



PRESS RELEASE

Theranos President Sentenced To More Than 12 Years For Fraud That Jeopardized Patient Health And Bilked Investors Of Millions

Wednesday, December 7, 2022

For Immediate Release

U.S. Attorney's Office, Northern District of California

SAN JOSE – Ramesh "Sunny" Balwani was sentenced today to 155 months (12 years, 11 months) in federal prison for fraud that risked patient health by misrepresenting the accuracy of Theranos blood analysis technology and that defrauded Theranos investors of millions of dollars, announced United States Attorney Stephanie M. Hinds, Federal Bureau of Investigation Special Agent in Charge Robert K. Tripp, Food and Drug Administration (FDA) Assistant Commissioner for Criminal Investigations Catherine A. Hermsen, and U.S. Postal Inspection Service (USPIS) San Francisco Division Acting Inspector in Charge Kevin Rho. United States District Judge Edward J. Davila presided over his jury trial and imposed today's sentence.

"Patient health is the highest priority of our healthcare system, and Silicon Valley has long been home to healthcare start-ups that enhance the care of patients through technological developments," said U.S. Attorney Stephanie M. Hinds. "Ramesh Balwani, in a desire to become a Silicon Valley titan, valued business success and personal wealth far more than patient safety. He chose deceit over candor with patients in need of medical care, and he treated his investors no better. Today's sentence should serve as a lesson to anyone considering fraud in their own push for success." A link to a video statement by U.S. Attorney Hinds is available here: https://youtu.be/GmA6GqCng_8.

"Balwani not only deliberately concealed defects in Theranos' blood-testing technology to mislead investors, he knowingly put patients' health at risk," said FBI Special Agent in Charge Robert Tripp. "Today's sentence reflects years of dedication by the FBI and our partners to investigate fraud within Theranos and bring the company's leadership to justice."

"Patients and their doctors rely on accurate, reliable test results to ensure a proper diagnosis of their condition. When individuals jeopardize patient health and put profits above the public health, the FDA will continue to investigate and bring them to justice," said FDA Assistant Commissioner for Criminal Investigations Catherine A. Hermsen.

"Postal Inspectors and our law enforcement partners will continue to bring criminals to justice for schemes to defraud investors looking for innovation or concerned patients seeking health care," said USPIS San Francisco Division Acting Inspector-In-Charge Kevin Rho. "Today's sentence should be considered a serious message to anyone else who would engages in high tech medical quackery."

Balwani, 57, of Fremont, Calif., was employed from September 2009 through July 2016 at Theranos, Inc. Over time he held the positions of board member, chief operating officer and president. Theranos, now defunct, was a blood testing company based in Palo Alto and Newark, Calif., that was founded in 2003 by Balwani's former romantic partner Elizabeth Holmes, 38, of Woodside, Calif. Trial evidence showed that Balwani and Holmes, who was chairperson and CEO, claimed Theranos developed a revolutionary blood analyzer, variously referred to as the Theranos Sample Processing Unit (TSPU), the Edison, and the minilab. They described the Theranos blood analyzer device as a single device that could run any blood test run by conventional labs using only a small blood sample drawn via a fingerstick, rather than the traditional draw from a vein. Balwani and Holmes asserted that the Theranos proprietary analyzer produced results that were cheaper, more reliable and less variable than existing methods, and obtained results at a speed faster than ever before possible.

Among many other representations, Balwani reviewed and approved a 2013 Wall Street Journal article suggesting that Theranos had "devices that automate and miniaturize more than 1,000 laboratory tests" and stating that "Theranos' processes are faster, cheaper, and more accurate than the conventional methods" and that "Theranos' technology eliminates multiple lab trips because it can 'run any combination of tests, including sets of follow-on tests,' at once, very quickly, all from a single microsample."

The descriptions approved by Balwani were false and misleading. Trial evidence demonstrated that both Balwani and Holmes knew that the analyzer performed only a few basic tests and was slower than existing devices. They repeatedly resorted to using conventional machines to obtain the blood test results that the Theranos analyzer was supposed to perform. However, they led investors and the public to believe that Theranos was conducting essentially all of its tests using only its Theranos analyzer. Evidence demonstrated that Balwani and Holmes were aware that the Theranos analyzer's limited capabilities meant it could not compete in the market, but they nevertheless trumpeted false

claims and representations about the analyzer's capabilities and conspired to convince patients and investors that the claims were true.

Evidence at trial and examples in a sentencing memorandum filed by the government demonstrate the dark reality these misrepresentations created for patients. To portray Theranos as a legitimate enterprise, Theranos eventually offered the blood analyzer to the public to perform a "full range" of tests, despite internal protests from Theranos employees and even resignations by staff. Numerous misdiagnoses followed. A physician who testified at trial had sought Theranos testing and repeatedly received extremely elevated PSA results in comparison to earlier conventional tests. Elevated PSA is an indicator of prostate cancer. The Theranos results were later proved inaccurate when traditional, FDA-approved methods tests were run. In another example, a pregnant woman who had suffered multiple miscarriages obtained HCG values from Theranos testing that strongly indicated she was miscarrying again. However, confirmatory tests by conventional methods indicated a viable pregnancy, and the woman went on to deliver a healthy baby. This scenario played out with multiple pregnant women who received erroneous HCG results from Theranos tests. Even Theranos employees were not immune from inaccurate tests. One Theranos employee took blood-thinning medicine due to a history of blood clots and, when tested at Theranos, received a series of results that showed markedly different levels from previous conventional tests. As a result, a doctor adjusted employee's medication. Confirmatory testing at a traditional lab showed the employee's levels were normal; the medication adjustment had been unnecessary.

These types of test results occurred many times. Theranos itself eventually concluded a patient impact existed for every test run on a patient and voided all tests with its analyzer.

Amidst their repeated technology failures, trial evidence showed that Balwani and Holmes chose to continue deceiving their investor-victims and to proceed with the elaborate investor fraud conspiracy. They induced dozens of investors, many of whom were prominent public figures, to invest hundreds of millions of dollars in Theranos by using consistently glowing but false representations to investors and potential investors about the analyzer's progress and its capabilities. Balwani and Holmes asserted to investors that the Theranos technology had been comprehensively validated by multiple major pharmaceutical companies and was being used by the Department of Defense to treat wounded soldiers where, it was represented, it "actually saved lives in the battlefield." In truth, pharmaceutical companies did little work with Theranos and did not validate its technology, and the Department of Defense never used Theranos' analyzer to clinically treat soldiers. False representations were also made that Theranos would dramatically increase its number of Wellness Centers within stores operated by its partner Walgreens from a few dozen to 900, despite Balwani and Holmes knowing at the time that the relationship with Walgreens was stagnating.

Trial evidence demonstrated that Balwani and Holmes continued to tout Theranos' analyzer as a revolution in healthcare while misrepresenting the dire financial status of Theranos. Despite Theranos having zero revenue in 2012 and 2013, they represented to investors in late

2013 and 2014 that Theranos had hundreds of millions in revenue from a combination of pharmaceutical companies and the military. Balwani conspired to induce Walgreens and Safeway to invest in Theranos based on false pharmaceutical company endorsements and fantastical revenue projections. By March 2015, Theranos raised more than \$730 million dollars from "Series C-1" and "Series C-2" investors who invested subsequent to Theranos' public relations push in 2013.

Trial evidence showed the fraud brought spectacular personal wealth to Balwani. Balwani owned nearly 30 million shares of Theranos – over 6% of the company – which were worth hundreds of millions of dollars at the peak of the fraud. The government's sentencing memo points out that, like Holmes, Balwani enjoyed the perks of serving as a Silicon Valley titan. Balwani's yearned to "build the true American empire. A monopoly. Our obligation to USA."

Federal criminal charges were initially filed against Balwani and Holmes on June 14, 2018. On July 28, 2020, a federal grand jury returned a superseding indictment charging both with two counts of conspiracy to commit wire fraud, in violation of 18 U.S.C. § 1349, and ten counts of wire fraud, in violation of 18 U.S.C. § 1343. Of the two conspiracy counts, one alleged Balwani and Holmes conspired to defraud investors and the second alleged Balwani and Holmes conspired to defraud patients who used Theranos services. Some of the ten counts of wire fraud alleged Balwani and Holmes committed fraud on individual investors while others alleged Balwani and Holmes defrauded patients who were induced to purchase Theranos services.

On July 7, 2022, after a four month trial, a federal jury convicted Balwani of all counts.

Balwani was tried separately from Holmes, and in her trial Holmes was not convicted of all counts. On January 3, 2022, a different federal jury convicted Holmes of one count of conspiracy to commit fraud on investors and three counts of committing fraud on individual investors, which involved wire transfers totaling more than \$140 million. The jury acquitted Holmes of the patient-related fraud conspiracy count and the three counts of fraud against individual patients. The jury could not reach a unanimous verdict with respect to three individual investor fraud counts against Holmes. An additional count of wire fraud relating to a Theranos patient had been dismissed during trial. On November 18, 2022, U.S. District Judge Davila sentenced Holmes to 135 months (11 years, 3 months) in federal prison. She was ordered to surrender to begin serving her sentence on April 27, 2023.

In addition to the 155 month prison term, U.S. District Judge Davila sentenced Balwani to three years of supervision following release from prison. A hearing to determine the amount of restitution to be paid by Balwani is to be scheduled in the future. Balwani was ordered to surrender on March 15, 2023, to begin serving his prison sentence.

Assistant U.S. Attorneys Robert S. Leach, Jeff Schenk, John C. Bostic, and Kelly Volkar prosecuted the case with the assistance of Madeline Wachs, Lakisha Holliman, Sara Slattery, Elise Etter, Susan Kreider, and Leeya Kekona. The prosecution is the result of an investigation

by the FBI, USPIS, and the FDA Office of Criminal Investigations.

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