

Bradley Merrill Thompson Quoted in “A ‘Disaster,’ or a ‘Clear Path’ Forward?: New FDA Guidance on AI in Medicine Sparks Strong Reactions”

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Bradley Merrill Thompson, Strategic Advisor with EBG Advisors and Member of the Firm at Epstein Becker Green, was quoted in *STAT*, in “A ‘Disaster,’ or a ‘Clear Path’ Forward?: New FDA Guidance on AI in Medicine Sparks Strong Reactions,” by Casey Ross. *(Read the full version – subscription required.)*

Following is an excerpt:

New guidance from the Food and Drug Administration is triggering strong reaction from researchers and regulatory experts, who see it as an attempt to significantly expand the oversight of software tools used to guide clinical decisions. But they are sharply divided on whether that’s a much-needed change, or a dramatic overreach by regulators.

One medical device lawyer that the document “violates” the 21st Century Cures Act passed by Congress in 2016 to exempt certain software products from regulatory review. The FDA’s guidance, meant to clarify how it will enforce the law, indicates that the agency intends to review some products, such as sepsis alerts, that it has ignored for years.

People



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