Bradley Merrill Thompson Quoted in “FDA Talks Takeaways from Software Precert Pilot”

POLITICO

September 27, 2022 | Media Coverage

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 *POLITICO,* in “Pfizer, Moderna Seek Omicron Booster EUAs for Kids: FDA Talks Takeaways from Software Precert Pilot,” by Lauren Gardner, David Lim, and Katherine Ellen Foley.

Following is an excerpt:

The FDA’s existing statutory and regulatory authorities limited its ability to implement a pilot program to explore whether a precertification program for manufacturers could provide a more agile regulatory environment for software as a medical device, the agency said in a new paper published Monday.

“FDA found that further development is needed before being able to identify low-risk devices where an organizational appraisal alone could be relied upon without further premarket review of the device,” the FDA white paper says. “In particular, FDA found that organizational appraisals would not be sufficient to take the place of device-specific clinical performance reviews and cybersecurity reviews for all moderate-risk devices.”

Brendan O'Leary, acting director of the FDA Digital Health Center of Excellence, wrote in a LinkedIn post that the pilot program was “an important first step towards identifying regulatory approaches to software that can better promote and protect public health.” The agency said that new authorities from Congress to overhaul the medical device regulatory framework could help supplement, but not replace, existing pathways.

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But some industry experts argue the pilot demonstrated that few devices could be exempted from premarket review if a similar precertification program was established.

“The system that they were proposing really revolved around a lot of trust,” said Bradley Merrill Thompson, an attorney at Epstein Becker & Green. “As the leadership of CDRH talked more with the rank and file and the review divisions, I think the rank and file said, ‘What are you talking about, we need to see the data for those types of submissions, just knowing that a company has a good culture does not give us comfort that this product is going to be safe and effective.’”