

James Boiani, Bradley Merrill Thompson Quoted in “And Over at FDA ...”

Axios

January 18, 2023 | Media Coverage

James A. Boiani and **Bradley Merrill Thompson**, Strategic Advisors with EBG Advisors and Members of the Firm at Epstein Becker Green, were quoted in *Axios*, in “And Over at FDA ...” by Maya Goldman. (*Read the full version - subscription required.*)

Following is an excerpt:

Diagnostic Testing Oversight:

The “VALID Act” didn’t make it into the recent omnibus, but FDA could try to increase oversight of lab-developed tests on its own, said James Boiani, a partner at law firm Epstein Becker Green.

FDA proposed a framework for this in 2014. If the agency moves toward lab test oversight again, legal action is likely, Boiani added.

“There’s no guarantee the courts necessarily agree with [FDA], especially now given the history of congressional work on looking at giving FDA explicit authority and not doing it,” he said.

Artificial intelligence:

FDA lawyers also wonder whether the agency will move forward with final guidance on how to handle premarket submissions for medical products that use AI.

“One of the parts of artificial intelligence that makes it hard to regulate is that... it constantly learns from what it does, and the FDA model doesn’t really account for that,” said Bradley Thompson, an FDA lawyer at Epstein Becker Green.

People



James A. Boiani
Strategic Advisor
Health Services & Technology
202-861-1891
jboiani@ebglaw.com



Bradley Merrill Thompson
Strategic Advisor
Artificial Intelligence
202-861-1817
bthompson@ebglaw.com

Focus Areas

Services

Health Care Compliance