Case Study (1) - Theranos: Unveiling the Realities of a Failed Health care Startup

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Abstract

Theranos, founded by Elizabeth Holmes in 2003, aimed to revolutionize healthcare through cheaper and faster blood tests using innovative technology. However, investigations in 2015 revealed the technology's failure, leading to fraud charges against Holmes and the company's downfall. This case study delves into the ethical, legal, and regulatory issues stemming from Theranos' actions, highlighting lessons learned and impacts on healthcare innovation and entrepreneurship.

Keywords: Theranos, Elizabeth Holmes, Healthcare, Innovation, Entrepreneurship

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Introduction

Theranos was a healthcare startup founded by Elizabeth Holmes in 2003. The company was based on the idea of providing a cheaper, faster, and more convenient alternative to traditional blood tests. The company claimed to have developed a revolutionary technology that could perform a wide range of tests using just a few drops of blood from a finger prick. However, in 2015, a series of investigative reports by the Wall Street Journal revealed that the

technology did not work as claimed, and that the company had been misleading investors, patients, and regulators. This led to the downfall of Theranos, and Elizabeth Holmes was charged with fraud and other crimes.

In this case study, we will examine the rise and fall of Theranos, and explore the ethical, legal, and regulatory issues that arose from the company's actions. We will also discuss the lessons that can be learned from the Theranos scandal, and how it has impacted the healthcare industry as a

whole. Additionally, we will consider the implications of the Theranos case for the future of healthcare innovation and entrepreneurship.

History

Elizabeth Holmes was born in 1984 in Washington, D.C. She was raised in Houston, Texas, and showed an early interest in science and technology. She was inspired by her uncle, who was an entrepreneur, and by her grandfather, who was a scientist. She enrolled at Stanford University in 2002 to study chemical engineering, and dropped out a year later to start Theranos. Adkins (2006)

The company's technology was based on a device called the Edison, which was supposed to be able to perform a wide range of tests using just a few drops of blood from a finger prick. The company claimed that the tests were faster, cheaper, and more convenient than traditional blood tests, and that they could be done at home or in pharmacies. The company also claimed that the technology was accurate and reliable, and that it had been validated by independent experts. Auletta (2014)

Theranos quickly attracted a lot of attention and investment. The company raised over \$700 million from investors, and was valued at over \$9 billion at its peak. Elizabeth Holmes was hailed as a visionary and a genius, and was featured on the cover of magazines like Forbes and Fortune. She was also named one of the most influential people in the world by Time magazine. Forbes (2016)

However, in 2015, a series of investigative reports by the Wall Street

Journal revealed that the technology did not work as claimed, and that the company had been misleading investors, patients, and regulators. The reports alleged that the tests were inaccurate and unreliable, and that the company had used traditional blood testing machines for most of its tests. The reports also alleged that the company had manipulated test results, and that it had failed to comply with regulatory requirements. Carreyrou et al., 2015

The revelations led to a series of investigations by federal and state authorities, and to lawsuits by investors and patients. The company was forced to shut

down its labs, and to void or correct thousands of test results. Elizabeth Holmes was charged with fraud and other crimes, and is currently awaiting trial. The company's valuation plummeted, and it was forced to lay off most of its employees and to close its offices. Stross, 2016

Vision and Mission

Theranos' vision was to revolutionize healthcare by making blood testing faster, cheaper, and more convenient. The company's mission was to empower individuals to take control of their health by providing them with access to affordable and accurate tests. The company believed that its technology could help to detect diseases earlier, to monitor chronic conditions more effectively, and to personalize treatments based on individual needs. The company also believed that its technology could help to reduce healthcare costs, to improve patient outcomes, and to promote preventive care. Theranos, 2018

The company's vision and mission were inspired by Elizabeth Holmes' personal experience with the healthcare system. She had a fear of needles, and had fainted during a blood test as a child. She believed that the experience was traumatic and unnecessary, and that it could have been avoided if the test had been done with just a few drops of blood. She also believed that the experience was emblematic of the problems with the healthcare system, and that it could be solved with the right technology. Holmes, 2014

Employees and investors were attracted to Theranos' vision and mission because they believed that the company could make a real difference in people's lives. They were inspired by the idea of using technology to transform healthcare, and by the prospect of disrupting the industry. They were also motivated by the opportunity to work with a charismatic and visionary leader like Elizabeth Holmes, and by the promise of financial rewards. Parloff, 2016

Issues and Challenges

The Theranos scandal raised a number of ethical, legal, and regulatory issues, including honesty, integrity, transparency, accountability, fraud, conspiracy, negligence, and violation of laws

and standards. The company's actions were unethical because they involved deception, fraud, and harm to stakeholders. The company's actions were illegal because they involved violation of laws and regulations. The company's actions were unethical and illegal because they violated the trust of stakeholders, and because they undermined the reputation of the healthcare industry. Carreyrou et al., 2015; Parloff, 2016; Stross, 2016

Challenges

Theranos faced challenges in meeting their commitments due to inaccurate representations of their technology. The US FDA certified their herpes virus test as reliable in July, but it was later revealed that they used third-party equipment from Siemens without disclosure. This lack of transparency extended to patients, investors, and business partners regarding the actual capabilities of their testing. Following an FDA investigation in 2015, Theranos acknowledged test errors shortly after. Elizabeth Holmes, the founder, was reported to have fabricated trivial details like her whereabouts to employees, creating a

culture of distrust. Many employees were let go or left due to questioning or criticism.

Despite laboratory staff noting flaws in the "Edison" technology and submitting error reports, these concerns were disregarded by management. Instead of focusing on rectifying issues, only accurate data was highlighted, and incorrect conclusions were overlooked. Carreyrou et al., 2015

Ethical Issues

The Theranos scandal raised a number of ethical issues, including honesty, integrity, transparency, and accountability. The company's actions were unethical because they involved deception, fraud, and harm to patients, investors, and employees. The company misled investors by exaggerating the capabilities of its technology, and by concealing the fact that it was using traditional blood testing machines for most of its tests. The company also misled patients by providing inaccurate and unreliable test results, and by failing to comply with regulatory requirements. The company misled employees by creating a toxic work environment, and by pressuring them to engage in unethical and illegal

activities. Carreyrou et al., 2015

The company's actions were also unethical because they violated the trust of stakeholders, and because they undermined the reputation of the healthcare industry. The company's actions eroded the trust of investors, who lost billions of dollars as a result of the scandal. The company's actions eroded the trust of patients, who received inaccurate and unreliable test results that could have put their health at risk. The company's actions eroded the trust of employees, who were subjected to abuse and retaliation if they raised concerns about the technology. The company's actions eroded the trust of regulators, who were misled about the company's compliance with requirements and standards. Parloff, 2016

Legal Issues

The Theranos scandal also raised a number of legal issues, including fraud, conspiracy, and negligence. The company's actions were illegal because they involved deception, misrepresentation, and violation of laws and regulations. The company committed fraud by making false and misleading statements to investors, patients,

and regulators. The company conspired to commit fraud by colluding with partners and suppliers to deceive stakeholders. The company was negligent by failing to exercise due care and diligence in the design, development, and testing of its technology. Stross, 2016

The company's actions violated a number of federal and state laws, including the Securities Act of 1933, the Securities Exchange Act of 1934, the Food, Drug, and Cosmetic Act, and the Health Insurance Portability and Accountability Act. The company's actions also violated a number of ethical and professional standards, including the American Medical Association Code of Medical Ethics, the American Society for Clinical Laboratory Science Code of Ethics, and the American Society for Clinical Pathology Code of Ethics. Association, 2016; for Clinical Laboratory Science, 2016; for Clinical Pathology, 2018

The company's actions resulted in a number of legal consequences, including criminal charges, civil lawsuits, and regulatory sanctions. Elizabeth Holmes was charged with wire fraud, conspiracy to

commit wire fraud, and other crimes. The company was sued by investors for securities fraud, by patients for medical malpractice, and by employees for wrongful termination. The company was fined by regulators for violations of laboratory standards, and was banned from operating in the healthcare industry. Johnson, 2018

Conclusions and Recommendations

The Theranos scandal has taught us a number of important lessons about entrepreneurship, innovation, and ethics. The scandal has shown us that success is not guaranteed, and that failure is always a possibility. It has shown us that innovation is not enough, and that execution is just as important. It has shown us that vision and

mission are not enough, and that values and culture are just as important. It has shown us that leadership is not enough, and that integrity and accountability are just as important. It has shown us that trust is not enough, and that transparency and honesty are just as important.

One may recommend that
entrepreneurs and innovators should focus
on solving real problems, and on creating
real value. They should focus on building
products and services that people need and
want, and that they are willing to pay for.
Not only should they focus on building
products and services that work, but also on
building products and services that are safe,
reliable, and effective.

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