

Nonprofit Ethical Case:

Theranos: Elizabeth Holmes: Toxic Leadership, Fraud—Leading with Ego... To What Cost?

Case Study #4:

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Summary

Theranos's business model was based around the idea that it could run blood tests, using proprietary technology that required only a finger pinprick and a small amount of blood. Elizabeth Holmes said the tests would be able to detect medical conditions like cancer and high cholesterol.



This gained a lot of interest from funders and future employees. Whistleblowers reported that the work environment was hostile, secretive, and employees were demanded to produce the desired results at any cost. After investigations and reports Theranos stopped operations and Elizabeth Holmes was charged with felonies.



Facts



- March 2004: Holmes drops out of Stanford to pursue Theranos
- September 2009: Ramesh “Sunny” Balwani joins Theranos as Holmes’ right-hand man
- September 2013: Holmes opens up; announces Walgreens partnership
- September 2014: Holmes named one of the richest women in America by Forbes; 30 under 30
- December 2014: Theranos has raised \$400 million
- July 2015: Theranos gets FDA approval for Herpes test

Facts. cont.



- October 2015: Theranos is the subject of a WSJ investigation; Holmes hits back
- November 2015: Theranos and Safeway partnership falls short
- January 2016: Federal regulators take issue with Theranos' California lab; Walgreens pulls back
- May 2016: Balwani steps down; Theranos voids two years of blood tests
- July 2016: Holmes is banned from running labs for two years
- January 2017: More layoffs, followed by a failed lab inspection

cont.

- March 2018: Holmes charged with massive fraud (SEC)
- June 2018: Holmes and Balwani indicted on criminal fraud charges
- September 2018: Theranos to dissolve
- September 2020: Holmes' possible defense strategy comes to light
- December 2020-January 2022: Trial delays, deliberations, Holmes found guilty on FOUR of 11 federal charges



Compliance

Legal and compliance issues behind the ethical issues of this case:

- Holmes fraudulently raised \$700m from investors, misleading them
- Deliberately made false claims made about the efficiency of the company's blood testing technology
 - Presenting false data
- After 2 weeks of inspections, FDA found 14 compliance issues



Individual Responsibility

Leadership style/Personality:

- Some of the same traits that make them successful also make them more susceptible to crossing the line
- Somewhat narcissistic, fine line between confidence and arrogance: High risk and low disregard for consequences (Ego driven)
- Age/Experience: Slow climb to success breeds increased social skills, self awareness and to self regulate against dangerous and negligent decision making

Lack of HONESTY and TRANSPARENCY

- Years of lying about the effectiveness of their product while still selling the idea of their product to investors, patients, and potential partners
- Former employee testified that Thernos implemented an "Outlier Deletion" system, cherry picking the best data points during quality control data collection
- Lack of transparency all around, ex. Walgreens deal gone bad

Organizational Responsibility

- Conflict of interest between Holmes/Theranos and Sunny
- Bystander vs. Bully work environment
- Whistleblowers: Tyler Shultz and Erica Chung
- Board of directors



George Schultz

Systemic Responsibility

Who did their homework?

- Elizabeth was featured in magazines, newspapers...
- Stakeholders supported her vision
- Walgreens invested before validating
- Many doctors and other Theranos staff continued their work
- FDA loophole: FDA does not enforce premarket review of “... in vitro diagnostic test that is designed, manufactured and used within a single laboratory.”



Stakeholders Analysis

- Patients relied on the results to make medical decisions
- Stakeholders contributed money to the cause and mission that was presented to them
- There may be some distrust in other Biotech Innovations
- Investors became involved based off of the credibility of other investors
- Many investors didn't have any experience in BioTech



Remedies

What would you do?



Remedies and Outcomes

- Stakeholder's should do more research
- Theranos was shut down in 2019
- Holmes was charged with 2 counts of conspiracy to commit wire fraud and 9 counts of wire fraud in March 2022
- Ramesh "Sunny" Balwani is set for trial 2022



Questions

- What do you think the Board of Directors role was in this case? Should they be held accountable?
- What do you think the role of Universities is to prepare students to make ethical decisions?
- Are there other systematic responsibilities that should be put in place or changed for companies or agencies? (Regulations, processes, etc.)
- Do you think Elizabeth Holmes deserved the criminal charges that resulted from the investigations of Theranos?
- Do you think Elizabeth set out to fraud investors with her company or do you think Elizabeth set out to “do good” and lied because of pressure or other influences?



Questions

References

- Gaps in the FDA Regulations
 - <https://theconversation.com/how-theranos-faulty-blood-tests-got-to-market-and-what-that-shows-about-gaps-in-fda-regulation-168050>
- Trial Discussion and Charges
 - <https://www.youtube.com/watch?v=wu8A7tRfP3c>
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