MEDTECH INSIGHT
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US Regulatory Roundup, October 2021: Medtronic And Stryker Talk Recalls; Spotlight On Breakthrough Devices; And More

by Shawn M. Schmitt

Medtech regulatory professionals talked about medical device recalls at a US FDA meeting, while experts said they're concerned about the future of the soon-to-be-withdrawn MCIT rule that would've given four years of Medicare coverage to breakthrough devices. These and other stories topped our list of most-read articles last month.

Safety And Recalls

Medical device safety and product recalls were hot topics in October, with news of the US Food and Drug Administration reclassifying surgical staplers from low-risk class I to moderate-risk class II being the most-read story for *Medtech Insight* readers.

The FDA proposed reclassifying the staplers in 2019 after reviewing reports of more than 40,000 adverse events related to the device – including 366 deaths and 9,000 serious injuries – received between 2011 and 2018. The FDA's General & Plastic Surgery Devices Advisory Committee backed the agency's recommendation of class II status for the tools in May 2019.

A final guidance document on stapler labeling and an updated letter to health care providers about the device were issued by the FDA alongside its 7 October reclassification order.

"The increasing reliance on surgical staplers by surgeons to perform more procedures that are minimally invasive, together with the agency's analysis of adverse events associated with surgical staplers and implantable staples, prompted the FDA to increase regulatory oversight of these devices while continuing to educate health care providers and patients about their benefits and risks," FDA device center chief medical officer William Maisel said in our *No. 1 story* from

last month.

Meanwhile, regulatory experts at medtech giants *Medtronic PLC* and *Stryker Corp.* talked about device recalls at an FDA Patient Engagement Advisory Committee (PEAC) meeting on the topic.

Laura Mauri, Medtronic's chief clinical and regulatory officer, said the company is investing in and developing a "systematic approach to receiving patient input" across the firm's premarket and postmarket activities, including recalls.

Mauri said in our *No. 5 story* that the PEAC meeting proved that the FDA, industry and stakeholders recognize "that we have more listening to do to be able to develop systematic approaches going forward." She added that Medtronic is "at the beginning of that journey" for developing a framework to make patient communication and input "more systematic" throughout the company.

"What that means is, we're looking at what's appropriate for different points in time and for different products, and trying to look at this from a centralized perspective to give each of our product areas the tools necessary to do that," Mauri said, noting that the firm is currently "defining what we think the best practices are in making that possible."

And in our *No. 7 story*, Ommeed Shahrokh, director of regulatory, compliance and QMS integration for Stryker, explained the manufacturer's decision-making process around product recalls and described what's included the firm's recall letters to customers. Shahrokh also spoke at the PEAC meeting.

Breakthrough Medical Devices

Medtech Insight readers also showed a strong interest in breakthrough medical devices in October. In our *No. 3 story*, a panel of experts in the health care and medical device industries said there's no clear path forward for Medicare coverage of the innovative devices.

In a move strongly criticized by industry, the US Centers for Medicare & Medicaid Services (CMS) announced in mid-September plans to withdraw the proposed Medicare Coverage for Innovative Technology – or MCIT – rule. MCIT would've automatically given four years of Medicare coverage to devices cleared via the FDA's breakthrough device pathway.

The panel was convened at AdvaMed's MedTech Conference in late September to discuss MCIT's future. It was moderated by Aparna Higgins, senior policy fellow at the Duke-Margolis Center for Health Policy, who said real-world evidence standards in MCIT – or rather, the lack thereof – are what's driving the momentum to repeal the rule.

> *"Without sustained attention to this issue, I'm concerned that the push for coverage will fade." – Steve Silverman*

"The evidence standards that are used to satisfy FDA safety and effectiveness criteria are not the same that Medicare uses in terms of determining what is reasonable and necessary," Higgins said. "There's also no way to ensure that there will be evidence upon approval that shows the benefits or risks for Medicare beneficiaries in clinical trials, and there is no authority to limit or remove coverage."

In episode two of our new podcast series Speaking Of Medtech – our *No. 8 offering* from October – former FDA compliance chief Steve Silverman said he's worried that the breakthrough reimbursement issue could slip through the cracks if a replacement for MCIT isn't drafted soon.

"For its part, CMS says that it will consider alternatives to the coverage rule that it rescinded. But I haven't seen anything specific so far and I don't know of any CMS plans to propose alternatives," he said. "Without sustained attention to this issue, I'm concerned that the push for coverage will fade."

Listen to Silverman's full comments on breakthrough devices in the Speaking Of Medtech podcast below:

Click here to explore this interactive content online

Other Top Stories

These five articles rounded out our Top 10 list in October:

- *No. 2 story*: The FDA has recognized a portion of the Oncology Knowledge Base, or OncoKB, which diagnostics makers can use as they work to complete premarket submissions. It's the first database of somatic variants in cancer to be listed in the agency's Public Human Genetic Variant Databases.

- *No. 4 story*: Steve Silverman argues in this opinion piece that while the FDA will adjust poor-fitting practices to accommodate digital devices, the agency isn't going to set aside product review, postmarket quality, and other basic requirements.

- *No. 6 story*: A breast reconstruction tool from Integra LifeSciences may face an uphill battle for approval from the FDA after a mixed recommendation from one of the agency's expert

advisory committees.

- *No. 9 story*: The FDA issued updated guidelines for the labeling of class I devices, which partially revises guidance the agency issued in July 2020. The new draft guidance, issued in mid-October, specifically updates the FDA's policy on Unique Device Identification labeling.

- *No. 10 story*: A final rule was issued by the FDA early last month for the agency's de novo classification program, increasing clarity for device makers whose products might reach the market via that review pathway.

The 10 most popular US regulation and policy stories in October, as determined by reader interest, are listed in the table below.

Rank	Story
1	*FDA Finalizes Class II Status For Surgical Staplers*
2	*FDA-Backed Tumor Mutation Database Gives Diagnostics Developers Another Premarket Submission Tool*
3	*Real-World Evidence Deemed Essential For Breakthrough Designations*
4	*What Does 'Digital' Mean For FDA's Device Center?*
5	*From Recalls To Clinical Trials, Medtronic's Developing A 'Systematic Approach' To Capturing Patient Input*
6	*FDA Panel Recommends Against Approval Of Integra Mesh For Breast Reconstruction*
7	*Compliance Corner: Here's How Stryker Decides Whether To Launch A Device Recall*
8	*Speaking Of Medtech, Ep. 2 – Breakthrough Medical Devices*
9	*FDA Updates Guidance On Unique Device Identification Labeling For Class I Devices*
10	*FDA Finalizes De Novo Process, Updates Related Guidance Docs*