

Commentary: Digital Health Companies Should Stay Away from FDA in 2021

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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, authored an article in *MobiHealthNews*, titled “Commentary: Digital Health Companies Should Stay Away from FDA in 2021.”

Following is an excerpt:

It’s been quite a year: COVID-19, a change in administration and a year of transition for FDA digital health policy. In light of all the change and uncertainty, many digital health companies are struggling to decide upon a regulatory strategy for 2021.

My advice? If at all possible, stay away from FDA. They have enough to do right now. The people I know at FDA have been working 12- and 15-hour days most of the year. They’ve been doing incredible work, both on the review side and the policy side, when it comes to COVID-19. In fact, if you haven’t already done so, I would recommend that you send anyone you know at FDA a holiday card. And thank them for their service.

But back to business. You need to stay away from FDA if you can. We need to confront reality. Here are three reasons why you should try to stay away. ...

People



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