Bradley Merrill Thompson Quoted in “FDA Acknowledges Shortcomings of Pre-Cert Pilot in Report”

RAPS Regulatory Focus

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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 *RAPS Regulatory Focus,* in “FDA Acknowledges Shortcomings of Pre-Cert Pilot in Report,” by Ferdous Al-Faruque.

Following is an excerpt:

The US Food and Drug Administration (FDA) said it needs additional Congressional authority to move forward with its digital health precertification (Pre-Cert) program. While the idea has been widely lauded by various stakeholders, at least one expert said he feels vindicated for warning the agency early on that it lacked the legal authority to fully implement pathway. ...

While FDA said its Digital Health Center of Excellence inside the Center for Devices and Radiological Health (CDRH) will continue to develop policies and tools within current authorities to efficiently get digital health products to market, it does not delve into what additional authorities it needs to make its vision of the Pre-Cert program a reality.

Unlike traditional medtech products, digital health products such as those with software need to be able to update themselves quickly and continuously to stay relevant. With this challenge in mind, the FDA proposed the Pre-Cert program and a potential new pathway for digital health which was received very optimistically by many experts and industry stakeholders. Bradley

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Merrill Thompson, an attorney at Epstein, Becker and Green, is skeptical of the idea.

Thompson said when he first read the September report, he felt a sense of relief as it seemed to validate much of what he's been warning FDA for years.

"I've been trying to suggest to FDA that the Pre-Cert program as they currently designed it has some flaws in it and the fact that they concluded that it really needs to go to Congress to be developed, to me is very encouraging," he told *Focus*.

Though it seems clear now that the Pre-Cert program as initially envisioned by FDA was not feasible, Thompson said he thinks the agency was driven to create a good manufacturing practice (GMP) regulation for digital health "on steroids" because it wants to understand the quality of such products beyond what testing the product can show and ensure companies have a culture of quality.

He said it's also evident that FDA wants more authority to request postmarket data on products to ensure companies use a total product lifecycle (TPLC) approach to their software that includes gathering real-world data (RWD), and they want more transparency about how companies do their business so they can hold them publicly accountable.

"I think they frankly believe that there's more than one way to regulate," said Thompson. "One way is for a regulator to enforce, another way is for a regulator to embarrass. I think they want to be able to take a lot of that data and use it as leverage to actually show the public that data in order to get companies to change their way."

Thompson said that while something like the Pre-Cert program needs to be developed, FDA's approach was too narrow. He said he hopes that if the matter is brought up before Congress, lawmakers will be able to take a broader approach to the development of a new pathway for digital health products.

The Pre-Cert program relies on excellence appraisals of manufacturers that FDA can use to decide if the sponsor of a product has the right corporate culture and safeguards in place to ensure their products are safe and effective. This means new sponsors entering the medtech sector are more likely to be disadvantaged compared to more established companies that can provide significant data to back up such appraisals.

Thompson said that he usually represents more established companies, and many of his clients

have been in the medtech sector for decades. However, he said that newer companies, such as startups that come out of academia or someone's garage, are essential to the medtech ecosystem.

Beyond additional Congressional authority, Thompson said FDA may already have some authorities to allow it to get certain software products to market. In particular, he pointed to the agencies 2019 white paper on change protocols for artificial intelligence/ machine learning (AI/ML) products.

That paper argued that FDA could allow AI/ML products that can automatically update over time on the market if sponsors presented a well-understood protocol for how a product's algorithm can change, and the protocols put in place to test those changes to ensure the product maintains a significant level of safety and efficacy.

"That model I think is rather good and I think a lot of that regulatory model can be used right now with existing statutory authorities," said Thompson. "In fact, FDA has made no secret that they have on several occasions already approved products on that basis and they're coming out with a guidance document at some point."

"Could we also improve on the [current] statute? Sure," he added. "But I really think there's a lot of stuff we can do while we're waiting for Congress to get around to taking a close look at this."

In 2019, CDRH Director Jeff Shuren also pitched the idea of asking Congress for broader regulatory authorities to stay up to date with the evolving medtech landscape in a framework that he called "Regulatory Legos." While the agency isn't specific about the kind of regulatory authority it needs to make the Pre-Cert program a reality, Thompson worries that the agency might be looking for that type of framework.

"That's the flavor I get from the report and that scares the crap out of me," Thompson said. "He's basically asking for not just more power, but unbridled power, more discretion on the part of the agency."

Ultimately, Thompson said that FDA has wasted time and resources over the past few years developing a program that they should have known from the beginning wasn't feasible based on the authorities they had. He also blames the medtech industry for cheering on the agency and for not being more critical about what it could accomplish.