EPSTEIN BECKER GREEN

Bradley Merrill Thompson Quoted in Article, "Bill Provides Guidance on FDA Mobile Medical Apps Regulation"

FierceMobileHealth

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Bradley Merrill Thompson, a Member of the Firm in the Health Care and Life Sciences practice, in the Washington, DC, office, was quoted in an article titled "Bill Provides Guidance on FDA Mobile Medical Apps Regulation."

Following is an excerpt:

A bipartisan group of House members—three Democrats and three Republicans—has introduced a bill to "provide regulatory clarity regarding mobile medical applications, clinical decision support, electronic health records and other healthcare related software," according to an announcement.

The Sensible Oversight for Technology which Advances Regulatory Efficiency (SOFTWARE) Act seeks to amend Section 201 of the Federal Food, Drug, and Cosmetic Act to regulate medical software and to provide guidance to the FDA about mobile medical app regulations. ?...

Earlier this year, Congresswoman Blackburn drafted a similar bill to amend Section 201 of the Federal Food, Drug and Cosmetic Act. However, after reviewing the proposed legislation, the mHealth Regulatory Coalition (MRC) raised questions about the proposed approach and the use of new terminology in the draft.

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Blackburn's earlier proposed bill included language that created a new category of "medical health technology," a definition that referred to both hardware and software. "We believe that these terms are too generic to meaningfully distinguish 'medical health technology' from traditional medical devices," wrote Bradley Merrill Thompson, the MRC's general counsel, in a July 12 letter to Blackburn.

"A pacemaker is hardware, and software includes firmware that resides in the pacemaker. It would not be logical for a pacemaker or firmware within a pacemaker to now be reclassified as 'medical health technology.'"