

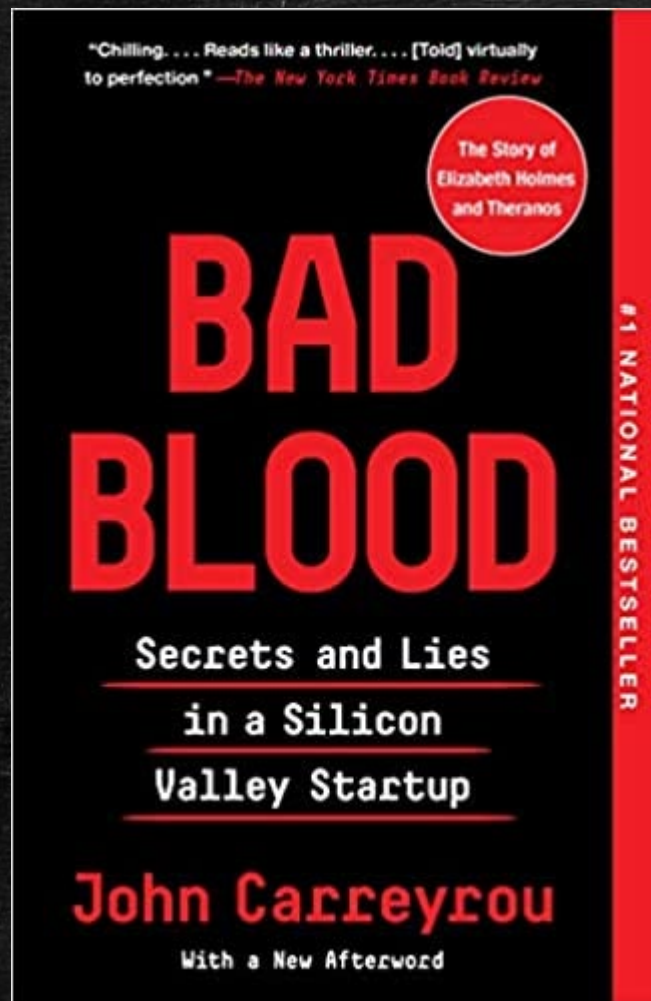


Elizabeth Holmes

Theranos Founder, CEO, and Convicted Felon

Brent Wilson, JD
Chief Compliance Officer, University of Utah Health

Sources for the Story:



The United States vs. Elizabeth A. Holmes

- Indictment:

- Count 1: Conspiracy to Commit Wire Fraud against Theranos Investors.
- Count 2: Conspiracy to Commit Wire Fraud against Doctors and Theranos Patients.
- Counts 3-8: Wire Fraud against Theranos investors.
- Counts 9-12: Wire Fraud against Theranos patients.





Verdict

- Count 1: Guilty Conspiracy to Commit Wire Fraud – investors.
- Count 2: Not Guilty Conspiracy to Commit Wire Fraud – patients.
- Counts 3-5: Hung Jury/no verdict Wire Fraud – investors.
- Count 6: Guilty Wire Fraud – investors.
- Count 7: Guilty Wire Fraud – investors.
- Count 8: Guilty Wire Fraud – investors.
- Counts 10-12: Not Guilt Wire Fraud – patients.

What made Holmes Different?

- Childhood aspirations.
- Elizabeth Holmes was different from other founders.
- Holding sway over investors and board members:
 - Don Lucas
 - George Schultz
 - Henry Kissinger
 - Robertson (Stanford Professor)
- Medical device start up.
 - No degree.
 - No scientific or medical experience.
- Sexism in Silicon Valley

The Idea

- Afraid of needles.
- Genome Institute in Singapore.
- The patch.
- The mini-lab.
- The Uncle.
- Medical technology Venture Capital firm – rejection.
- Co-Founder doubts.



Dr. Phyllis Gardner – Early Impressions



- Stanford professor, was an early mentor to Holmes.
 - Stanford students would ask to invite Holmes to speak as a female founder, but Gardner wouldn't allow it.
 - "I support women. I always have. I've gotten in trouble for it. I've pushed hard ... But I'm not going to support a fraud — I don't care what your gender is."
 - "You put people in danger ... I don't forgive that."

TedMed 2014



Unpacking TedMed Talk

- It does not appear Holmes was at all close to her uncle.
 - He died 18 months before the TedMed talk, long after Holmes came up with the idea for a miniaturized lab.
 - Bad Blood: “To family members who knew the reality of their relationship, using his death to promote her company felt phony and exploitative...”.
- “Actionable” health information and access to care.
 - Sales pitch.
 - No information about how the technology works.
 - No explanation for what patients might do with “actionable” health information.

Dissent: Not Tolerated

- CFO Henry Mosley.
- Avie Tevanian.
- Todd Surdey and Michael Esquivel.
- Kevin Hunter.
- Lieutenant Colonel David Shoemaker.
- Employee Dossiers.



Science Stuff – finger sticks and research

- Ken Auletta [New Yorker](#):
 - Quest : finger stick blood tests are not reliable for clinical diagnostics.
 - “Comically vague.”
 - Asked Theranos for third party data to verify; none provided.
- [Some research studies](#) suggest that finger sticks may not be reliable for diagnostic purposes.
- Theranos [damaged](#) other testing companies' efforts.
- Some scientists say Holmes's idea is [impossible](#).
- Complete lack of peer review or third-party verification
- “Move fast, break stuff” ethos does not work for medical startups.
- Alternative Approach: peer reviewed or clinical research.
 - [Belmont Report](#). Ethical Principles and Guidelines for the Protection of Human Subjects of Research

Ducking FDA Oversight

- FDA approves blood testing equipment that is sold by a manufacturer to a testing company.
 - For example: Siemens makes blood testing devices and testing companies like Quest and LabCore purchase them. FDA must approve Siemens machines.
- Theranos manufactured its own devices.
 - This does not require FDA approval as long as Theranos did not sell their machines or allow them for use outside of its own lab.
- Zero scientific testing.
- Zero peer review.
- Zero disclosure about how the testing device actually works.

Ian Gibbons

- Seasoned scientist.
- Friends with Channing Robertson.
- Realized that they could not make the math add up.
- Holmes fired, then re-hired, but in a demoted position.
- Theranos sued Richard Fuisz over a patent dispute and Fuisz asked to depose Gibbons.
- Discovered that Holmes was added to all Theranos patents as lead inventor.

The Whistleblowers



- [Erika Cheung](#) and [Tyler Schultz](#) help blow the lid off.
- Noticed the machines did not work as intended.
- Emailed CLIA.
- Reported to Holmes.
- Quit/fired and ambushed.
- Reported to CMS – lab inspection.
- Holmes at trial: [wishes she had treated them better.](#)

Prosecution vs. Defense - Trial Strategy

- Robert Leach – lead DOJ prosecutor:
 - Manipulative fraudster.
 - Lied to get money.
- Lance Wade:
 - Blind faith in Balwani and trusted lab directors, who were responsible for the lab.
 - Mistakes do not equal crime.
 - Investors failed due diligence.



The Smoking Guns



CONFIDENTIAL



For this study, an instrument was deployed in the home of each patient; four others were installed at the Cancer Center.

Three assays were performed simultaneously in multiplex by the system on a finger-stick sample of fresh whole blood. The analytes were Vascular Endothelial Growth Factor (VEGF), soluble VEGF receptor R2 (sVEGFR2, usually referred to as VEGFR2) and Placental Growth Factor (PLGF). Each assay was controlled using within-cartridge control measurements.

The system was calibrated at Theranos. Multiple cartridge lots were produced each with successively more clinically relevant specifications once samples were received from patients in the trial, as samples were not available during assay validation. Each lot was independently calibrated.

- The Pfizer Letter/pharma reports:
 - Holmes altered herself.
 - Logo indicated Pfizer support.
- Financial Projections:
 - Essentially a fantasy.
- Fortune Article.
 - Lied about lab.
- Texts:
 - CMS inspection.
 - Media coverage brings deals.

Key Testimony

- Holmes: I was in charge.
- Holmes's claims to investors that technology was currently in use were lies.
- Balwani abuse.
 - Met at Stanford Chinese immersion program; Holmes 18, Balwani 38.
 - Controlling.
 - Sexual assault.
 - Balwani denies abuse.
 - "He impacted everything about who I was, and I don't fully understand that."
 - Jury: believed Holmes, but not relevant.



Post Trial Motions and Appeal

- Kevin Downey and John Cline, Connelly & Williams, defense counsel for Elizabeth Holmes.
- Defense counsel indicated it will file motions for an acquittal and for new trial.
- An appeal will inevitably follow – likelihood of success?
- Holmes will likely remain free during any appeals process.



Sentencing

- Currently set for Sept. 26.
- Experts vary, but most believe the sentence will include some prison time.
- Sentencing Guidelines:
 - Long:
 - Hundreds of millions in fraud.
 - Led the fraud.
 - Many investors involved.
 - Short:
 - First time offender.
 - New mother.
 - Abuse victim.



Balwani Trial

- Initially indicted together.
- Trials separated because of Holmes's defense strategies.
- The prosecution began calling witnesses late last week.
- Opening Statements:
 - DOJ: partners in crime.
 - Defense: this was all Holmes.

