

# Bradley Merrill Thompson Quoted in “Torres Says Regulatory Alignment a Pressing Consideration for AI Change Control Draft”

*BioWorld*

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**Bradley Merrill Thompson**, Strategic Advisor with EBG Advisors and Member of the Firm in the Health Care & Life Sciences practice at Epstein Becker Green, was quoted in *BioWorld*, in “Torres Says Regulatory Alignment a Pressing Consideration for AI Change Control Draft,” by Mark McCarty. *(Read the full version – subscription required.)*

Following is an excerpt:

The U.S. FDA recently released its guidance agenda for fiscal 2023, a plan that de-emphasizes the oft-promised draft guidance for change control for artificial intelligence (AI) algorithms, which is listed as a B priority instead of an A draft guidance priority. At this year’s Medtech Conference here in Boston, the FDA’s Melissa Torres disavowed the notion that any national regulatory authority is delaying another authority’s policy on software change control, but she acknowledged that these conversations about regulatory harmonization typically predate formal policy development. ...

Brad Thompson, of Epstein Becker & Green P.C., said he was disappointed that the FDA had relegated the change control draft to a secondary priority, stating that the agency had previously indicated that this draft guidance was a high priority. “We desperately need a new approach to regulating AI as a medical device,” Thompson said, adding that he was similarly disappointed that the FDA had applied resources to its failed software pre-certification program when those resources might have been better applied toward development of a software

## People



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

## Focus Areas

### Services

Artificial Intelligence  
Health Services & Technology  
Life Sciences

change control policy.