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Bradley Merrill Thompson Quoted in "FDA Ignores Advamed Requests in Final RWE Device Guidance"

FDA Week

September 8, 2017 | Media Coverage

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 "FDA Ignores Advamed Requests in Final RWE Device Guidance," by David Lim.

Following is an excerpt:

FDA's recently finalized guidance on real-world evidence appears to have not heeded calls from the device industry to provide additional examples of how RWE applies to class II medical devices and in vitro diagnostic devices. ...

"I think at least some people wanted a sort of a cookie-cutter approach, with the guidance laying out very specifically what sponsors could accomplish with real-world data from a regulatory decision standpoint. But I'm sympathetic with FDA, because as I think about the incredible variety of uses of RWD, there's just no way to cover that variety in a single guidance document. Further, frankly it's early in our experience with RWD to fully appreciate all of the nuances of the use of that data in regulatory decision-making. I actually think FDA has done a relatively good job of laying out a very broad and admittedly high level framework for analyzing data. What impresses me is FDA's apparent open-mindedness about the wide variety of uses of RWD," Brad Thompson, attorney at Epstein, Becker & Green, told *IHP.*

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