



## Theranos founder counters fraud charges in federal trial

Elizabeth Holmes, founder of medical company Theranos, has given evidence in the trial, with a verdict due next month. Susan Jaffe reports.

The trial of Elizabeth Holmes, founder of the medical startup Theranos, for fraud continued this week in Palo Alto, CA, USA. Holmes charmed statesmen, A-list investors, the media, and even some government regulators with promises that her blood-testing technology would revolutionise health care. The technology would use just a few drops of blood drawn from a finger prick to perform around 200 tests. Diseases could be detected and treated earlier, potentially saving lives and health-care costs.

Federal prosecutors charged Holmes and former Theranos president Ramesh Balwani with wire fraud and conspiracy to commit wire fraud, alleging that they deceived investors and patients and their doctors by claiming that Theranos's machine could produce accurate test results from blood collected in its tiny "nanotainer" device instead of several vials. But witnesses for the prosecution testified that the devices did not operate as promised.

In her testimony on Nov 22, Holmes, former executive of the company she created at age 19 years in 2003 and valued at US\$9 billion by 2014, appeared in charge and polished. Under questioning from her attorney, Holmes said the Theranos equipment "performed well" in tests and mentioned "positive feedback" from pharmaceutical companies interested in using the technology, according to news reports (the federal court judge has banned recordings of the trial.) Yet, during the first 11 weeks of the trial, her lawyers have depicted Holmes as inexperienced and naive, and sought to place some responsibility for the company's demise on investors who took a gamble without the usual due diligence.

Holmes and Balwani have pleaded not guilty and are being tried separately.

They face a maximum of 20 years in prison and a fine of \$250 000 for each of 11 fraud charges. A verdict in Holmes' trial is expected in December. Balwani's trial begins next year.

Prosecutors countered with witnesses who said she evaded requests for financial information and provided misleading details about the performance of the Theranos technology. Her lawyers argued that secrecy was necessary to protect the company's intellectual property rights, among other reasons. To convict her, the jury must be convinced that she was wilfully deceptive.

"If something looks too good to be true, then that's an even stronger call for transparency", said Roy Silverstein, a haematologist and chair of medicine at the Medical College of Wisconsin (Milwaukee, WI, USA). "From my perspective, as a clinician and a researcher, when something is brought forward as the next new thing regardless of whether it's a drug or device, it needs to go through the process of rigorous scientific and clinical testing, then presented to the scientific community for peer review and ultimately publication", said Silverstein. "And I'm not aware of any single publication that ever came out of this Theranos technology."

During her testimony, Holmes' attorney mentioned a Theranos study published in a peer-reviewed journal and displayed a copy of the article to the jury without naming the journal, according to *The New York Times*. He did not respond to *The Lancet's* request for details.

"When I first heard of Theranos and its device that, on a pinprick of blood, could do all of these tests, I strongly suspected it was a fraud", said Edward Ashwood, director of clinical laboratories at the University

of Colorado's School of Medicine (Aurora, CO, USA) and president of the American Board of Pathology. "It was clear to me having done so much test development that what they were describing was impossible."

Another obstacle for the defence is the belated Government response that came after *The Wall Street Journal* relied on former employees and company emails to expose how "Theranos has struggled behind the scenes to turn the excitement over its technology into reality", as reporter John Carreyrou wrote in October, 2015.

The Centers for Medicare and Medicaid Services (CMS) inspected Theranos's California laboratory in November, 2015, and in January, 2016, issued a report concluding that "deficient practices of the laboratory pose immediate jeopardy to patient health and safety." The company later told CMS it had voided or revised all blood tests done in 2014 and 2015, *The Wall Street Journal* reported in May, 2016.

The US Food and Drug Administration (FDA) was also slow to discover problems at Theranos. "For 2 years, Theranos was shipping their nanotainers to California, Arizona, and Pennsylvania without proper FDA clearance", said John Wiksw, professor of biomedical engineering at Vanderbilt University (Nashville, TN, USA). The FDA later classified nanotainers as higher-risk class-two medical devices subject to additional safety requirements.

Holmes' defence team concedes that Theranos failed. "But failure is not a crime", Lance Wade, one of her attorneys, told the jury when the trial began. "Trying your hardest and coming up short is not a crime."

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