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Theranos: How Did a \$9 Billion Health Tech Startup End Up DOA?

We see a world in which every person has access to actionable health information at the time it matters.

A world in which no one ever has to say, "if only I'd known sooner."

—ELIZABETH HOLMES, FOUNDER, THERANOS¹

A 19-year old Stanford University drop-out wanted to disrupt the traditional \$75 billion blood-testing business. People would no longer need to fear a long needle going into their arm vein to draw a vial or more of blood. Instead, Elizabeth Holmes' idea was that only one drop from a finger prick would revolutionize the process. Theranos, the name a combination of therapy and diagnosis, was founded in 2003. The tantalizing claim of the founder was to have invented a groundbreaking new technology that allowed a full range of laboratory tests from a tiny blood sample. Goodbye to the standard syringe-full of blood and established laboratory chains. Holmes promised a simple home blood test would become the model in which "we're determining the onset of disease in time for therapy to be effective—we will change outcomes."

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¹ From a presentation at TEDMED (2014): https://www.youtube.com/watch?v=sBN7esso4wY

The Silicon Valley company quickly assembled a powerful board and high-profile investors, becoming a media darling valued at \$9 billion. By 2018, federal prosecutors filed criminal charges alleging Holmes and President and CEO Ramesh "Sunny" Balwani, also Holmes' boyfriend, had defrauded investors out of hundreds of millions of dollars and mislead doctors and patients. That year, Theranos told investors it was in default and would cease operations.²

The health technology company that had created the youngest self-made female billionaire in the world³—called the next Steve Jobs thanks to Holmes' ubiquitous black turtlenecks—crashed from its unicorn status with its founders accused of massive fraud.⁴ If Theranos never made good on its blood-testing promise, how did it last 15 years? What factors silenced doubters for so long and drove high-profile investors to keep the money flowing? Could this have been prevented?

Entrepreneurship Was In Her Blood

Elizabeth Holmes grew up a bookish teenager who said she was only scared of one thing – to have blood drawn. To her, it was a disturbing "torture experiment." Her family was not well off; however, Holmes' parents moved in powerful circles and had generational wealth. They nurtured her ambitions and expected her to achieve. Her mother Noel Holmes worked in foreign policy on Capitol Hill and her father Christian worked at Enron and then for government agencies where he oversaw humanitarian efforts. The family tree included an ancestor who established the University of Cincinnati's medical school and another branch was the family of Fleischmann Yeast Company fortune.

Holmes' mother pushed her to take Mandarin Chinese which became the entree for a summer program at Stanford.⁵ In 2002, Holmes was admitted to Stanford where she chose to study chemical engineering. Barely into her sophomore year, she dropped out, filed a patent application for an arm patch that would both diagnose and treat medical conditions, and filed the paperwork to start the company that became Theranos.⁶

One of the company's first investors said Holmes' pedigree factored into his decision. Don Lucas, Jr, of Lucas Venture Group, said she possessed two qualifications to start Theranos — a family with history in both business and medicine. "Her great-grandfather was an entrepreneur, very successful. And it turned out later that the hospital near where her family lives is named after her great-uncle."

"I grew up with those stories about greatness," said Holmes about her family's conversations about entrepreneurial drive and the negative impact of not choosing a purposeful life.⁸

² http://online.wsj.com/public/resources/documents/Theranos Stockholders Letter 2018.pdf

³ https://www.forbes.com/sites/jenniferwang/2015/09/29/the-youngest-moneymakers-on-the-forbes-400-17-under-40/#c06d85a6c440

⁴ https://www.wsj.com/articles/u-s-files-criminal-charges-against-theranoss-elizabeth-holmes-ramesh-balwani-1529096005

⁵ https://www.biography.com/business-figure/elizabeth-holmes

⁶ https://www.penguinrandomhouse.com/books/549478/bad-blood-by-john-carreyrou/

⁷ https://abc.com/shows/2020/episode-guide/2019-03/15-the-dropout

⁸ https://www.newyorker.com/magazine/2014/12/15/blood-simpler

From R&D to Testing Real People

Theranos sought to disrupt the \$75 billion a year diagnostic lab testing market - a segment dominated by two main players in which testing methods had not changed much through the years. For decades, blood testing had been performed in a doctor's office to diagnose and treat common health conditions from diabetes, high cholesterol, STDs, and cancer. Holmes dreamed blood testing could be less painful, less expensive, and even done at home with a "mini lab" in a box named Edison after inventor the Thomas Edison. The mission to change outcomes plus key connections attracted the rich and famous. The board of directors included prominent men such as former Secretaries of State George Shultz and Henry Kissinger, former Secretaries of Defense Gen. James Mattis and William Perry and former U.S. Senators Bill Frist and Sam Nunn. The investors were equally high-profile: Fox News owner and media mogul Rupert Murdoch invested \$125 million, Walmart's owner the Walton family invested \$150 million, and U.S. Secretary of Education Betsy DeVos and her wealthy family invested \$100 million. Other investors included Oracle co-founder Larry Ellison and New England Patriots owner Robert Kraft.⁹

The news media shone the spotlight on Theranos placing Holmes on the cover of Forbes, Fortune, Inc., and Bloomberg Businessweek. She gave a talk at TEDMED in 2014 and was introduced by former president Bill Clinton at a panel of health care disrupters.¹⁰

In the seven years of its research and development phase, however, Theranos made numerous iterations without finding a reliable solution to deliver on its promise. Theranos claimed to be able to perform 240 tests on the Edison. Yet, several employees said only 15 were actually performed on the company's machine with the rest done on competitors' machines purchased by Theranos. On occasions when Theranos wanted to "prove" its technology to visitors such as potential investors, it pricked their finger, filled a half-inch tall nanotainer with blood, put it in the Edison, and then invented a reason to take the visitor elsewhere (an office tour perhaps). Biochemist Douglas Matje, who said the device was a "comedy of errors" which performed poorly and spilled blood, described what happened after visitors were walked out of the room containing the Edison, "Immediately afterwards, an engineer would run in, grab the cartridge and bring it out to the lab where my team would do the assays at the bench." Then the engineer would run back into the room so results were ready when the visitors were brought back in.

In 2010, Theranos moved past the R&D phase to offer testing to the public through wellness centers at Walgreen's. The contract was key to shoring up the company's financing. A Walgreen's group arrived at the company's Palo Alto headquarters for a two-day meeting. One participant was lab consultant Kevin Hunter hired by Walgreens to help evaluate the startup. During the meeting, Hunter requested to use the bathroom and was surprised when Holmes and Balwani said that anyone leaving the conference room would need to be escorted. Balwani himself escorted Hunter. The consultant's suspicions grew when Holmes and Balwani rejected his repeated requests to see the laboratory or to demonstrate a live vitamin D test. Hunter's meeting report warned that the two execs were likely "overselling or overstating" their device. Hunter continued to try to vet the technology. He recommended Walgreens embed someone to ensure the pilot launched smoothly but Theranos rejected that idea. When he learned several Walgreen executives had their blood drawn, he asked to see the results but that never happened.

⁹ https://finance.yahoo.com/news/theranos-investors-lost-millions-164453131.html

¹⁰ https://www.youtube.com/watch?v=AAlM8aGF6yo

¹¹ https://www.wsj.com/articles/theranos-has-struggled-with-blood-tests-1444881901

Also, he recommended a comparison study which never happened. Hunter confided to Walgreen executive Renaat Van den Hoof that he saw too many red flags. The executive replied, "We can't not pursue this. We can't risk a scenario where CVS has a deal with them in six months and it ends up being real."

Next, Safeway signed a deal with Theranos, loaning the company \$30 million and promising to remodel its stores to add clinics where customers could test their blood on Theranos' devices.

With these retail partners on board, the company looked rosy from the outside even though some employees who knew blood was being diluted and results were being faked complained quietly about their concerns. In October 2015, these rumblings gained widespread attention with a front-page article in the Wall Street Journal. Holmes went on CNBC's Mad Money the same day to refute the allegations. She explained away all allegations as backlash against disruptive innovation. "First they think you're crazy, then they fight you, and then all of a sudden, you change the world." 12

The Journal's reporting continued, casting further doubt and inspection into the reliability of Theranos' blood testing. In 2016, The Journal of Clinical Investigation found tests from retail sites in Phoenix, Arizona, to have significant discrepancies. In addition, an assessment from the Centers of Medicare & Medicaid Services (CMS) questioned Theranos' ability to run its California laboratory citing, "a global and long-term failure of the quality control program." CMS banned Holmes from working in the blood testing industry for two years; the company appealed the ruling. In her first interview after these public reports of inaccuracy, Holmes insisted the technology was never at fault, stating instead "we didn't have the right leadership in the laboratory." Theranos also came under scrutiny by the U.S. Attorney's Office and the Securities and Exchange Commission. Is

In 2016, Walgreens ended its relationship with Theranos, closing all 40 Theranos Wellness Centers in stores in Arizona, a decision which reportedly lost Walgreens \$50 million. 16

A Stifling Company Culture

Reporter John Carreyrou who broke the fraud story, said from his years of reporting that he thought Theranos was an "outlier" where "secrecy, paranoia, fear, and intimidation" were more extreme than in other companies in the Valley.¹⁷

Receptionist Cheryl Gafner was surprised when Holmes joined her job interview, later learning that no one "got past her in order to get hired." Gafner also learned she was being "keystroked" where anything she typed was monitored. An engineer said at his job interview he was only told a fraction of what Theranos actually did in comparison to other Bay Area tech companies. A Theranos biochemist said he had only a vague idea of what his employer was doing. Engineers said when they warned that a box as tiny as Holmes wanted simply couldn't perform all the

¹² https://www.youtube.com/watch?v=rGfaJZAdfNE

¹³ https://www.wsj.com/articles/theranos-has-struggled-with-blood-tests-1444881901#pq=Jd8MoW

¹⁴ https://www.fiercebiotech.com/medical-devices/theranos-will-appeal-cms-sanctions

¹⁵ https://www.youtube.com/watch?v=VHWxVLP03Fo

 $^{{\}color{blue} {^{16}} \, \underline{^{https://www.fiercebiotech.com/medical-devices/walgreens-terminates-theranos-deal-closes-all-40-az-wellness-centers} }$

¹⁷ https://www.theringer.com/2018/5/22/17378494/bad-blood-theranos-john-carreyrou-interview

necessary tests, they were told to go work for another company if they didn't share the Theranos vision. Others noticed that Holmes tightly guarded access to Edison prototypes.

Employees observed physical security measures such as body guards for Holmes and Balwani and bullet-proof glass. Balwani tracked all key card entries and exits. He personally monitored computer activity. Erika Cheung noticed emails not sent to Holmes or Balwani would be responded to by them, "That was a very big turning point for me. You are being monitored."

The company's non-disclosure agreement told employees not to tell their families what they did for a living or to list their position on LinkedIn. Employees said measures such as these made employees paranoid of each other and created silos. Also, the frequent firings gave new meaning to the word "disappear."

Theranos Insider Actions

A variety of Theranos employees saw red flags and raised concerns through the years.

Erika Cheung: A freshly minted Berkeley grad, this lab associate idolized Holmes for being a female leader in Silicon Valley, "I was super naive and almost drank the Kool-Aid a little too quickly." She recounted her unease when tasked with running a quality control, "I kept running [the test] and it kept failing. I don't feel comfortable sending out this patient's sample." A senior research associate responded to her concerns by simply deleting the data points, "these are outliers – you can get rid of these." Despite her unease, she remembered thinking, "This is my first-big girl job. This doesn't seem right, this doesn't work right with the general principles of scientific integrity, but maybe I'm not seeing something. Maybe this is normal." Cheung's concerns grew when Theranos began testing real people for serious conditions like infectious diseases, Hepatitis C, prostate cancer and syphilis. When she continued raising her concerns over quality control issues, intimidation increased. She eventually quit. But even as she worked for a new employer, Theranos' hard-charging lawyer David Boies would come after her threatening legal action.

Henry Mosley: The Theranos CFO was one of the first to call out malfunctioning equipment and question the reliability and integrity of the company's lab-testing systems. A colleague confided to Mosley that because the device didn't always produce results, the company faked demos. Moseley told Holmes they couldn't keep "fooling investors." She accused him of not being a team player fired him. ¹⁹

Tyler Shultz: The grandson of George Shultz and whistleblower employee filed the first-known regulatory complaint, even though he said, "you want it to be true so badly." At times, Shultz doubted himself, calling Holmes extremely convincing. "She really makes you feel she cares so much about you, about helping the world." But Shultz was alarmed to learn that an Edison test of 100 people with sexually-transmitted infectious could show falsely that one-third had no disease. Holmes and others tried to show why his analysis was incorrect. Balwani responded by belittling Shultz' grasp of laboratory science. His high-profile grandfather didn't believe his

¹⁸ https://alumni.berkeley.edu/california-magazine/just-in/2019-03-16/whistleblower-erika-cheung-on-working-at-theranos

¹⁹ https://ctmfile.com/story/the-cfo-who-called-out-deception-at-theranos

²⁰ https://www.forbes.com/sites/elliekincaid/2017/10/03/after-blowing-the-whistle-on-theranos-tyler-shultz-is-going-back-into-diagnostic-testing/#6090ec0f575a

concerns at first about doctored research and failed quality-control checks. Holmes even used her connections with the elder Shultz to complain about Tyler's "vendetta" against her.

Channing Robertson: Bad Blood author John Carreyrou calls this Stanford engineering professor Holmes "original enabler" who gave Holmes credibility. The popular professor joined the Theranos board and stayed with the company for 12 years. Robertson was paid \$500,000 by Theranos as a consultant and remained loyal, stating in a 2015 article that the company would have to have been "certifiable" to go to market with an unreliable device knowing people's lives depended on it.²¹

Ian Gibbons: This biochemist helped develop a key Theranos patent and worked at Theranos for eight years. Gibbons said Holmes lied through his years of working with her so that he no longer trusted her. She fired and then re-hired him. In 2013, he committed suicide after becoming distraught by its culture of fear and secrecy and its lack of progress with its technology. ²² His widow said he became depressed due to all the things wrong with the technology.

Legal Action

In 2018, the indictment by the Federal Bureau of Investigation in San Francisco alleged conspiracy to defraud investors yet said there was a worse outcome "More egregiously, this conspiracy misled doctors and patients about the reliability of medical tests that endangered health and lives."

As of October 2020, Holmes and Balwani continue to deny the allegations against them. The U.S. Attorney's Office alleges the two defendants knew that Theranos technology did not produce consistent outcomes and was likely to produce "inaccurate and unreliable results." Holmes is charged with a dozen felony counts of fraud and a trial is scheduled for March 2021. She faces the potential of a 20-year prison sentence, up to \$2.75 million in fines, and restitution. ²⁵

https://www.bloomberg.com/news/articles/2015-12-10/can-theranos-ceo-elizabeth-holmes-fend-off-her-critics-

https://www.wsj.com/articles/blood-testing-firm-theranos-to-dissolve-1536115130

²³ https://www.wsj.com/articles/u-s-files-criminal-charges-against-theranoss-elizabeth-holmes-ramesh-balwani-1529096005

²⁴ https://www.justice.gov/usao-ndca/us-v-elizabeth-holmes-et-al

²⁵ https://www.mercurvnews.com/2020/10/14/theranos-founder-elizabeth-holmes-scattershot-bid-to-nix-charges-goes-down-hard/

Case Discussion Questions

- 1. The outcome of the Theranos saga is quite exceptional. How exceptional do you think the underlying situation and pressures highlighted in this case are, relative to other innovative ventures?
- 2. Consider the incentives for innovative entrepreneurs when it comes to extolling the virtues of their product. Should innovative entrepreneurs overpromise, or misrepresent in any way their products? Can they avoid it?
- 3. How would you characterize the working conditions and culture in Theranos, especially in regards to the flow of information and leadership attitudes toward dissent?
- 4. Employees can question managerial practices and potentially act as whistleblowers. What were the incentives to do so in the case of Theranos?
- 5. What factors make it harder to detect fraud and other violations of public trust in the corporate world?
- 6. What might be the role of media, regulation, and moral values in curbing violations of trust?