MEDTECH INSIGHT
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02 Jul 2019 | **Data**

US Regulatory Roundup, June 2019: FDA's Efforts To 'Bring MedTech Manufacturing Home,' Publicly Release Millions Of Summarized MDRs Gain Wide Attention

by Shawn M. Schmitt

The FDA's plan to "shift more [device] production to the United States" was the story of most interest to online readers of *Medtech Insight* in June, but the agency's move to end its controversial Alternative Summary Reporting Program for adverse events also garnered significant attention. Here are last month's 10 most popular US regulation and policy stories.

The US Food and Drug Administration wants manufacturers to make more medical devices in the US, and it's using its popular-with-industry *Case for Quality* initiative as the vehicle to do just that.

The agency's plan to "Bring MedTech Manufacturing Home" was the story of most interest to online readers of *Medtech Insight* in June. The initiative is needed, the FDA says, to "shift more [device] production to the United States" because "manufacturing innovation has stagnated in recent years as manufacturers have focused on meeting the basic requirements to ensure compliance with FDA regulations."

The framework for Bring MedTech Manufacturing Home includes a voluntary program for device-makers to become certified for meeting specific manufacturing and product quality criteria. If that sounds familiar, that's because the agency is already doing that with its Case for Quality Voluntary Improvement Program. CFQ VIP aims to elevate product, manufacturing and process quality at device firms by appraising the companies against an industry-modified version of the *Capability Maturity Model Integration* (CMMI) framework.

The FDA received $6m in funding in fiscal year 2019 for Bring MedTech Manufacturing Home –

which will eventually branch out to initiatives other than CFQ VIP – and the agency has asked for an additional $12m for FY 2020 for the America-centric initiative.

Also of significant interest to *Medtech Insight* readers last month was the *FDA's move to end its controversial Alternative Summary Reporting Program* for adverse events. The ASR Program allowed manufacturers to submit abbreviated reports in a summarized, line-item format. It was established in 1997 in an effort by the agency to review adverse events more efficiently for well-established risks, but it caused reports of medical device failures to be hidden from public view.

In a 21 June announcement that the ASR Program was officially shuttered, FDA device center director Jeff Shuren noted that millions of summarized adverse events sent to the agency between 1999 and 2019 are now *available to the public*. He also said the FDA will make MAUDE more user-friendly within the next few years; *MAUDE* is the agency's Manufacturer and User Device Experience database, where all Medical Device Reports are stored.

Meanwhile, news on a pair of FDA advisory panel meetings snagged the No. 5 and No. 6 spots on our most-read list for June. The first meeting, on concerns about the mortality risk tied to the use of paclitaxel-coated balloons and stents, was *previewed by Medtech Insight in an 11 June article*. (A full story on the two-day, 19-20 June panel meeting can be found *here*.)

A second agency panel meeting, *this one on the risks of surgical staplers*, found the FDA being advised by its General and Plastic Surgery Devices Advisory Committee to upclassify the error-prone staplers as class II devices. The agency has been increasingly concerned about surgical stapler safety in recent years due to a growing rate of associated complications. The FDA said it received more than 41,000 adverse event reports related to the staplers between 2011 and early 2018, including 366 deaths and more than 9,000 serious injuries.

And speaking of advisory panels, the FDA assured *Medtech Insight* that *its device panels are exempt from a controversial Trump administration order* to cut the number of federal advisory committees by a third – although it's unclear what the order's larger ramifications might be.

Also in June, the agency released to *Medtech Insight* its count of quality-related warning letters it sent to device-makers in calendar year 2018, and the number was eye-opening: *Only two dozen of the enforcement missives were issued last year*, marking an all-time low.

Other articles of interest to readers included a report on *a new TAVR national coverage decision by the Centers for Medicare and Medicaid Services* that is favored by industry; news that the National Evaluation System for health Technology Coordinating Center *(NESTcc) selected 12 new test cases that use real-world evidence* to examine device industry priorities; and a report that *AdvaMed hired a former Democratic congressional staffer* as the device industry advocacy group continues its work to repeal the 2.3% medical device excise tax.

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

Rank	Title
1	*Make America Manufacture Again? FDA Incentivizing 'Smart Manufacturing Solutions' To Shift Device-Making To US*
2	*FDA Ends Summary Reporting Program, Releases 20 Years Of Adverse Events, Vows To Make MAUDE 'User-Friendly'*
3	*Manufacturers Support CMS' New TAVR National Coverage Decision*
4	*FDA Misses Hoped-For May End Date For Problematic Summary Adverse Event Reporting Program*
5	*FDA Finds Paclitaxel Mortality Risk In Panel Lead-Up*
6	*Panel Backs FDA's Suggestion Of Class II Stapler Status*
7	*A Record-Low 24 Warning Letters Were Sent To Device Firms In 2018. That's Because A 'Big Hammer' Isn't The Best Tool To Ensure Compliance, FDA Says*
8	*Medical Device Groups Protected From Advisory Panel Cuts, FDA Says*
9	*NESTcc Test Case List Includes Apple Watch, Pelvic Mesh*
10	*Veteran Political Operative Joins AdvaMed To Lobby Dems*