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Government Investigations & White Collar Alert

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The rise and fall of Elizabeth Holmes and Theranos: Lessons learned

By Hannah Bornstein and Brian K. French

Key takeaways that the business and legal world can glean from the Theranos saga and Ms. Holmes' 11-year sentence.



What's the Impact?

- / Questionable business practices, toxic company cultures, and reckless pursuit of profit can quickly turn a promising business into a cautionary tale
- / Protect your company and its investors by ensuring regulatory compliance and encouraging open internal communication

Much has been written about the rise and fall of Elizabeth Holmes and Theranos, starting with John Carreyrou's groundbreaking *Wall Street Journal* reporting, followed by his bestselling book *Bad Blood: Secrets and Lies in a Silicon Valley Startup*. Much has been discussed about Elizabeth Holmes and Theranos, including in the podcast *The Dropout*. And much has been depicted on screen, including documentaries and series that can be streamed on a variety of channels, including Hulu and AppleTV.

How a promise led to prison

Many believed that Theranos' technology had the potential to revolutionize healthcare: just one drop of blood, taken through a finger prick rather than an intra-venous blood draw, would be run through a small, sleek machine that could perform hundreds of diagnostic tests on a minute blood sample. The product, had it worked, promised to disrupt the blood-testing industry, provide early detection for a number of diseases, and significantly reduce the costs associated with blood work and lab analyses.

What was an exciting vision was marketed as an actual, working product. But in reality, Theranos rushed from the R&D phase to commercialization well before its device was ready. Ultimately, the promise of Theranos' product never came to fruition, an outcome revealed over time as patients and doctors reported faulty test results for acute medical conditions and journalists uncovered that Theranos had secretly used other third-party devices to perform tests that its own product could not achieve.

One can spend many fascinating hours reading the detail, hearing the voices, and watching the storylines underpinning this story: how Theranos became the Silicon Valley unicorn company that promised innovation and disruption to blood-testing technology, disease screening, and healthcare affordability; how a young Stanford dropout rose to stardom and graced primetime news shows and magazine covers; how internal whistleblowers navigated a harsh, unforgiving corporate culture to ultimately report Theranos practices to the United States government; how Theranos unraveled through government inspection and investigation; and how the government indicted Elizabeth Holmes and Sunny Balwani, Holmes's former partner and former Theranos president and chief operating officer, and tried them in a court of law, with the undercurrent of Holmes' and Balwani's personal relationship lurking in court filings, witness testimony, and news reports.

While the Elizabeth Holmes and Theranos story is extreme and does not mirror the arc of most corporate journeys, the story has important lessons and takeaways from which business leaders and professionals in all fields and industries can learn.

A complex regulatory regime does not excuse or mitigate fraud

The life sciences industry is a highly regulated space, with myriad rules and regulations for companies to follow. Compliance with these rules and regulations is complex, and many regulatory and compliance questions do not have clear black-and-white answers.

Theranos appears to have proceeded to market via the FDA's so-called laboratory-developed test ("LDT") pathway, which is one of the murkiest areas of the FDA's regulation and includes a [2014 FDA draft guidance document](#), which was subsequently replaced in 2017 with an [FDA discussion paper](#) rather than a final guidance document, and followed by [further regulatory evolution during the COVID-19 pandemic](#).

Had the government brought misbranding or adulteration charges against Holmes for marketing an unapproved or defective product, defense counsel most certainly would have had a

field day introducing the LDT regulatory uncertainty in their efforts to cast reasonable doubt as to the criminality of Holmes' intent and conduct.

But the government [charged](#) Holmes with old-fashioned wire fraud and conspiracy to commit wire fraud for lying to investors and to patients. The government's charges serve as an important reminder that no matter how complex complying with voluminous FDA or other agency rules and regulations can be, the government has multiple enforcement tools in its arsenal.

The moral of the story, while not new, bears repeating: don't lie, don't engage in fraudulent activity, and don't obstruct a government investigation.

A cautionary tale of "FOMO"

Fear of missing out led investors to ignore fundamental red flags in the diligence process

Theranos investors included well-established names, and the hype around Theranos was high. But in the end, individuals and businesses that invested in Theranos lost enormous sums of money. While any investment has risks, and while we now have the benefit of hindsight, certain red flags in the Theranos story are—and were at the time—notable:

- / As mentioned in multiple reporting sources, traditional VC healthcare investors declined to invest in Theranos. Many of Theranos' big investors were high profile, wealthy investors, but they were not necessarily well-versed or expert in medical devices or lab technology. In retrospect, the lack of expert healthcare investment in Theranos was an early signal that something was not right.
- / Similarly, the Theranos board of directors had high profile members, including former United States secretaries of state, a former United States secretary of defense, a former Marine Corps four-star general, and former executives of well-known companies. However, the board was not comprised of directors with robust expertise in medical devices, clinical lab testing, or blood science. In retrospect, the lack of relevant expertise on the Theranos board reflects another signal that something was not right, and almost certainly reduced the likelihood that the hard regulatory, compliance, clinical, and product performance questions were being effectively asked at the board level.
- / Theranos had no published peer-reviewed clinical literature for its technology. In the end, all of the reporting on Theranos strongly suggests that its promised product simply did not do what it said it could do. Peer-reviewed clinical literature is typical in the medical field and helps to substantiate that others have been able to replicate the scientific results or clinical findings relating to a product or treatment.

Take a step back

Investing early in a company that has the potential to bring disruptive innovation to market and achieve high profits is a common investment ideal, but getting caught up in the excitement and hype generated by the press, the business community, and friends can blind investors to

potential hidden dangers if care is not taken in the diligence process. The diligence process does not always permit a close review of hidden lab rooms or scathing internal emails that might tell a company's true story, but taking time to step back and assess a potential investment's foundational aspects is time well spent.

Company culture matters

Toxic executive leadership is fraught with peril

One of the most striking components portrayed in the various book, podcast, and screen depictions of the Theranos story is the harsh, unforgiving culture that seems to have been pervasive through the life of the company. Anyone who dared to question Theranos practices or its technology risked their position within or employment at the company. Ultimately, internal employees concerned about Theranos practices reported the company to government agencies, which hastened the company's downward spiral.

Communication aids compliance

As a general point, company employees who are ignored after internally reporting concerns about company practices or possible patient safety issues may ultimately feel compelled to report the conduct to the government. Does a company have an independent hotline that allows for anonymous reports to be made, and are those reports investigated? Does a company's board allocate responsibilities for the compliance function, and are compliance matters routine components of board reports and discussions? Does a company's internal compliance function have independence and authority to implement necessary compliance practices? Do company executives message and instill a culture of compliance and ethics within a company such that a company's compliance commitment is not a paper-only commitment?

The answers to these questions may have important consequences to how a matter involving potential misconduct unfolds, and whether the problem can be rectified internally or if the potential problem results in government review. And if government review does come to fruition, the more a company can demonstrate a strong commitment to compliance, the more a company can advocate for the government to consider its compliance commitment in the course of resolving the matter.

Yes, Big Brother is watching

One of the "splashiest" pieces of evidence offered by the government at trial were text messages between Holmes and Balwani. The text messages contained a mix of business and personal content, including messages relating to their prior romantic relationship.

Text like the government will read every single text, emoji, and GIF you and your company's employees ever send to anyone, anywhere

Text messages, WhatsApp communications, and other ephemeral communications are increasingly becoming central to government investigations and litigation. It is possible that during an investigation, the government may contend that if one text message in a string of

messages is responsive, the entire string is responsive, no matter how far back in time the text message string goes or whether personal content is intermixed between responsive messages. The format of the production of the text messages in the Holmes matter provides [an instructive example](#).

The role that text messages can play in a government investigation or litigation cuts across all industries and is not limited to life sciences companies. The seriousness and potential impact of potential liability relating to text message communications is reflected in the SEC's [recent fine of multiple Wall Street banks for \\$1.8 billion](#) for the use of text messaging apps that the government deemed to be in violation of rules requiring storage of written communications.

The government likely will not care if a company employee uses a personal phone to conduct business communications, and may request the production of content of business-related communications regardless of the source of the data. As such, companies would be prudent to examine their internal business policies on phone and ephemeral messaging communications, and to assess the need to preserve such communications in the event of a government investigation or litigation.

While you may still want to "dance like no one is watching," we urge consideration of the precautionary measure to "text like everyone is watching."

Lessons learned

- / **Don't lose the forest for the trees:** Regulatory compliance is complex, but the big picture matters too. Government agencies have myriad enforcement tools available.
- / **Never neglect due diligence:** While early investment is exciting and has the potential to generate significant profits, failing to review your investment's foundational aspects has equal potential to undermine you in the long run.
- / **Listen to your employees:** The Theranos culture created a toxic, intimidating work environment that turned into a breeding ground for whistleblowers. Leadership should commit to open communication and compliance.
- / **It's not personal, it's strictly business:** Companies should review policies regarding employee ephemeral messaging practices.

For more information on the content of this alert, please contact your Nixon Peabody attorney or:

[Hannah Bornstein](#)

617.345.1217

hbornstein@nixonpeabody.com

[Brian K. French](#)

617.345.1258

bfrench@nixonpeabody.com
