MEDTECH INSIGHT
CITELINE COMMERCIAL

06 May 2019 | **Data**

US Regulatory Roundup, April 2019: Making CAPA 'Cool,' The STAR Act, New FDA Guidance Docs, And More

by Shawn M. Schmitt

An effort led by Medtronic quality experts to rethink the corrective and preventive action (CAPA) process garnered the most attention of *Medtech Insight*'s online readers last month – but news about a new STAR Act from Congress, various guidance documents and artificial intelligence also was of significant interest. These issues and more were the most popular US regulatory and policy articles in April.

An effort led by Medtronic quality experts to overhaul the corrective and preventive action (CAPA) process for the medtech industry garnered the most attention of online readers of *Medtech Insight* in April 2019 – but news about a new STAR Act from Congress, various guidance documents and artificial intelligence also was of significant interest.

Our *No. 1 story from last month* shone a spotlight on Luann Pendy, senior VP of global quality for Medtronic, who began a quest to rethink the CAPA process when she learned the company was spending upwards of $150m to conduct CAPA activities at its various manufacturing sites. She worked with the US FDA and the Medical Device Innovation Consortium through its joint Case for Quality to devise a so-called "#makeCAPAcool" initiative to recast CAPA as a continuous learning tool, rather than a place where problems go to linger, be ignored and never die.

#makeCAPAcool finalized a CAPA framework at a March meeting in Chicago, and the group is currently drafting a white paper on the topic and best practices for industry. The voluntary framework will be rolled out to manufacturers later this year.

Also in April, readers were *interested in an amendment to the Physician Payment Sunshine Act* that would require manufacturers to report the value of any sample devices given to physicians – a requirement that could include some free samples that doctors use when educating patients on

device use.

H.R. 2113, the "Prescription Drug Sunshine, Transparency, Accountability and Reporting Act," or STAR Act, was approved by the House Ways and Means Committee on 9 April. A provision of the bill requires makers of "drugs, devices, biologicals and medical suppliers" to report to the US Centers for Medicare and Medicaid Services (CMS) the value of "free samples" given to doctors. The goal is to make this information more transparent for the public.

Meanwhile, artificial intelligence – specifically, a chat with *Philips CEO Frans von Houten* about AI platforms and a *proposed AI guidance document* from the FDA – also garnered heavy reader interest last month.

Beyond AI, there was oodles of other FDA guidance news in April, including the release of two final documents – one that explains to device-makers *how to conduct a product recall*, and another that describes *actions the agency will take during a facility inspection*.

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

Rank	Title
1	*How A Team Led By Medtronic Quality Experts Plans To Stand Up To 'A Monster Called CAPA' – And Make It 'Cool'*
2	*Device Firms Would Have To Report Value Of Device Samples For Patient Use Under STAR Act*
3	*Rise Of The Machines: FDA Artificial Intelligence Guidance Is Coming*
4	*FDA Explains Why It Approved Apple Watch's De Novo Despite Missing Primary Endpoint*
5	*Beyond The Hype: Philips CEO Says The Future Is AI Platforms*
6	*FDA Yanks Transvaginal Mesh From US Market; Boston Sci 'Surprised'; Firms Have 10 Days To Submit Withdraw Plan*
7	*Device-Makers Can Be 'Recall Ready' With This New Step-By-Step Guidance From FDA*
8	*Gottlieb Points To Breakthrough And Localized Therapy Devices For Non-Opioid Pain Control*
9	*Diversity, More Advocacy Among Lobo's Top Priorities As New AdvaMed Board Chair*
10	*With Fresh Guidance, US FDA Aims For Consistency In Device Facility Inspections*