Bradley Merrill Thompson Quoted in “FDA Draft Guidance Allows AI/ML Devices to Evolve Without Requiring New Submissions”

RAPS Regulatory Focus

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Bradley Merrill Thompson, Strategic Advisor with EBG Advisors and Member of the Firm at Epstein Becker Green, was quoted in *RAPS Regulatory Focus,* in “FDA Draft Guidance Allows AI/ML Devices to Evolve Without Requiring New Submissions,” by Ferdous Al-Faruque.

Following is an excerpt:

The US Food and Drug Administration (FDA) published a draft guidance outlining how sponsors of artificial intelligence and machine learning (AI/ML) products can submit predetermined change control plans (PCCP) in their product applications. It has been a priority for industry, which successfully lobbied for the issue as part of last year’s omnibus spending bill.

The draft guidance outlines what the agency needs from AI/ML device sponsors to ensure their change control protocols are safe and well-understood. If approved, manufacturers can update their product without the need to submit a new application or supplement.

While the agency has already allowed more than 500 AI/ML products on the market, many of which already allow PCCP, Congress passed legislation as part of the 2023 Consolidated Appropriations Act that gave FDA explicit authority to approve PCCPs as part of AI/ML product applications. …

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who has often been critical of the FDA's work on digital health technologies such as AI/ML agreed. He said the draft guidance will encourage innovation and get new medical technologies to market sooner.

"Even though this is only a draft guidance, I would note that companies are already submitting change control plans and should start to follow this guidance immediately," he told *Focus*. "Going forward, for developers of machine learning driven medical devices, it will be crazy not to include a PCCP section from here on."

"All machine learning driven devices will need to evolve over time, so it would be wasteful and irresponsible to not try to anticipate what those changes might be and plan for them accordingly in an initial FDA submission," he added.

While he's optimistic about the guidance, Thompson said the guidance "hugely increases" the burden on AI/ML developers to plan ahead, as the agency is asking for a lot of details. He said that drafting PCCP in product applications needs to take into consideration what are the most likely changes that will result from the plans, how those changes will be managed and then tested.

Thompson also noted that the guidance asks for "an enormous amount of documentation" on what changes happen and how they affect the product.

"Essentially, they will have to periodically write what amount to [new product submissions,] but they just don't have to file them with FDA," said Thompson. "All that documentation needs to be in their files should FDA come to inspect."
A key issue for AI/ML technology has been that the data used to train the products often have inherent biases toward certain minority demographics as they are often underrepresented in clinical research. Representation in medical research has been a priority, especially for the Biden administration, and is addressed in the draft guidance. ...
Thompson agreed, saying that from his reading of the guidance, "it's apparent that FDA is giving a lot of thought to bias and transparency these days. They are significant themes, and FDA wants to see them addressed."

Thompson also noted that based on the level of detail and high expectations FDA has set in the guidance, he expects the agency to see a significant increase in product submissions. On the other hand, he argued that regulators are proposing to only allow "fairly modest" changes that do not change the intended use or indication of the device.

"They also constrained obviously that if it's in the context of a premarket notification, the changes

themselves have to be within the realm of substantially equivalent to the predicate," said Thompson. "Given that the changes need to be identified with significant specificity, this is not going to result in significantly evolving products. It just reduces the number of submissions for more minor, anticipatable changes."

Overall, Thompson said he's excited about the guidance because it allows AI/ML products to evolve and significantly increases the kinds of changes they can undergo without sponsors having to file multiple product applications every time there is a change.

"Technically FDA will permit automatic evolution in the anticipated direction, but I get the sense that the bar will be higher for anything that doesn't involve manual decision-making by the developer," he added.