



Holmes verdicts prompt questions over justice for patients

The founder of Theranos was found guilty of defrauding some investors, but cleared of charges that she misled patients. Susan Jaffe reports.

On Jan 3, a federal jury in California found Elizabeth Holmes, creator of the blood-testing startup Theranos, guilty of lying to some of her investors about a portable blood analyser that she claimed would transform health care. It could run dozens of tests from a fingerprick of blood, she said, and deliver dependable results quickly. However, government prosecutors' account of Holmes's empty promises and hype failed to convince the jury that she also deceived patients and their doctors who depended on her device's inaccurate readings.

"There were over a million tests that patients had which were fraudulent", said Eric Topol, a cardiologist and founder and director of the Scripps Research Translational Institute (La Jolla, CA, USA), where he is a professor of molecular medicine. "That is the most egregious part."

Holmes was convicted of four charges of wire fraud for swindling some investors out of at least US\$144.3 million, according to the federal indictment. Each charge carries a maximum 20 year prison term and a fine up of to \$250 000. However, the

jury could not agree on three other fraud charges involving a total of \$11.5 million, and found her not guilty of four more charges of defrauding patients who used Theranos blood tests.

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Holmes remains free on bond while her legal team decides whether to file an appeal. As this report went to press, a sentencing date had not been set and lawyers for the US Department of Justice, which filed the charges against Holmes, had not yet said whether they will seek a retrial on the three undecided charges. Holmes has no previous criminal convictions and is not expected to receive the maximum 20 year prison terms for each of her guilty verdicts. Former Theranos president Ramesh Balwani faces the same charges, and his trial is expected to begin in the coming weeks. He has pled not guilty.

Patients left behind

During the 15 week trial, 29 witnesses took the stand, but only three were patients or doctors. Two witnesses testified about getting Theranos tests that incorrectly detected HIV/AIDS and prostate cancer. A third person testified that a Theranos blood test she took at an Arizona Walgreens pharmacy showed a high level of a hormone indicating she was having a miscarriage. When the test was repeated twice by a different laboratory, the results showed that her pregnancy was still viable. The three witnesses spent a total of just 65 min on the stand, and eight other patients who were on a list of potential witnesses never testified, *The Wall Street Journal* reported.

Some legal experts have concluded that the prosecution's evidence was not strong enough to tie Holmes directly to the company's fraudulent assurances provided to doctors and patients. "She's not the one who's actually having the communications with the doctors or the patients, while she was the one who had the communications with the investors", said Howard Fischer, a former senior trial prosecutor at the New York office of the US Securities and Exchange Commission who specialised in investment fraud cases and is now a partner at the New York law firm Moses & Singer. "I wasn't in the jury room, but I would imagine that the jurors probably looked at the attenuated connection between her and the patients as reasons to come up with a not guilty verdict."

However, Edward Ashwood, director of clinical laboratories at the University of Colorado's School of Medicine (Aurora, CO, USA), pointed to efforts by Theranos to sell its tests to patients. "Theranos rallied the support of Arizona physician groups and government officials to change the law to allow companies to market laboratory tests directly to consumers", said Ashwood, who is the immediate past president of the American Board of Pathology. "They were going directly at the docs and patients with everything they had."

In 2015, Arizona's governor signed legislation, which was co-authored by Theranos, into law at a Theranos laboratory in Scottsdale, AZ, the newspaper *USA Today* reported. The law allows patients to get blood tests without a doctor's order. "This bill demonstrates that we can facilitate a new era between physicians and patients", Holmes told *USA Today*. "If people begin to engage, they can test and monitor their health before they get sick."



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Rise and fall

Holmes established Theranos in 2003 at the age of 19, and, by 2014, it was valued at \$9 billion, of which she owned half. "Her \$4.5 billion net worth makes her both the youngest, and the richest, self-made female billionaire on the Forbes 400", the magazine declared in 2014.

A year earlier, Topol interviewed Holmes at the Theranos headquarters in Palo Alto, CA, for the medical news website Medscape, where he was also editor-in-chief. Before the interview, Topol wanted to get a Theranos blood test. It was surprisingly painless. When he asked to see how the Theranos technology would analyse his blood sample, Holmes told him he could not because that process was a trade secret.

He got the results in an email after the visit, while he was travelling back to the airport. The 20 tests were all normal and in line with tests he had done a few months before. "The fact that she got these results for me, gave her some credibility", he said. "Maybe she was the real deal."

During the interview, Holmes described why her device could make a difference to patients' lives. "To me, there was nothing greater that I could build than something that would change the reality in our health-care system today, which is that when someone you love gets really, really sick, usually by the time you find that out, it's too late to be able to do something about it."

"I wanted her to succeed", Topol remembered. "She's a young person with a good idea and something that we could really use." Looking back, he said his positive impression of Holmes was influenced by "confirmation bias". (Topol was on the list of potential witnesses for the prosecution but was not called on to testify in her trial).

Topol credits John Carreyrou with exposing the Theranos scandal in a series of reports for *The Wall Street Journal* beginning in late 2015. Soon

after, the Centers for Medicare & Medicaid Services found that the Theranos laboratory violated federal rules, and the US Food and Drug Administration reclassified the nanotainers—devices that store the droplets of blood—as higher-risk medical devices subject to additional safety requirements.

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In 2017, Theranos agreed to pay more than 76 000 Arizona customers \$4.6 million to settle claims by the Arizona Attorney General that the company's "advertisements misrepresented the method, accuracy, and reliability of its blood testing and that the company was out of compliance with federal regulations contained in the Clinical Laboratory Improvement Amendments of 1988".

The US Securities and Exchange Commission landed a further blow in March, 2018, charging Holmes and Balwani "with raising more than \$700 million from investors through an elaborate, years-long fraud in which they exaggerated or made false statements about the company's technology, business, and financial performance". To resolve the charges, the company paid a \$500 000 penalty, and Holmes gave up control of the company and returned 18.9 million shares in the company that she obtained fraudulently. 3 months later, the federal government indicted Holmes and Balwani for defrauding investors and patients. By the end of 2018, Theranos was dissolved. *Forbes* has revised her net worth down from \$4.5 billion to zero.

In September, 2021, a three-judge panel of the US Court Of Appeals for the Ninth Circuit allowed a class action lawsuit to proceed against Holmes, Balwani, and Walgreens filed by patients in California and Arizona who

received Theranos blood tests. If they are successful, thousands of patients could receive compensation.

Impact on innovation

Even though Holmes was in charge of the company and was its masterful champion, her lawyers claimed that Holmes—a Stanford University dropout—was misled by the scientists employed by her who provided assurances that the Theranos equipment worked. They also claimed she was abused by Balwani, who was also her romantic partner for several years. Additionally, they claimed that wealthy A-list investors should have done their own due diligence before parting with hundreds of millions of their dollars.

"In the criminal context, victims don't have an obligation to ensure that they're not being defrauded", said Fischer. "We've been accustomed in the last few years to companies that explode and which make their early investors phenomenally wealthy. And everyone wants to be part of the next PayPal, the next Facebook, the next Google and they ignore the fact that it could be the next WeWork."

Fischer does not think that the Holmes verdict will dissuade investors from backing biomedical startups. "There is a far greater store of money than there are opportunities to invest it", said Fischer. "Secondly, with interest rates so low, the only real way to make money is to take significant risks. And that means investing in startups that might not have a product out but have a good story." Additionally, Ashwood is not worried that the verdict will stifle biomedical innovation. "I've seen no diminution in how many new tests are coming onto the market", he said. "People are always trying to invent new things. I try to invent new things. What it should stifle is fraud."

Susan Jaffe