EPSTEIN BECKER GREEN

James Boiani Quoted in "Lawyers: FDA's CLIA Waiver Guidances Give Industry More Flexibility"

InsideHealthPolicy

December 10, 2018 | Media Coverage

James A. Boiani, Member of the Firm in the Health Care & Life Sciences practice, in the firm's Washington, DC, office, was quoted in *InsideHealthPolicy,* in "Lawyers: FDA's CLIA Waiver Guidances Give Industry More Flexibility."

Following is an excerpt:

When Congress passed 21st Century Cures in 2016, it required FDA to update its 2008 guidance on CLIA waiver application in in vitro diagnostic device manufacturers, specifically the section of the guidance that covers how to demonstrate insignificant risk of an erroneous result. Cures required FDA to update the guidance to say that tests would be considered accurate foe CLIA waiver purposes "if the result by trained and untrained users are comparable" the act says.

James Boiani, a member of the firm at Epstein Becker Green, told Inside Health Policy that the 2017 guidances focused on gauging test accuracy, rather than on assessing the comparison of results between trained and untrained users as Congress intended.

"Congress has said that if a diagnostic test allows trained and untrained users to get comparable results, and the test is simple, it is entitled to a waiver," Boiani wrote in comments he submitted to FDA in March as general counsel to the Coalition for CLIA Waiver Reform. "FDA's guidance needs to reflect Congress's intent, and recognize—as Congress has—the value of expanded access to new and innovative CLIAwaived tests."

People

James A. Boiani
Member of the Firm
Regulatory Strategy, Product Development, and Product Approvals
Washington, DC
202-861-1891
jboiani@ebglaw.com

Focus Areas

Services

Regulatory Strategy, Product Development, and Product Approvals

Industries

Health Care Industry