Paper 3

ENMG 656: Engineering Law and Ethics

Case Study:

THERANOS SCANDAL

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Introduction:

In 2003, at the age of 19, Elizabeth Holmes launched the privately held healthcare technology company Theranos Corp. The company boasted it could identify diseases with merely a few drops of blood and predicted it would transform the blood-testing industry. The Theranos incident was one significant incidence of corporate fraud where they claimed to have developed a technology to test blood, but all these claims turned out to be fake later. Theranos claimed the device could run a variety of tests on a patient's physiology in minutes and at a fraction of the cost of existing technology by using the Edison testing method and the nanotainer a tiny instrument designed to extract, hold, and examine a droplet of blood from a patient's fingertip, are exclusive to the company. It was discovered that most common blood tests could not be reliably performed using Theranos' in-house Edison devices due to defects. For most of its testing, Theranos was secretly employing conventional commercial analyzers from other businesses. (Zaw Thiha Tun (February 2024)) Thanks to its tech commitments, Theranos succeeded in managing to raise roughly $700 million from venture capitalists and private investors, culminating in a $9 billion value in 2013–2014. Notwithstanding nearly ten years of fundraising efforts and an estimated value of over 10 billion dollars, the trends began to alter in 2015 partly because of journalistic suspicion. Holmes's fortune deteriorated from 4.5 billion to $0 dollars around the end of 2016. Furthermore, Holmes and previous president Ramesh Balwani both have been found to have falsified or overinflated facts regarding the company's technological in nature, commercial, and financial capabilities by the Securities and Exchange Commission in 2018. Ultimately, fraud resulted in Holmes and Balwani's imprisonment.

Engineering Issue:

The main engineering challenge was to develop a system that could conduct numerous medical tests using a limited quantity of blood droplets. Engineers were crucial to this initiative since they designed, developed, and sold the technology. But as the technology failed to live up to expectations, problems with it developed, resulting in inaccurate test results and risks for patients. Theranos' engineers worked to find solutions for a variety of problems, including quality control, getting precise findings from tiny blood samples, and miniaturizing all the many chemical tests and detection techniques to operate on a small scale. About the importance of engineers, it was said that the company employed talented engineers early on to work on developing the key technologies. Many of these engineers, nevertheless, left because they were unable to get the systems to function as promised. Reports state that as deadlines approached, Theranos resorted to short cuts, such as utilizing commercial analyzers covertly, diluting small samples to run on common equipment, or fabricating investor demonstrations. Therefore, rather than candidly acknowledging that the engineering barrier could not yet be reliably overcome, Theranos started to lie when the miniaturized

testing failed to scale technically, even though the company had engaged engineers to try to make it work. The ethical dilemmas were clear-cut they involved dishonesty, fraud, and risky testing procedures that endangered patient safety. Theranos's culture of fear and secrecy is the reason behind the company's dearth of whistleblowers. The engineers' responses varied; some may have taken part in the scam, while others may have raised concerns internally but were ignored. (Lisa Eitel (April 2019))

Technical Issues:

Theranos' proprietary blood testing equipment and procedures had several significant technological flaws and restrictions that ultimately contributed to the company's demise. Conventional blood testing necessitates taking vials of blood from veins, which is more invasive and painful for patients. Using cutting-edge methods like nanotainers and microfluidics, Theranos asserted that their own Edison devices could perform the same tests with a little sample. However, getting this to function consistently across a broad range of intricate blood tests presented considerable hurdles. (Julia Belluz (Oct 2015)) During a blood collection process, a technician used a rocket-shaped plastic tool to draw blood from a donor's finger. The blood was then supposed to be transferred to nanotainers that were located at the tool's base. The insertion of the twin tubes into the device was complicated by a loud burst that resulted in the explosion of one of the nanotainers and the spilling of blood. This incident provided as an excellent example of the procedure's shortcomings. BackChannel (May 2018) Theranos claimed it could perform several blood tests using very small amounts of blood, but it had difficulty condensing complex chemical reactions and detecting techniques. Because of the tiny sample sizes, even little errors were large, leading to incorrect results. Overall dependability was impacted by their reduced-size test cartridges' uneven reliability. Despite promises, Theranos's devices could only conduct a limited number of tests, frequently produce erroneous findings, and malfunctioned frequently, making them unusable for real-world use. Theranos misjudged how difficult it would be to automate and reduce the complex biochemical procedures, fluid handling, and quality control that were necessary to live up to its lofty promises. The list of dishonest practices employed by Theranos included passing off fraudulent results as authentic, presenting phony demos to venture capitalists, and using test results from other firms' devices on Therano's. (Jessica Ying (March 2019))

Stakeholders:

Many parties were impacted by the Theranos crisis, including the public, investors, staff members, whistleblowers, patients, and partners. At the company's 2014 high valuation of US$9 billion, Holmes owned a US$4.5 billion stake. However, the SEC accused Holmes and Theranos in March

2018 of using a complex, multi-year fraud scheme to raise over $700 million from investors by making false and inflated claims about the company's financial, economic, and technological performance. (Anand Narasimhan and Nancy Lane (June 2018)) Numerous investors lost money, as did patients whose health might have been jeopardized by erroneous test results, regulators overseeing the healthcare industry, and employees complicit in the company's culture of secrecy and dishonesty. Based on the promise of its ground-breaking blood testing technology, Theranos attracted over $700 million in investment from wealthy people and venture capital firms. Among the notable investors were the Walton family, Rupert Murdoch, and Tim Draper. When Theranos failed, they lost most or all their investments. Theranos partnered with businesses like Walgreens, resulting into many patients having their blood procedures conducted using defective equipment due to exaggerated claims about Theranos' competency. It appears that the board of Theranos disregarded a persistent and widespread deception. Nevertheless, its members included three former cabinet secretaries, two former senators, and retired officials. (Anand Narasimhan and Nancy Lane (June 2018))

Ethical Issues:

Hearing about the complexities of the Theranos Case raises several challenging ethical considerations. Theranos's founder/CEO and president/COO violated several ethical rules and values. It's critical to comprehend the ethical implications of the case to recognize warning signs of possible fraud and make an informed decision about whether to report it. (Tala Khalifeh (June 2022)) When Holmes gave investors misleading information and staged phony presentations of the medical testing equipment to get their money, she violated the standards of integrity and honesty. As a result, she lost her reputation as a successful businesswoman and was convicted of cheating Theranos investors. Even in internal meetings, Holmes demonstrated a great deal of confidence in the device, and it was reported that her magnetic personality made it simple for her to persuade many staff members and potential investors to have faith in Theranos's innovation and long-term goals. Among the main issues were the lack of a CFO, the absence of an auditor's opinion report, and the severe secrecy culture. It was not permitted for employees at Theranos to voice concerns or ask questions. Instead, they should feel free to do so. Former workers said that they brought up an ethical concern and were fired as a result. Every day, ethical conundrums arise in every business, at every level, and throughout the world. (Jessica Ying (March 2019)) Employees like Schultz and financial experts like Mosley are actual instances of how more unethical behavior often begins after people start to speak out. (Tala Khalifeh (June 2022)) Scandals of this kind must be prevented by promoting transparency, protecting whistleblowers, stepping up regulatory oversight, and upholding moral principles. Companies must also temper their grandiose claims with logical assertions backed up by evidence. We can ultimately conclude that there was a serious violation of ethical standards and concepts like honesty, integrity, and credibility when the jury found Holmes guilty of three counts of wire fraud and of defrauding investors.

Whistleblowers:

Whistleblowers Tyler Schultz and Erica Cheung, who were once employed by Theranos, were troubled by the company's flawed blood testing technology. They continued to expose Theranos' dishonesty even after the firm first addressed their issues internally and then they left. They revealed details about fake reports, machine functions, lab procedures, and erroneous test findings. Legal threats were Theranos' response, claiming that if they came out, they would be accused of stealing trade secrets. One form of retribution was the use of the Defend Trade Secrets Act. (Hannah Dawson (Dec 2023)) Their revelations played a crucial role in highlighting Theranos' technological shortcomings. Results from tests were inconsistent, and stakeholders were given false validation data. This deceit exposed Theranos's efforts to hide the shortcomings in their technology and emphasized the value of whistleblowers in exposing corporate malfeasance and preserving public confidence. Employees at Theranos were threatened with legal action if they disregarded non-disclosure agreements, and the company promoted an intensely private culture. This probably deterred a lot of people from speaking up. After disclosing corporate misconduct, whistleblowers frequently experience personal attacks, job setbacks, and professional retaliation. More voices may have been suppressed if they hadn't been afraid of ruining their own jobs in the close-knit Silicon Valley. Furthermore, it's possible that some workers lacked hard proof or were unsure of the severity of the improper behavior. In summary, it seems that the corporate culture of intimidation and secrecy has been successful in silencing other potential whistleblowers in the past. (EQS Team (Nov 2023))

Engineers' Responses to Ethical Problems:

Many of Theranos' scientists and engineers responded to the moral dilemmas and difficulties they encountered in an ethically responsible manner. The lead design architect of Theranos, Ana Arriola, was concerned that using human beings to test an unstable technology might go beyond ethical bounds. Arriola questioned Holmes with the issues with the Theranos system and its possible impact on people, and she was advised to put the pilot research on hold until the dependability issues were fixed. Holmes declined, citing the big drug corporations' demand for the blood-testing equipment. On the sections of the system that fell under their purview, the engineering and chemical groups were carrying out their corresponding tests. But nobody was testing the system. If the differences between the results of several test runs are fewer than 10 percent, the blood test is usually regarded as precise. In its validation report for that exam, Schultz noted that in certain instances, these percentages notwithstanding. Shultz started to think Theranos was misrepresenting results from additional testing. Holmes was questioned by Cheung with the argument that providing people with inaccurate information about their health state is not justified merely because Theranos

testing may be less expensive. You shouldn't receive a lower-quality test result just because you paid less for it. Holmes persisted in the dubious activity, and ultimately the company was barred from operating clinical labs. Cheung and Schultz faced legal threats from Theranos for reportedly breaking a confidentiality agreement. (Robert E. McGinn (August 2022))

Corporate responses to the ethical problems:

Holmes originally angrily refuted the accusations made against her and the business. Theranos's detractors had started requesting evidence that the company's technology is reliable and accurate. Ultimately, the data supporting this was confidential: The FDA had not approved Theranos's testing. Holmes also never submitted her assertions to peer-reviewed publications for publication. By pointing to issues with intellectual property and implying that any criticisms were being staged by competing testing firms like Quest and Laboratory Corporation, Holmes and Theranos' public relations staff managed to sidestep these detractors. In an additional report, the Wall Street Journal revealed that Theranos has been under pressure from the FDA to discontinue utilizing its Edison technology on all but one of its blood tests due to worries regarding the accuracy of the device. Finally, Holmes acknowledged that, except for one test, Theranos was no longer collecting pinprick blood samples. The company claims that, while the findings are still pending, it has been working with the FDA to authenticate its blood testing. Theranos appears to have been primarily functioning as a conventional blood testing facility up until it got FDA approval, drawing blood from patients via needles in their arms and analyzing the blood using conventional technologies. (Julia Belluz (Oct 2015))

Professional codes or standards:

Reports from the FDA's inquiry into Theranos were made public. They exposed problems such as "uncleared medical device(s)," inadequate record-keeping, improper treatment of complaints, and a failure to carry out audits and confirm supplier qualifications. Investigators discovered that a medical equipment that was not identified did not satisfy indicated user criteria and lacked validation under real-world use circumstances. CMS issued a 10-day deadline for fixes or face fines in 2016 after deeming a Theranos-affiliated lab in California to be in "immediate jeopardy" for patient safety. (Zaw Thiha Tun (February 2024)) Holmes lost control, had to surrender shares, and was barred from holding positions in public companies for ten years because of Theranos and Holmes' settlement of fraud charges. Holmes and Balwani were found guilty of fraud in 2022 for conspiracy and wire fraud, following 11 years jail for Holmes, and nearly 13 years for Balwani. Due to all this Holmes resigned in 2018 as CEO. This resulted in Theranos' closure following an FBI probe, leaving former workers unsure of their futures. (Connie Roff (March 2024))

Role of government oversight or regulation:

Significant weaknesses in government oversight and regulation were exposed by the Theranos case, which allowed dishonest business practices to continue unchallenged. Theranos was able to evade appropriate examination due to regulatory weaknesses and insufficient FDA probes. Undersufficient control of the use of incorrect blood testing services was made possible by partnerships with corporations such as Walgreens. By classifying their gadgets as lab-developed tests, Theranos was able to circumvent FDA approval, expose patients to uncleared testing, and take advantage of legal loopholes. Additionally, the business avoided investigation from SEC and other securities regulators by raising millions through false statements. This demonstrated the necessity of updating corporate governance, updating whistleblower channels, and updating lab regulations. Theranos' demise was a result of legal disputes and heightened government scrutiny, underscoring the significance of closing regulatory gaps to shield investors and patients from dishonest business practices. (Scott Gottlieb (Apr 28, 2016))

Preventions and recommendations:

Theranos clearly exploited access to people's lives for monetary advantage without realizing the repercussions of their actions or owning up to their wrongdoings. Journalists helped bring attention to the issue because of the courageous decisions made by Schultz and Cheung. If regulatory bodies such as the FDA, CMS, and SEC had conducted inspections and enforcements over diagnostic tests, clinical labs, and investors, they could have closed loopholes that allow investors to sidestep approvals and prevented all of this. Because of the intimidating atmosphere at Theranos, workers didn't feel safe expressing their opinions or showing what they had witnessed. If whistleblowers been safeguarded from disclosing corporate misconduct without fear of reprisal, the problem might not have seemed so remote. Those who started and supported this scandal showed lack of regard for ethics, accountability, or openness. Everyone needs to be aware of this, and actions like notifying customers, shareholders, and the public to view overstated assertions with greater skepticism until they are thoroughly verified are crucial, particularly in the complicated deep tech industries. Integrity-focused workplaces, moral leadership, and employee voices must all be reinforced.

References:

[1] Zaw Thiha Tun (February 2024) https://www.investopedia.com/articles/investing/020116/theranos-fallen-unicorn.asp#:~:text=Theranos%20CEO%20Elizabeth%20Holmes%20claimed,were%20eventually%20imprisoned%20for%20fraud.

[2] Lisa Eitel (April 2019) https://www.designworldonline.com/schadenfreude-for-theranos-and-satisfaction-in-how-engineering-doesnt-lie/

[3] BackChannel (May 2018) https://www.wired.com/story/a-new-look-inside-theranos-dysfunctional-corporate-culture/

[4] Julia Belluz (Oct 2015) https://www.vox.com/2015/10/20/9576501/theranos-elizabeth-holmes

[5] Jessica Ying (March 2019) https://medium.com/the-coleman-fung-institute/case-study-lessons-learned-from-theranos-corporate-culture-1a836515c139

[6] Anand Narasimhan and Nancy Lane (June 2018) https://www.imd.org/research-knowledge/ethics/articles/theranos-founder-fooled-investors-with-the-promise-to-revolutionise-healthcare-it-offers-three-big-lessons-for-companies/

[7] Tala Khalifeh (June 2022) https://www.sfmagazine.com/articles/2022/june/theranos-cautionary-tale-of-ethical-failings/#:~:text=After%20the%20jury%20reached%20a,honesty%2C%20integrity%2C%20and%20credibility.

[8] EQS Team (Nov 2023) https://www.integrityline.com/expertise/blog/elizabeth-holmes-theranos/

[9] Hannah Dawson (Dec 2023) https://blogs.luc.edu/ipbytes/2023/12/29/whistleblowers-and-trade-secrets-a-theranos-case-study/

[10] Robert E. McGinn (August 2022) https://www.researchgate.net/journal/Science-and-Engineering-Ethics-1471-5546/publication/363127559_Startup_Ethics_Ethically_Responsible_Conduct_of_Scientists_and_Engineers_at_Theranos/links/630ec4875eed5e4bd13260ea/Startup-Ethics-Ethically-Responsible-Conduct-of-Scientists-and-Engineers-at-Theranos.pdf?origin=journalDetail&_tp=eyJwYWdlIjoiam91cm5hbERldGFpbCJ9

[11] Connie Roff (March 2024) https://www.panmacmillan.com/blogs/literary/theranos-elizabeth-holmes-john-carreyrou

[12] Scott Gottlieb (Apr 28, 2016) https://www.forbes.com/sites/scottgottlieb/2016/04/28/theranos-woes-offer-lesson-in-how-labs-should-be-regulated/?sh=15475a7148d9