Bradley Merrill Thompson Quoted in “FDA Regulation of AI Complicated by Hospital’s Use of In-House Algorithms”

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Bradley Merrill Thompson, Strategic Advisor with EBG Advisors and Member of the Firm at Epstein Becker Green, was quoted in *BioWorld,* in “FDA Regulation of AI Complicated by Hospital’s Use of In-House Algorithms,” by Mark McCarty.

Following is an excerpt:

The authors of a recent journal article see problems with the FDA’s approach to premarket review of artificial intelligence (AI) algorithms, including an undue reliance on single-site algorithm development. Regulatory attorney Brad Thompson told *BioWorld*, however, that hospital administrators want algorithms that maximize accuracy for their populations and are not averse to in-house development of just such an algorithm, thus creating a source of tension between what hospitals want and what the FDA expects. ...

Thompson, an attorney at the D.C. office of Epstein, Becker & Green P.C., said U.S.-based developers know most of the world employs a four-tier risk system, but noted that the authors have a good reason for using the four tiers under the software 510(k) changes guidance. “An algorithm is most likely to be improved two weeks or so after the first iteration,” Thompson said, which complicates matters for developers due to the prospect that they will have to file a new 510(k) for that algorithm after only one or two months on the market.

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Thompson also confirmed that "all the issues raised [in the paper] are issues the FDA is well aware of, and in fact is working on." Consequently, the impact of the paper is more likely to be on the users of these algorithms than the FDA. Administrators at hospitals and other clinical sites need to be aware of the limitations of these products, but these administrators – and the doctors at the clinical site – want a high degree of sensitivity and specificity for the patients seen at their institution, not at a clinical site on the other side of the country.

The problem for the FDA is that this dynamic creates an incentive to develop a location-specific product while the agency's regulatory framework is unavoidably a national framework. Thompson said that while he does not have a window into what hospital systems are doing in terms of hires for in-house IT staff, he is under the impression that at least some hospital systems are indeed staffed to handle development of such an algorithm.

Resources still an issue where inspections concerned

"It's a conundrum for the FDA," Thompson said, because the agency is not staffed to conduct inspections of hospital IT departments. He also pointed out that the FDA's medical device data systems guidance exempts these in-house developments if they are for in-house use only. One of the associated problems is that the line between an exempt and non-exempt system is not always clear, but Thompson said the FDA currently seems to lack the appetite to dive back into the question of hospital IT regulation.

The FDA has been making the point about using multiple sites to validate an algorithm for some time, but Thompson said the agency has been a little more vocal about this of late. Some of these products are marketed internationally, so at times there is the question of not just the number of sites in total, but the number of sites located in the U.S.

However, Thompson said the FDA has not offered a particularly helpful set of guidelines for what constitutes a sufficient level of demographic diversity in these training and validation sets despite that this question is front and center for the agency. "It's tough to know when you've achieved enough diversity to satisfy the FDA," he said, adding that developers believe that it is time for the FDA to offer written guidance on the question.