The rise and fall of Theranos: analysing the corporate and regulatory collapse.

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The rise and fall of Theranos represents one of the most emblematic scandals of governance and business ethics in modern history. Founded by the Stanford dropout Elizabeth Holmes, the company promised to revolutionize the medical diagnosis by developing a new machine, that only needed a few drops of blood to run hundreds of medical tests. At its peak between 2014 and 2015, Theranos achieved a private valuation of $9 billion (Carreyrou, 2018; SEC, 2018). However, by mid-2016, following regulatory investigations and exposed inaccurate diagnostics, its equity valuation sank to $0 prior to its formal dissolution (Carreyrou, 2018; Herper, 2016).

This collapse raised fundamental questions regarding the efficiency of corporate governance mechanisms and external oversight mechanisms.

To address these systemic breakdowns, this paper addresses the following research question: *how do structural governance deficiencies and regulatory blind spots enable prolonged, large-scale corporate fraud?*

To answer this question, this study primarily focuses on an in-depth analysis of Theranos' development, internal governance structure and regulatory evasion tactics. Subsequently, it proposes a comparison with Germany's Wirecard scandal, to demonstrate that Theranos is not an isolated case confined to a single firm or jurisdiction (BaFin, 2020; McCrum, 2020).



1. Factual analysis

In 2002, while still being enrolled as an undergraduate at Stanford University, Elizabeth Holmes proposed an initial idea for a microfluidic patch designed to deliver targeted antibiotics, while continuously monitoring patient biomarkers for infections (Bostag, 2019; Carreyrou 2018).

Holmes proposed it to Dr. Phyllis Gardner, a professor of medicine and pharmacology at Stanford University School of Medicine. The professor evaluated the proposed patch as scientifically unviable, due to physical constraint on microfluid delivery. She also urged and advised Holmes to focus on her engineering studies (Carreyrou, 2018; Gardner, 2018).

Modelling her public persona and operating after Apple co-founder Steve Jobs, Holmes withdrew from Stanford during her sophomore year to invest her tuition funds towards commercializing a revised microfluidic concept: blood diagnostics obtained via a single finger prick-sample (Carreyrou, 2018; Bilton, 2016). Her purpose was to make blood testing more accessible, easier and faster, also by avoiding needles, that scare people. She aimed to make people test more and discover eventual illnesses early and on time.

To initiate clinical development, Elizabeth recruited early scientific staff, including Ian Gibbson, a Cambridge-educated biochemist who became Theranos' chief scientist. Everyone was very enthusiastic to be part of such a noble work that would change MedTech and make people's life easier. However, convincing investors was more difficult. The main issue was that the patch was in a trial phase; there were no reliable tests yet. Investors wanted results and it was too early: trials need more time and lots of resources. She had to find a way to get investors, so she decided to rely on something else than actual results: charisma. As she started meeting companies, she would avoid the topic and focus on the possible outcome: a revolution in the medical world. She also bypassed standard healthcare-focused institutional investors, who demanded peer-reviewed technological

validation, relying instead on high-net-worth individual private investors and politically connected board members (Carreyrou, 2018; SEC, 2018).

By 2008, internal friction intensified between executive management and early financial backers. Members of the Board of Directors expressed significant concern over Holmes' managerial skills and proposed to replace her with an experienced healthcare executive (Carreyrou, 2018). In order to keep the situation under control, she introduced Ramesh "Sunny" Balwani to the company, a software entrepreneur with whom Holmes was in a romantic relationship. He provided a $13milion personal loan guarantee to the company and was later appointed Chief Operating Officer (COO) and President in 2009 (Carreyrou, 2018; SEC, 2018). It lead to an unaddressed conflict of interests, since executive power was concentrated within an undisclosed personal partnership.

In 2013, the firm signed a major retail partnership with Walgreens: the largest drugstore chain in the United States at the time. The commercialisation proceeded despite severe internal failure rates in their machine, known as the Edison (Carreyrou, 2018; CMS, 2016). To fulfil the high-volume clinical testing agreements with Walgreens, Theranos secretly bypassed their own technology. The management acquired third-party analysers manufactured by Siemens, which were used wrongly, as they tested diluted finger-prick blood samples, which eventually lead to false results. Operating these modified commercial analysers without clinical validation meant violating federal regulations under the Clinical Laboratory Improvement Amendments of 1988. To cover this kind of violations and to maintain the company's reputation, executive management enforced operational opacity internally by requiring all the employees to sign stringent NDAs. Although legally unenforceable against reporting crime and regulatory violations, Holmes and Balwani used them as aggressive legal intimidation tactics to deter whistleblowing.

After over a decade of Theranos' empire, a journalist from the *Wall Street Journal*, John Carreyrou, managed to investigate on what was happening inside closed doors. His biggest tool were the tips he obtained from whistleblowers Tyler Shultz, Erika Cheung and Doctor Adam Rosendorff. Tyler Shultz, grandson of the Board member Goerge Shultz, and Erika Cheung, were newly graduates, who were working in labs under the lead of Doctor Rosendorff. The noble purpose they thought they were working for vanished after being hired. Upon observing systemic quality control falsifications and patient safety risks, Cheung and Schultz attempted to raise concerns through internal corporate governance channels. When the executive leadership suppressed their complaints, the two young researches resigned and submitted regulatory disclosure directly to the Centres for Medicare & Medicaid Services (CMS) and the investigative reporter John Carreyrou of *The Wall Street Journal* (Carreyrou, 2015, 2018). Theranos' external legal counsel, led by the well-known David Boies, engaged in

extensive legal intimidation campaigns, threatening expensive litigations against the whistleblowers and the journal to obstruct the publication.

On October, John Carreyrou finally published the article, despite the legal treats (Carreyrou, 2018). He exposed the technological failures and reliance on third-party commercial analysers (Carreyrou, 2015).

The lid was taken off: in 2016, CMS issued formal sanction warnings, unannounced laboratory inspections and revoked Theranos' CLIA operating certificate, while also imposing a two-year laboratory ban on Holmes. In June 2018 a federal grand jury indicted both Holmes and Balwani on multiple counts of wire fraud and conspiracy to commit wire fraud (U.S. Department of Justice, 2018). The indictment broke the charges into two distinct schemes: defrauding of patients and investors. In September 2018 Theranos formally ceased all operations and completed equity liquidation (Carreyrou, 2018).

The former executives were finally convicted in 2022 in the U.S. District Court in the Northern District of California. Holmes was convicted on four counts: one count of conspiracy to commit wire fraud against investors and three individual wire-fraud counts related to investors. She was acquitted of all patient related fraud and conspiracy counts submitted to the jury. She was sentenced to over 11 years in federal prison. Balwani, who was tried separately, was convicted on 12 counts of fraud, including both investor and patient related fraud counts, and sentenced to almost 13 years in federal prison (U.S. Department of Justice, 2018).



Elizabeth Holmes, the chief executive officer and founder of Theranos, a health care technology company, listens as Deputy Secretary of Defense Ash Carter speaks at Stanford University in Palo Alto, Calif., April 17, 2013. (DoD photo by Glenn Fawcett/Released)

3. Governance failures.

3.1 Organisational level

On an organisational level, Theranos was characterized by extreme secrecy: employees had to sign non-disclosure agreements as soon as hired. They were not allowed to speak about what was happening inside the labs with the outside world. Inside the company, people from different laboratories were not allowed to discuss their work and they would disincentive any confrontation happening between colleagues. This lack of transparency was the best way to avoid any flow of information and to keep the Pandora box closed.

This operational opacity was aggravated by structural vulnerabilities within the Board of Directors. Instead of appointing directors with specialized background within the scientifical field, Holmes assembled a board dominated by high-profile political diplomatic figures, such as former Secretaries of State George Shultz and Henry Kissinger, and retired General James Mattis (Carreyrou, 2018; Executive Guidance, 2020). While these members possessed immense geopolitical stature, they lacked the required technical expertise to evaluate clinical data or conduct independent medical due diligence (Bostag, 2019; Carreyrou, 2018). Although the board did include medical professionals, such as Dr. William Foege, former director of the Centres for Disease Control and Prevention, their influence was secondary, leaving the board functionally incapable of executing rigorous medical oversight.

Due to this lack of competence, they were able to keep up with the façade without anyone from the outside noticing, except from the people inside the labs who were constantly silenced.

The strategic implementation of a dual-class shares structure and voting-rights concentration guaranteed Holmes' absolute control. By issuing Class B common shares carrying 100 votes per share alongside Class A single-vote preferred shares, Holmes secured approximately 99% of total voting control (Executive Guidance, 2020; SEC, 2018).

3.2 **Lack of checks and balances.**

The structure of publicly listed companies requires the presence of an audit committee, as an internal check on accounting integrity and financial reporting. Because Theranos operated as a closely held private startup, it was legally exempt from the public-company audit committee and SEC periodic-reporting requirements. However, this exemption did not exempt Theranos of general corporate accounting standard, tax obligations and contractual reporting duties to its investors.

Holmes and Balwani controlled financial information, leading to a constant misrepresentation of their financial achievements. There was a lack of transparency, which mislead investors and the public.

The lack of Whistleblowing channels obstructed any internal feedback, which stopped their employees from reporting any ethical breaches. The management weaponized NDAs, active surveillance, threats of immediate termination and aggressive legal intimidation by outside counsels. When researchers identified inaccurate diagnosis, executive management re-

sponded with retaliation. They would reassign them, revoke system access and issue formal litigation warning (Carreyrou, 2018).

3.3 **Regulatory blind spots.**

To reduce the pre-market review by the U.S. Food and Drug Administration (FDA), they classified their product as Laboratory-Developed Tests. This qualification was designed for localised diagnostic tests, that according to MDC Associates were designed, manufactured, and used within a single clinical laboratory. Theranos exploited this regulatory grey area, arguing that their tests were developed in their centralised CLIA-certified laboratory in California, meaning they were not supposed to obtain the pre-market FDA approval. However, they did not place the company entirely outside FDA oversight: Theranos obtained clearance for its HSV-1 assay in 2015, and the FDA later inspected the company, classifying its blood-collection container, the "Nanotainer", as an uncleared medical device and forcing Theranos to suspend its use.

At the state level, oversight fell under the primary jurisdiction of the California department of Public Health (CDPH), which governed the primary laboratory, and the Arizona Department of Health Services, that oversaw the regional testing operations established through the Walgreens partnership (CMS, 2016; Carreyrou, 2018). Despite having a clear legal authority to inspect and sanction clinical laboratories, these regional authorities failed to uncover this fraud.

Primarily, because they relied on scheduled relicensing inspections rather than unannounced forensic audits. These surveys only evaluated standard administrative compliance, rather than conduct or algorithmic forensic reviews of proprietary diagnostic instrumentation (Carreyrou, 2018; CMS, 2016).

Secondarily, when state health authorities conducted on-site evaluations, Holmes and Balwani obstructed the auditing, through active deception and data curation. Regional auditors were shown a stage-managed representation of the laboratory's capabilities (Carreyrou, 2018).

Ultimately, they manipulated and selected the data reporting when submitting Quality Control and proficiency testing (CMS, 2016; SEC, 2018).

Through these tactics, Theranos and Wirecard successfully manufactured a façade of regulatory compliance.

4. **Comparison: Theranos versus Wirecard**

To evaluate whether the governance failures analysed at Theranos represent an isolated corporate anomaly, it is elucidating to compare the company's collapse with Germany's Wirecard (McCrum, 2020; European Parliament, 2020).

Wirecard, the "German PayPal" was a payment services provider, which processed electronic payments for online merchants (McCrum, 2020). The fraud consisted in a 25% of total assets allegedly held in Asia, which then turned out not to exist.

First, we can easily see a few common threads such as lies and secrecy. Both scandals show how extreme structural opacity can obstruct external oversight across regulatory environments.

Theranos maintained opacity through the technical "black box" of the Edison machine and aggressive trade secrecy (Carreyrou, 2018). At Wirecard, opacity was obtained through the reliance on Third-Party Acquiring in Asia, where transactions were conducted through opaque offshore firms that obscured the information flow to statutory auditors (BaFin, 2020; McCrum, 2020).

Furthermore, both organizations were characterised by centralised executive leadership that bypassed traditional board oversight. Just as Balwani and Holmes dominated operational decisions through voting control, Wirecard Ceo Markus Braun and COO Jan Marsalek exercised autocratic management over operational reporting, isolating supervisory board members from direct access to transactional audit logs (BaFin, 2020; McCru, 2020).

Intimidation is a very common thread among high management, especially when aiming to prevent the flow of information. It can happen through different forms: behaviours, raising voices, threats, relentless legal teams. Theranos has distinguished itself because of the culture of fear: Balwani was very aggressive, and the signed NDAs were a threat (Carreyrou, 2018).

Wirecard executed a structurally parallel strategy of suppression to protect its public stock valuation and executive reputation, by also extending intimidation tactics beyond employees to external critics and financial journalists (BaFin, 2020; McCrum, 2020). When Dan McCrum, a journalist from the Financial Times, published investigative reports exposing the ongoing fraud involving Third-Party acquiring transactions in Singapore and the Philippines, Wirecard's CEO Markus Braun publicly denied all allegations. Wirecard also initiated criminal complaint and civil litigations to launch criminal investigations against the journalist (BaFin, 2020; European Parliament, 2020; McCrum, 2020).

Both companies applied the same strategy: anything to suppress the truth in favor of maintaining the stock price and the founder's image.

Another common thread was the collapse of the so called "watchdogs", including regulatory and oversight bodies. Regarding Theranos, CMS and state health regulators relied on self-reported validation metrics and staged representations of the laboratory's capacities, which allowed the company to hide severe flaws in testing and quality control. However, a distinction must be made between clinical regulatory oversight and criminal financial fraud: CMS and CLIA regulators were tasked with enforcing laboratory safety standards, not detecting investor fraud. While Theranos exploited loopholes to bypass health regulations, uncovering the broader scheme to deceive investors ultimately required the intervention of federal prosecutors and securities regulators.

In Wirecard, the German Federal Financial Supervisory Authority (BaFin) was heavily criticised for its handling of the fraud allegations reported by Dan McCrum. Because of Germany's two tiered regulatory framework and Wirecard's classification as a technology company rather than a financial institution, BaFin lacked direct authority over the parent entity's accounting. Instead of launching an investigation, which fell under the jurisdiction of the Financial Reporting Enforcement Panel (FREP), BaFin focused on market manipulation, imposing a temporary two month ban on short-selling Wirecard stock and filing criminal complaints against investigative journalists (BaFin, 2020). While widely seen as a watchdog failure, this response was the result of internal structural limits.

Whistleblowers helped open Pandora's boxes in both cases. People were able to overcome the obstacles coming from the companies, such as different kind of intimidations. In Theranos the most impactful ones were Tyler Schulz and Erika Cheung. In Wirecard it was Pav Gill, who overcame legal threats to report their criminal conduct to investigative journalists (Carreyrou, 2018; McCrum 2020).

The comparison between these two scandals proves and confirms how governance collapses of this scale are not governance anomalies, but rather results of regulatory voids in high growth sectors, governance failures and severe information asymmetry (BaFin, 2020; Bostag, 2019).

5. **Conclusion.**

The collapse of Theranos, and the other mentioned one, are a strong reminder that innovation without oversight is a charade. The common thread between these scandals was a glamorous façade used to avoid due diligence and watchdogs.

The lack of transparency witnessed, especially in the field of MedTech, was endangering human lives and resulting into a dystopian ethical disaster.

Corporate and institutional governance is a fundamental tool for ensuring proper corporate conduct in defence of employees and the public, so its significance and usefulness should not be understated.

To prevent similar failures institutional governance bodies must mandate independent technical due diligence before entering the market and enforce Whistleblower's' channels and their protection.

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