

Bradley Merrill Thompson Quoted in “FDA Ends Pre-Cert but Could Revisit in the Future, with Congress’ Help”

Inside Health Policy

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Bradley Merrill Thompson, Strategic Advisor with EBG Advisors and Member of the Firm in the Health Care & Life Sciences practice at Epstein Becker Green, was quoted in *Inside Health Policy*, in “FDA Ends Pre-Cert but Could Revisit in the Future, with Congress’ Help,” by Kelly Lienhard. (*Read the full version – subscription required.*)

Following is an excerpt:

FDA recently decided to end its device software precertification pilot program and hand development over to the Medical Device Innovation Consortium, saying it needs additional authority from Congress to implement the program as envisioned, but it may not be the end of the road for the initiative. One former FDA official believes the agency may eventually try to revisit the pre-cert program, though he acknowledged it could take years, especially as Congress would need to sign off. ...

The shift from FDA to MDIC will raise scientific and policy questions, Brad Thompson, a member of the firm at Epstein Becker & Green, told *IHP*. Thompson specifically is concerned that MDIC’s research will mirror FDA’s priorities and focus solely on safety and efficacy concerns, while overlooking other public policy issues, such as the program’s potential impact on innovation.

For example, the pre-cert program as run by FDA favored larger companies since bigger companies can invest more money in

People



Bradley Merrill Thompson
Strategic Advisor
Artificial Intelligence
202-861-1817
bthompson@ebglaw.com

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developing systems that allow them to push products to market quickly, Thompson said.

"A start up by some university researchers would never have those resources and would therefore not benefit from [the pre-certification program]," Thompson stated. "That puts them at a competitive disadvantage in bringing products to market and can inhibit innovation."

MDIC does have the ability to shift pre-cert's focus from larger companies to smaller device manufacturers, but Thompson said it is hard to know what MDIC will focus on.

"There's a lot to work out," Thompson said. "I fear the only thing they're really focused on is the scientific equivalents, when these other issues also deserve attention."