Theranos

Team 3

IS 471 Cyber Ethics

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Abstract

Team 3 will be conducting an in-depth case analysis on the unethical and illegal behaviors of the now defunct Silicon Valley company Theranos for this project. In 2003, Elizabeth Holmes, a 19-year-old Stanford dropout, founded “Real-Time Cures” which is now known as Theranos, a privately held healthcare technology company. Holmes claimed that her machine, “The Edison”, could run over 100 tests in minutes and at a fraction of the cost of current technology by using a small device called the nanotainer to draw and analyze a drop of blood from a patient's finger. Team 3 will be looking into how and why upper manager CEO Elizabeth Holmes and COO/President Romesh Sunny Balwani defrauded investors by selling them a vision of a technology that wasn’t feasible and didn’t work. Team 3 will discuss Theranos culture, intimidation tactics, and technology within the company that repeatedly failed its quality assurance testing and continued to misrepresent the facts about its so-called revolutionary technology. Theranos continued to demonstrate a great deal of negligence by continuing to report false positives on their blood testing devices that could have led patient to receive false diagnoses and procedures that could have caused harm or even death. Team 3 will also discuss former employee Tyler Shultz and his experience with the ethical and moral issues within Theranos that led him to blow the whistle on former employer Holmes. Because of Shultz, WSJ, and the SEC Holmes was convicted on 4 counts of fraud and faces up to 20 years.

**Keywords**: Ethics, morals, code of conduct, misrepresentation, fraud, negligence.

1. INTRODUCTION

In 2003, the health care company Theranos was founded by Elizabeth Holmes. The goal of the company was to revolutionize the healthcare industry. The company's way to revolutionize the healthcare industry was with their new product that would have the ability to run 100 tests in minutes at much less expense. Since 2010 Theranos has been going through legal trouble as they were convicted of fraud on multiple occasions. The company persuaded investors with false claims. This paper will go over the ethics of the situation.

2. ELIZABETH HOLMES AND THERANOS

Holmes

Elizabeth Anne Holmes is a former biotechnology entrepreneur of Theranos which was founded in 2003. Holmes was convicted in January of 2022 of committing multiple acts of fraud against investors and patients (Allyn, 2022). She allegedly founded Theranos to revolutionize and alter blood testing for the better. As this paper will explore, the claims were not only false, but she led the company in increasingly unethical pursuits with investors, the press, and her own employees. Elizabeth Holmes cultivated her company and her own persona to great effect which was not illegal but purposeful to attract attention and more investment.

Theranos

Part of the draw of Theranos was the pedigree of its board of directors, some of the most powerful and respected names in business and government. They included: Henry Kissinger (former United States Secretary of State); Jim Mattis (retired Marine Corps four-star general); George Shultz (former United States Secretary of State); [Richard Kovacevich](https://www.crunchbase.com/person/richard-m-kovacevich) (former CEO of [Wells Fargo](https://www.crunchbase.com/organization/wells-fargo-bank)); William Perry (former United States Secretary of Defense); and [William Foege](https://www.crunchbase.com/person/william-foege) (former director of the [Centers for Disease Control and Prevention](https://www.crunchbase.com/organization/centers-for-disease-control-and-prevention)) (Kunthara, 2021). The shear level of experience and respect the members of the board brought to the company further shielded it from scrutiny. Note the only member with any medical expertise was William Foege.

The company created an analyzer, the Edison, which they claimed was able to perform a full range of clinical tests using small blood samples drawn from a finger. Holmes showed that the analyzer could produce results that were more accurate and reliable than those created by conventional method, all at a faster speed than previously imagined.

Edison

The Edison device was supposed to be able to conduct more than 70 tests on a 25-30 microliter sample of blood.

As the results of the trial (Allyn, 2022) showed, the device never worked, nor was any actual working prototype demonstrated. Hundreds of millions of dollars were invested up front, and two massive corporations (Walgreens and Safeway) signed a deal with Theranos, and at one point Theranos was valued at US$9 billion. How could such vast sums of money be spent on a product that never was a real product? There was a severe breakdown in ethical behavior that skirted legal boundaries.

3. INITIAL INVESTORS

Family Connections

The first investors were billionaires with ties to the Elizabeth Holmes family. One of the earliest was Tim Draper of the venture capital firm Draper Fisher Jurveston; he was a neighbor of Holmes growing up. Another early investor was neighbor Victor Palmieri. Former Secretary of Education Betsy Devos and her family invested $100 million toward the now defunct company.

The previous section outlined many famous, powerful, and high-profile names that sat on the Theranos board of directors. The family connections added more gravitas to the project in terms of money and name, which was leveraged to gain other investors.

Leverage

Other investors included The Walton family ($150 million); Rupert Murdoch ($125 million); Cox Enterprises ($100 million); Carlos Slim ($30 million); Andreas Dracopoulos ($25 million); the Oppenheimer family ($20 million); Riley Bechtel ($6 million); Chris Lucas ($ 5.4 million) and Robert Kraft ($1 million) (Liu, 2022). These are well known names whose involvement in the company brought more attention and investment. These people are better known for their roles in politics, business and global finance than their interest in MedTech startups.

By leveraging family connections, a cultivated image and investors with more money than knowledge of medical technology Holmes enabled Theranos at its height to be valued at $9 billion. All while never producing a working Edison machine. According to Steve Vassallo, a general partner at Foundation Capital, “In some of the harder tech spaces like health care and bio sciences, it would be impossible for any investor to apply enough due diligence to figure out whether the core science [behind a project], which might have taken a PhD or a team of postdocs literally decades to come up with, [is accurate]. There’s a bit more trust involved,” (McCluskey, 2021).

This collective weight of name, power, and money this massive leverage provided, Holmes was able to unethically manipulate purchasers, media, and her own employees.

4. THERANOS CULTURE

Fear

Fear, lies, secrecy, manipulation, and distrust were some of the key elements that made up Theranos culture. The internal competition among the engineering team was hostile and made employees feel stressed and isolated (Ying, 2019).

Elizabeth told engineers to work around the clock including weekends to make a device that could do what she projected, which was to conduct more than 70 tests on a 25-30 microliter sample of blood. When engineers said it wasn't possible to make such a device, Elizabeth hired another engineering team and put them against each other (Ying, 2019).

This purposeful internal competition left the company starving for talent due to the constant amount of stress employees would have to endure; they resigned or got terminated if unreasonable expectations were not met. Rather than listen to the doubts expressed by experts in and out of the company, employees were pressed to deliver on Holme’s idea.

As the years went by, whenever employees or experts raised concerns, Holmes and her COO Ramesh Balwani would stop, avoid, bully, or threaten those who dared to criticize Theranos (Jezior, 2022). Some people think that maybe her idea could have worked (Jezior, 2022), but there wasn't a good way to talk about problems or work together to solve them. The Theranos culture forced employees to keep their heads down and go along with the sham because they knew there would be consequences, like lawsuits or getting fired.

Fear as a driving force on a team or as a way to lead could be the biggest sign that there are problems with the company's culture. In fact, some leaders don't even realize they're creating a culture of fear or seeing what's wrong with it. Fear causes people to make poor choices, and this interferes with their success.

Manipulation

Manipulation played a big role in Theranos culture and here are some examples of the tactics used by Holmes.

* Thinking that your work will make a difference (purpose, social value)
* Whether you stay or leave is up to you (reverse psychology, guilt)
* We're all in this together (acceptance)
* The whole world is against us, and we all have the same enemy (belonging)
* (Torres, 2019)

Holmes had a grandiose vision of radically changing healthcare, and she was consistent in telling her employees that “The minilab (name of the blood-testing device) was the most important thing that humanity has ever created and if there were any naysayers they could leave now.” (Torres, M. 2019).

Falsification

Holmes was able to mislead many people to gain investors using media and public relations (PR). One of the most important misrepresentations was getting the FDA approval of the blood testing machine, which allowed her to gain creditability of the product. According to Rutschman (2021), “The FDA concluded in 2015 that the nanocontainer was a Class II device, which requires special labels, certain performance standards and post-market surveillance. But Theranos claimed it was Class I and for two years was shipping it without proper clearance from the FDA.” The FDA states, “The Medical Device Amendments of 1976 to the Federal Food, Drug and Cosmetic Act established three regulatory classes for medical devices. The three classes are based on the degree of control necessary to assure the various types of devices are safe and effective.” (Center for Devices and Radiological Health, 2017).

However, there was a loophole in FDA regulatory category of laboratory-developed tests, which Theranos was able to offer the product to patients without evaluation testing by regulators. This gained the attention of the former Vice President Joe Biden, which he stated during a healthcare innovation summit with Holmes in July 2015, “This is inspiration. It is amazing to me, Elizabeth, what you’ve been able to do. What’s most impressive to me is you’re not only making these lab tests more accessible ... empowering people whether they live in the barrio or a mansion, putting them in a position to help take control of their own health.” Cava (2015). This gave Elizabeth the support from the government and increased the credibility of Theranos, which made it easier to mislead others about Theranos FDA approval.

Sales

Both Walgreens and Safeway, two large companies, signed a deal with Theranos. It is important to note that even without a working device, Holmes and Theranos made millions of dollars in sales.

Public Relations

When the company was criticized by a journalist that published an article in the Wall Street Journal, Holmes refuted the article by making appearances to multiple media outlets. During an interview with Cramer from Mad Money, stating the attention Theranos was receiving was because, “This is what happens when we work to change things…”, “…we’re working to make a difference and that makes people raise questions.” (CNBC, 2015). Holmes also made a statement claiming that the Journal refused Theranos’ offer to bring the technology to the journal offices. This was an approach to discredit the journal from their claims. This began the downfall of Theranos.

5. Whistleblowers

Tired of the lies and manipulation of the data and employees, Erika Cheung and Tyler Schultz spoke out about Theranos and Elizabeth. Cheung described the initial atmosphere as one of "a lot of eager folks." (Dunn, Thompson & Jarvis 2019). Although during the first several months, "things started to unravel where you realize you were working a lot and priorities were constantly changing but things didn't quite make sense" (Dunn, Thompson & Jarvis 2019).

Things started to make less sense when Erika tried to bring up the discrepancies with the quality control testing and its results, the machines kept failing, she stated that she kept running the test over and over with the same results. The way she said it got resolved was by selecting the data points from samples that agreed with the expected results. Erika voiced her concerns directly with Balwani about the testing, but she was met with rage, disrespect, and more manipulation tactics. One example of this is when she brought up concerns about the quality control test in the lab, stating that the test routinely fails. The response she got from Balwani was “You just graduated from UC Berkeley, and what do you know about laboratory diagnostics?' to make these calls? 'Your presence in this organization is completely invisible’” (Khorram, 2021).

Schultz realized that Theranos was using third-party machines like Siemens to conduct most of the testing. Schultz tried to bring this information to his grandfather George Schultz, former U.S Secretary of state and Theranos board member but he was also met with disbelief.

Cheung and Schultz teamed up and started to keep track of issues as they arose and how many times the machines failed. Eventually, Schultz addressed the issues in an email to Holmes after multiple attempts to meet outlining the issues. Holmes responded with “Tyler, these are very, very serious comments and allegations that you're making." (Dunn, Thompson & Jarvis 2019). She went on to say she'd "have the teams go through this line by line, so it will take some time before I get back to you on this.” (Dunn, Thompson & Jarvis 2019)

6. Fallout

Financial

As mentioned in Sales, Walgreens and Safeway had signed a deal with Theranos for the Edison. Later both companies ended their partnership with Theranos after being brought an unfinished product.

Walgreens filed a lawsuit against Theranos for one hundred forty million in restitution. Later Walgreens settled out of court for significantly less than they intended. Safeway invested a significant amount of money into Theranos which allowed them to start preparing for new blood testing machines. This has resulted in negative reputation for both Holmes and the company Theranos.

Bob Kocher had this to say, “When investors are making early-stage investments, there are certain risks they’re worried about … Investors generally aren’t worried about fraud and lying and [falsified] data. That’s far outside of the realm of typical risks that you encounter with startups.” (McCluskey, 2021).

Testimony

During testimony one of the main arguments by the Defense was that the device didn’t need FDA approval as a lab-developed test (a category of tests developed and used within a single lab not going through the typical FDA process) (Wetsman, 2021). This kind of misrepresentation has been addressed in Section 4. Theranos culture of falsification.

This was also a one of the reasons Theranos board member and family friend General James Mattis wasn’t concerned with some of the company’s actions. Among the initial group of investors there was a skepticism of the regulatory process. The Devos family examined binders of information on the blood testing tech and took a trip to the Palo Alto headquarters but never involved scientific personnel in their due diligence. It appears the DeVos’s fear of missing out on a testing device which Holmes promised would change the world, and the salesmanship of Holmes herself, were the impetus for their eventual $100 million dollar loss. While this overpromising was perhaps ethically reprehensible it wasn’t illegal.

Conviction

“Holmes faces a maximum sentence of twenty (20) years in prison, and a fine of $250,000, plus restitution, for the conspiracy count and each count of wire fraud.” (Justice, 2022).

7. Conclusion

Theranos was a company that made multiple unethical decisions involving their investors, customers, and employees. Theranos lied and stole from its own investors with their claims. Holmes was found guilty of multiple offences. The company made many unethical decisions and has since felt the consequences. Theranos has filed for bankruptcy. Examining this situation highlights the dangers of unethical business practices, and the importance of ensuring ethical behavior.

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