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Bradley Merrill Thompson Quoted in "One Small Step for US FDA, but Maybe a Giant Leap for SaMDs"

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Bradley Merrill Thompson, Member of the Firm in the Health Care & Life Sciences practice, in the firm's Washington, DC, office, was quoted in *Medtech Insight Pharma Intelligence,* in "One Small Step for US FDA, but Maybe a Giant Leap for SaMDs," by Ferdous Al-Faruque. *(Read the full version – subscription required.)*

Following is an excerpt:

"What I find interesting is that FDA's description of how it conducted this retrospective testing is basically to take the same information that has historically been submitted, and repackage it for review under the Precertification Program," said Bradley Merrill Thompson, an attorney at Epstein Becker & Green who works with digital health and device firms, and combination drug-device product-makers.

"That suggests that there's really fundamentally nothing different about pre-cert: It's looking at the same information, only packaged differently and reviewed over three different reviews - the Excellence Appraisal, the Review Pathway Determination and the Streamlined Review - with the added feature that real-world performance will also be evaluated in the future," Thompson said.

He says the bottom line is the latest update still doesn't answer a number of key questions about the program, such as will it provide the same level of assurance in a product's safety and

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efficacy that the agency currently requires, will it be faster than going through the traditional pathways, will it be less burdensome, and will it be equitable to all companies so as not to create unfair advantages.

Thompson is also concerned the agency's analysis of the pre-cert program is not very scientific because the pool of participants in the pre-cert pilot program is only limited to nine companies and the number of mock reviews they have conducted so far is very limited.

"There certainly is no suggestion that the number of reviews they are doing will be statistically significant or that they are taking other measures to assure the integrity of the data, such as random sampling and blinding," he added. "It all seems very anecdotal and, in a statistical sense, biased."

However, the greatest concern for Thompson is whether the pre-cert program will create unfair advantages for certain companies.

"The process has to be fair, and so far, there are just simply too many ways it would appear that some can manipulate the process to their advantage," he said. "Part of this is interjecting a whole new level of subjectivity in the review process, beyond the scientific questions of safety and effectiveness, to the questions of organizational competence embedded in the Excellence Appraisal."