

Health Law Vitals - A Healthcare Newsletter from Haynes and Boone, April 2019

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PRACTICES OSHA, Healthcare Transactions and Regulatory, ERISA and Other Benefits Litigation, False Claims Act and Qui Tam Defense, FDA Regulatory and Compliance, Healthcare and Life Sciences, Labor and Employment

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Fiduciary Duties of Directors in the Medical Technology Industry

Theranos Inc., a former biotech company in Silicon Valley, and the source of significant media coverage since 2015, presents a unique case study for members of the boards of directors of corporations in the medical technology industry. According to allegations by the [SEC](#) and the [DOJ](#), Theranos, Elizabeth Holmes (its founder and CEO) and Ramesh “Sunny” Balwani (its COO): (1) defrauded investors, doctors and patients by leading them to believe that Theranos’ key product could conduct comprehensive blood tests from small drops of blood (in actuality, Theranos’ device produced inaccurate results and could only complete a small number of tests and, to keep this fact from its investors and the general public, Theranos, as it is alleged, conducted the majority of its tests on commercially available and/or modified analyzers manufactured by unrelated third parties), and (2) overstated and made false statements about Theranos’ business and financial performance to investors and customers.

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Telehealth Promises and Pitfalls: Remote Prescribing of Controlled Substances, the SUPPORT Act, and Remaining Risks

The healthcare industry is in the midst of a historic transformation, as the ongoing proliferation of technological advancements continues to improve the quality of medical care, increasing patient access, and revolutionizing the practice of medicine in the United States. In the context of telemedicine, more specifically in relation to remote prescribing of controlled substances, the ability to capitalize on innovation has, thus far, been stifled in certain respects by the Ryan Haight Online Consumer Protection Act of 2008 (“Haight Act”). However, more recently, the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (“SUPPORT Act”) was signed into law with the promise to reduce the obstacles imposed by the Haight Act and better equip the medical community to fight the opioid epidemic. While the SUPPORT Act will likely give providers more flexibility in prescribing controlled substances via telemedicine, it is important to understand the regulatory barriers and risks that remain.

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The FDA Expands the Abbreviated 510(k) Pathway (aka, the “Safety and Performance Based Pathway”)

On January 22, FDA Commissioner Scott Gottlieb announced the FDA’s latest steps to strengthen the FDA’s 510(k) program for premarket review of medical devices. As part of this initiative, the FDA finalized its framework for the Safety and Performance Based Pathway by finalizing a draft

guidance formerly known as “Expansion of the Abbreviated 510(k) Program: Demonstrating Substantial Equivalence through Performance Criteria.”

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***Peterson v. UnitedHealth*: Cross-Plan Offsetting May Draw ERISA Litigation**

In an opinion issued by the Eighth Circuit on a matter of first-impression, the court in *Peterson v. UnitedHealth Group Inc.* left insurers rushing to revise plan documents to preserve their ability to offset overpayments on one plan by withholding payments on another.

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FDA Announces Plan to Increase Oversight of Dietary Supplements

The FDA’s recent [statement](#) unveiling its goal to implement “one of the most significant modernizations of dietary supplement regulation and oversight in more than 25 years” (the “Statement”) emphasizes FDA Commissioner Scott Gottlieb’s continued focus on enforcement against unlawful activities – including product promotions and advertising – that create substantial public health risk.

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Employers May Be Cited for Workplace Violence Incidents as Violation of OSHA’s General Duty Standard

The Occupational Safety and Health Act does not contain a specific standard governing workplace violence. But on March 4, 2019, in *Secretary of Labor v. Integra Health Mgmt., Inc.*, a case of first impression, the Occupational Safety and Health Review Commission held that the Act’s general duty standard obligates employers to protect their employees from workplace violence.

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