system for recalling these devices.

When it comes to specific products, the Alaris infusion pump manufactured by BD (Becton, Dickinson and Co.) tops the list with the most recalls so far this year at a current total of seven. There are an additional four associated with the Heartware system from Medtronic, too.

Medtronic has issued the most recalls so far this year with a total of seven, followed by Boston Scientific with a total of five. Medtronic and Boston Scientific declined to provide a comment.

Now as the FDA is starting to get back to normal in terms of operations, recalls are expected to continue increasing. “We're starting to see more in-person audits,” Boiani said. He has had recent discussions with the FDA about the sort of delays from COVID-19 in terms of processing.

“I think the FDA will leverage remote audits going forward as a way to keep further oversight in a cost-effective manner of the manufacturers,” Boiani added. But it is going to start showing up at the door again, too, especially for more complex manufacturing sites. “Now, any latitude companies have been getting over the last 18 months is winding down to business as usual.”

Similarly, the number of FDA warning letters (https://www.bioworld.com/articles/509298-us-federal-government-agencies-tightening-their-focus-on-med-tech) is expected to see a significant increase this year.