

Disruptor Meets Regulator, and Regulator Wins: Lessons Learned from Theranos

Although Theranos's history – which includes several administrative penalties for the troubled blood-testing company – has received an outsize amount of media attention, its experience with regulatory agencies highlights several important issues for start-up and emerging health care entities, writes **Robert E. Wanerman** in **Epstein Becker & Green's Health Law Advisor** blog.

He discusses four major questions raised in this type of case, with these headings: What Do Regulators Want?, What Do Health Care Providers and Payors Want?, Who Is Investing in the Venture?, and Who's on Board?

On the first point, he wrote that “even in an environment that encourages innovation, health care organizations must understand the scope of regulatory oversight at the federal and state levels, and the range of remedies available to regulators for noncompliance. Every organization should also have a protocol in place for responding to regulatory inquiries or inspections.”

Read the article.