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Bradley Merrill Thompson Quoted in "Medical Device Experts Criticize FDA's Clinical Decision Support Draft Guide"

FDA Week

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Bradley Merrill Thompson, a Member of the Firm in the Health Care and Life Sciences practice, in the firm's Washington, DC, office, was quoted in *FDA Week,* in "Medical Device Experts Criticize FDA's Clinical Decision Support Draft Guide," by Beth Wang. *(Read the full version – subscription required.)*

Following is an excerpt:

Legal experts representing the clinical decision support (CDS) software industry take strong issue with FDA's draft guidance on CDS software, published Dec. 7. The experts complain that FDA's guidance doesn't adopt a risk-based enforcement approach, fails to provide meaningful examples and explanations of regulated and unregulated software, and is unclear when it comes to the criteria for determining when CDS will be regulated. ...

Bradley Merrill Thompson, member of law firm Epstein Becker & Green, said that he was "pretty excited" about the guidance and "prepared to praise it" but that he cannot, as it lacks useful information. He added that FDA "seems to have walked away from making a risk-based determination." Thompson also serves as general counsel for the CDS Coalition, but underscores that all of the comments are his own and not the coalition's.

"What I think many of us in industry were hoping for was an effort by FDA to distinguish high from low risk as a basis for regulation. We didn't get that. Worse, it appears based on the guidance that FDA is not interested in drawing that line,"

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Thompson wrote in an email.

Thompson criticized the agency for only mentioning enforcement for low-risk professional use software in reference to its 2015 “Mobile Medical Applications” (MMA) guidance, which provides a list of mobile apps that allow clinicians to perform simple medical calculations in clinical practice.

“The only place that FDA even references applying enforcement discretion for low risk professional use software is in lines 332 three 340 where the agency makes a cryptic reference to enforcement discretion previously applied in the mobile medical app guidance,” Thompson said.