## Theranos: When Good Intentions Go Awry

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WRIT 159A (Scientific Literacy)

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March 19th, 2023

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In June of 2013, Tyler Shultz graduated from Stanford University with a B.S. in biology. Although he was originally pursuing a degree in mechanical engineering, Tyler changed his major to biology midway through his sophomore year (Williams, 2022). He wanted to work for one of Silicon Valley's most influential biotechnology companies, which meant he would have to permanently alter his career path. His heart was already set on a career with the company, however. His grandfather, George Shultz, even introduced him to the CEO herself: a confident young woman who dreamed of democratizing healthcare. Her company, Theranos, promised a world where people would have access to crucial health information (literally) at their fingertips.

Tyler Shultz joined Theranos just three months after his graduation. After a short career of just eight months, he would leave the company and play a major role in exposing its fraudulent practices, potentially saving thousands of lives. But what was Theranos, and what about it was so enticing that it drove Tyler to change the course of his life forever?

In 2003, Theranos was an up-and-coming tech startup in the heart of Silicon Valley, newly founded by a 19 year-old Elizabeth Holmes (O'Brien, 2022). Holmes wasn't satisfied by the idea of a safe and lofty career; she wanted to create something truly groundbreaking that would advance humanity forward, following in the footsteps of her idol, Steve Jobs. It's likely that this mindset is what motivated Holmes to drop out of Stanford in 2004, using the very last of her tuition to get Theranos off the ground (Auletta, 2014).

Holmes' ambition was to reimagine the blood testing process by making them more accessible, convenient, and needle-free (Holmes would often cite her fear of needles as a motivating factor behind creating Theranos) (Auletta, 2014; Belvedere, 2015). In a truly Steve Jobs-like fashion, Holmes wanted to "miniaturize and automatize" (Auletta, 2014) the process,

stripping it down to its most fundamental components: a blood sample and a machine to run tests. To accomplish this, Holmes created the Edison machine, a device that could test for a variety of conditions using the same blood sample (Auletta, 2014; Diamandis, 2015). To take the blood test, all the patient would have to do is prick their finger with a fingerstick device, extract a few drops of blood, and send the sample to their nearest Theranos facility (Auletta, 2014).

It's worth noting that Holmes herself had virtually no qualifications and very limited knowledge on the science behind what the Edison device was supposed to do. For context, traditional blood testing protocols are a far more complex and involved process: before receiving a blood test, the patient has to meet with their healthcare provider to confirm whether or not a test is even necessary. Upon receiving a referral, patients need to visit the appropriate testing facility, where they'll be sat down as doctors extract their blood directly from the median cubital vein (Rickard, 2015). Each unique test requires its own sample; once the tests are conducted, results are sent directly to the patient's healthcare provider for diagnostic information (Rickard, 2015). The process can be tedious and downright painful, but these protocols exist for good reason. Taking blood directly from the vein mitigates the threat of environmental contamination (Auletta, 2014), and accurate results can only be obtained with a sufficiently large sample of blood. The Edison had no apparent means of mitigating the risks of automatizing the blood testing process, leaving many questioning how it was supposed to work (assuming it worked at all). These questions would ultimately go unanswered.

Holmes' apparent lack of qualifications was just as apparent as the absence of peer-reviewed research supporting the technology (Ioannidis, 2015). Despite this, investors and the media flocked to support Theranos. This was undoubtedly in part due its all-star cast of board members, featuring prominent figures such as former cabinet member Henry Kissinger and

epidemiologist William H. Foege (Auletta, 2014). Among Theranos' repertoire of powerful allies was American politician George Shultz, who met Holmes personally in 2011 before joining the board a few years later (Primeaux, 2019). It was during this fateful meeting that his grandson, Tyler Shultz, was introduced to Holmes herself. Tyler was absolutely captivated by Holmes' vision. Less than a year later, he switched his major from mechanical engineering to biology with the intent to join Theranos immediately after he graduated.

When Tyler began working for Theranos in September of 2013, he was one of a select few who discovered the secret behind Theranos' impossible technology: the Edison device didn't work. Employees would regularly encounter a slew of problems with the Edison device, such as doors failing to close, gears jamming, and the machine even failing to regulate its own temperature (Primeaux, 2019). When it did work, the resulting data was almost always inaccurate. Tyler and his coworkers were forced to adopt a "repeat and delete" approach: outliers and unusual results in the data would be deleted and replaced with data from subsequent tests (Berke, 2019; Primeaux, 2019). In some cases, tests had to be conducted on competitors' equipment-- but regardless of the source, consumers were always led to believe that their tests were run with the Edison (Berke, 2019; Primeaux, 2019).

While employees suffered behind the scenes, Theranos hid under a veneer of deliberate secrecy. The contents of the Edison were "treated as a state secret" in the media (Auletta, 2014), and employees were prohibited from sharing any details of their work with those outside the company (Primeaux, 2019). When Holmes herself was asked how the Edison worked, her answer was appropriately vague: "A chemistry is performed so that a chemical reaction occurs and generates a signal from the chemical interaction with the sample, which is translated into a result, which is then reviewed by certified laboratory personnel." (Auletta, 2014) Admittedly,

Holmes did think to co-author a peer-reviewed pilot study to verify the accuracy of the machine's results (Chan et al., 2014). The data from the Edison was, of course, collected internally at a Theranos facility with no external observers to speak of.

In early 2014, Tyler began meeting with fellow employee Erika Cheung, who joined the company only a month after he did (Berke, 2019; Primeaux, 2019). They discussed their many failed attempts to bring up the problems they experienced with higher management and even Holmes herself. Theranos' extraordinary claims would never stand up to scrutiny if they were brought to light; everyone within the company knew this, but the insular company culture prevented anyone from speaking up. Without intervention, Holmes' fraud would likely go unnoticed until it was too late.

In April of the same year, Tyler and Cheung ultimately made the decision to blow the whistle, contacting the New York State Department of Health and leaving the company shortly afterwards (Primeaux, 2019). The call triggered a series of in-depth investigations on Theranos from 2014 to 2015, during which Tyler would remain in close contact with Wall Street Journal reporter John Carreyou (Primeaux, 2019). The situation pitted Tyler against his own grandfather, who continued to work with Holmes throughout the investigation; at one point, Shultz even worked with Theranos lawyers to prevent his own grandson from taking action against the company. On multiple occasions, lawyers from Theranos would appear in their family home and attempt to intimidate Tyler into signing several legal documents that would incriminate him for attempting to leak "trade secrets" (Primeaux, 2019). He refused to sign anything and remained in contact with Carreyou throughout 2015.

The story broke into mainstream consciousness in October 2015 when Carreyou published an article in the Wall Street Journal that echoed many of Tyler's findings, namely that

Theranos ran their test on competitors' equipment (Carreyou, 2015). What followed was a steep and rapid decline as people lost faith in Holmes' vision. By 2016, Theranos had lost almost all of its partnerships with corporate monoliths such as Walgreens and Safeway, leaving the company with virtually no financial backers. Once touted by Forbes as the world's "youngest female billionaire", Holmes' net worth had now dropped to zero (O'Brien, 2016). Two years later, Theranos would be dissolved and Holmes would be indicted for criminal fraud. Tyler would eventually go on to repair his relationship with his grandfather, who would unfortunately pass away in 2021. Both would go on to found Ethics in Entrepreneurship, a non-profit dedicated to preventing fraud in the commercial sciences; to this day, they remain colleagues and close friends (Berke, 2019; Primeaux, 2019).

Theranos was an utter catastrophe fueled by scientific fraud that put countless lives at risk.; that being said, it could be argued that Theranos' failings came almost entirely from the rapid execution of its core idea. Although the idea was truly exceptional, the technology behind the Edison device would have to be leaps and bounds ahead of current science to be even remotely functional. However, the unrelenting torrent of positive media attention around both Theranos and Holmes herself-- especially given her status as a female self-made billionaire in STEM-- created pressure to deliver a marketable product under a set deadline; this fast-paced, profit-focused mindset is incompatible with the slow-paced and methodical way in which science is meant to run its course. Theranos would've needed far more time and expertise to develop its core idea into something useful. When we rush scientific inquiry to push profit-based interests, we sabotage the development of science itself, turning potentially brilliant ideas into stories of failure and deception.

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