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Bradley Merrill Thompson Quoted in "Combo Product Safety: US FDA Rule on Post-Market Reporting Nears Finalization"

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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 *Medtech Insight,* in "Combo Product Safety: US FDA Rule on Post-Market Reporting Nears Finalization," by Michael Cipriano. *(Read the full version – subscription required).*

Following is an excerpt:

Industry, however, has been eagerly waiting for the proposed rule to become finalized, as development of combination products has grown significantly in recent years. Brad Thompson, attorney with Epstein Becker & Green and general counsel to the industry Combination Products Coalition, tells *Medtech Insight* that the final rule has been "languishing for quite some time." Industry is awaiting guidance on the topic of adverse event reporting for combo products, but, Thompson says, FDA has to finish the rule before it can work on a guidance.

"The guidance is really indispensable because there's a level of detail that we need that just isn't [in the rule]," he said. "The final rule isn't out and hasn't been out for quite some time. It's just very frustrating, the pace at which things go. Good intentions on the part of FDA; just they're not executing it," Thompson said

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Thompson added that the delay to finalizing the rule was likely initially related to retooling the IT systems at the agency, but now it appears to more a matter of inattention.

“It’s just FDA has go so many rules and so few resources, that it’s just been sitting in the queue,” Thompson said. "My understanding is it’s as simple as that. It just hasn’t been moved forward.”