Bradley Merrill Thompson Quoted in “3 Key FDA Topics for Medtechs in 2022”

Medtech Dive

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Bradley Merrill Thompson, Strategic Advisor with EBG Advisors and Member of the Firm in the Health Care & Life Sciences practice at Epstein Becker Green, was quoted in *Medtech Dive,* in “3 Key FDA Topics for Medtechs in 2022,” by Ricky Zipp and Greg Slabodkin.

Following is an excerpt:

After the coronavirus pandemic upended regulatory plans for the last two years, COVID-19 is poised to remain the top U.S. regulatory priority in 2022 at the FDA. The rapid spread of the highly contagious omicron variant in December and January drove home once again the unpredictable nature of the virus.

It's a lesson that the FDA's Center for Devices and Radiological Health has learned repeatedly during this public health emergency as it has struggled to keep up with an unprecedented workload. Entering 2022, the CDRH was receiving more than 100 emergency use authorization requests per month and expected more than 1,000 in-vitro diagnostics (IVD) pre-EUA and EUA submissions for the year. ...

Nonetheless, there are indications the CDRH will move back to some sense of normalcy.

In January, the center began accepting pre-submissions requesting feedback for in-vitro diagnostics that require a premarket approval application or De Novo filing, ending a multi-month hiatus with hopes of accepting all IVD pre-submission requests by the late spring or early summer.

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However, the FDA said the reviews may take longer than usual, with the goal of transitioning "toward normal [Medical Device User Fee Amendments (MDUFA)] timelines during the course of 2022." The CDRH is more optimistic on non-IVD medical devices, which it expects to "transition back to most of the MDUFA review timeframes" in 2022.

The new year got off to a shaky start with the omicron surge and the FDA failing to send the final MDUFA V agreement to Congress by the Jan. 15 deadline. The missed deadline follows months of talks that signaled the agency and industry were at odds over critical elements of the MDUFA program.

Another area of uncertainty is whether former FDA head Robert Califf, President Joe Biden's nominee, will be confirmed by the Senate and return to the agency as its commissioner. *Bloomberg* reported last week that Califf's confirmation is being "stymied by Democratic skepticism of the longtime cardiologist's regulatory track record and a new GOP push to kill his nomination."

Here's what to expect in 2022 as the FDA grapples with both pandemic and non-COVID-19 workloads. ...

CDS, post-pandemic guidance

The FDA in October released its list of proposed draft and final medical device guidance documents for fiscal year 2022. The list is heavy on documents related to software, including the long-awaited final guidance on clinical decision support (CDS) software.

The CDS document has been five years in the making, with the first draft version released by the agency in 2017 and a revised draft in 2019. It outlines how the FDA will regulate software tools, such as sepsis alerts, which are reviewed by clinicians. The FDA's second draft was better received by the medtech industry for taking a risk-based approach after the first draft drew a multitude of complaints.

"With regard to decision support, I anticipate that FDA will come out with its final CDS guidance in the not-too-distant future," said Bradley Merrill Thompson, an attorney at Epstein Becker Green. "I hope it will be different from the proposal, but we shall see. They have been overreaching in trying to discourage CDS that addresses higher risk diseases and conditions."