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As Cases Drive Home, Ignoring Complaints Plays Role in Fraud Cases

By Nina Youngstrom

Silencing or ignoring employees who report compliance problems tends to backfire, a compliance truism that has played out in recent high-stakes cases. Sometimes this causes nicks and cuts to the corporate culture that can be repaired, and at other times the wounds are more devastating, a compliance expert said. Two of the object lessons in this area come from The Boeing Company and Theranos.

“If you ignore complaints, you will create whistleblowers,” said Margaret Scavotto, president of Management Performance Associates, at a Jan. 10 webinar on compliance culture case studies sponsored by the Health Care Compliance Association.^[1] The cases also highlight questions about putting profits before safety. “Competing interests are a compliance nightmare,” she noted. “Unresolved conflicts between financial interests and safety and quality will destroy your compliance culture.”

The Theranos blood-testing company debacle illustrates the dangers of ignoring complaints and data “to achieve a goal,” Scavotto said. Elizabeth Holmes founded Theranos at age 19 after dropping out of Stanford University in 2003 and brought her boyfriend, Sunny Balwani, in as CEO in 2009. The Theranos concept was to perform 200 blood tests from a tiny prick of fingertip blood that was put in a cartridge the size of a credit card and then placed in a toaster-sized box that would analyze the blood, Scavotto said. “The problem: It didn’t always work. And it couldn’t perform that many tests,” she noted. Based on Holmes’ deceptions, Theranos got contracts with Walgreens and Safeway, according to reporting by *Wall Street Journal* reporter John Carreyrou, author of the book *Bad Blood*, which brought the Theranos scandal to light. “Because the Theranos devices could not perform many tests, most patients had their blood drawn by needle. Employees waited up to two weeks for their results because Theranos was secretly outsourcing the blood tests to a lab. And the test results were abnormal. When retested in a different lab, results came back normal,” Scavotto said.

Despite problems with the technology and the lies told to investors (e.g., that the finger-stick blood tests corresponded to 1,300 CPT codes), investor money kept rolling in. “Investors didn’t question the technology,” Scavotto said. A couple questions could have revealed the falsity of revenue projections. “That’s the first red flag from a culture standpoint,” she said.

‘You Have to Protect and Prove That Mission’

Multiple employees raised concerns about Theranos, Scavotto said. For example, former lab director Adam Rosendorff, who was given the pseudonym Alan Beam in *Bad Blood*, had raised concerns with quality control, according to *The Washington Post*.^[2] “They ignored him,” Scavotto said. Carreyrou tweeted that “Adam was my first and most important source.”^[3] He also testified at Holmes’ trial. Former Theranos lab assistant Erika Cheung complained to CMS, which surveyed Theranos and found it posed immediate jeopardy to the health and safety of beneficiaries. Cheung also testified at Holmes’ trial, according to news reports. And Theranos ignored complaints from employee Tyler Schultz, the nephew of board member George Schultz, the late former secretary of state. “Tyler Shultz used an alias to file a complaint with New York’s public health lab, alleging that Theranos

was violating federal and state requirements with proficiency testing ‘cheating,’” Scavotto said. The company dissolved in 2018.

Holmes was convicted of four counts of fraud Jan. 3, and Balwani is scheduled to go to trial this year.

There are compliance culture lessons in the Theranos story, Scavotto said. For one thing, obviously it’s dangerous to tune out compliance and quality concerns and ignore data to achieve a goal. “Compliance has to bring data to the table,” she said. If you’re blindly following the mission at all costs and don’t have data, you can get off track. “You need a mission, but you have to protect and prove that mission,” Scavotto said. An “idea is not enough in health care. You need a product that passes health care protocols. If revenue and profit are up here and patient safety is down there, disaster will happen.”

‘All My Internal Warning Bells Are Going Off’

Scavotto also described the series of events leading up to crashes of Boeing’s 737 Max airplane and how whistleblowers allegedly were ignored. Boeing had always dominated plane manufacturing, but in 2010, a competitor, Airbus, introduced a new plane. In response, Boeing decided to revamp its 737 plane instead of designing a new aircraft because it could be done faster, she said.

The 737 Max had a relocated engine with a tendency to tip the nose of the plane up, Scavotto said. To compensate, a new Maneuvering Characteristics Augmentation System (MCAS) kicked in to nudge the nose back down. But the pilots allegedly weren’t trained on it at the time, she said. “That’s where we started seeing challenges with the 737 Max and what went wrong,” Scavotto said. “Simulator training is very expensive.”

Then tragedy struck and two 737 Max planes were at the heart of it. In October 2018, Lion Air Flight 610 crashed off the coast of Indonesia, killing all 189 people aboard. After the crash, Boeing sent a memo to pilots telling them to shut off power to the stabilizer tail of the plane if the MCAS malfunctioned, and the company worked to improve the software, Scavotto said. But in March 2019, Ethiopian Airlines Flight 302 crashed, and all 157 people were killed. After the second crash, the plane was grounded.

It turned out that people had been raising concerns about the 737 Max inside and outside Boeing. For example, Edward Pierson, a former senior manager at Boeing’s plant in Renton, Washington, where the 737 Max was built, told the House Transportation and Infrastructure Committee in December 2019 that he “witnessed a factory in chaos and reported serious concerns about production quality to senior Boeing leadership months before the first crash. I formally reported again before the second crash.” Pierson said no actions resulted from his reports. “As a retired Naval Officer and former Squadron Commanding Officer, I know how dangerous even the smallest of defects can be to the safety of an airplane. Frankly right now all my internal warning bells are going off. And for the first time in my life, I’m sorry to say that I’m hesitant about putting my family on a Boeing airplane,” Pierson said in his statement.^[4]

On Jan. 7, 2021, the Department of Justice (DOJ) announced that Boeing agreed to resolve a criminal charge stemming from a conspiracy to defraud the Federal Aviation Administration (FAA) Aircraft Evaluation Group (AEG) related to the 737 Max.^[5] Boeing entered into a deferred prosecution agreement related to a criminal information filed by the U.S. Attorney’s Office for the Northern District of Texas and paid \$2.5 billion.

Boeing admitted in court documents that two of its 737 Max flight technical pilots deceived the FAA AEG about the MCAS, according to DOJ. Around November 2016, two of Boeing’s 737 Max Flight Technical Pilots found information about an important MCAS change. “Rather than sharing information about this change with the FAA AEG, Boeing, through these two 737 MAX Flight Technical Pilots, concealed this information and deceived the FAA AEG about MCAS,” DOJ said. “Because of this deceit, the FAA AEG deleted all information about MCAS from

the final version of the 737 MAX FSB Report published in July 2017. In turn, airplane manuals and pilot training materials for U.S.-based airlines lacked information about MCAS, and pilots flying the 737 MAX for Boeing's airline customers were not provided any information about MCAS in their manuals and training materials."

During an investigation of aviation safety oversight in the wake of the plane crashes by the Senate Committee on Commerce, Science, and Transportation, it came out that Boeing and FAA employees had raised concerns about the safety of the plane. "Multiple whistleblowers alleged Boeing intentionally misled FAA certification efforts and downplayed the significance of MCAS," according to the 2020 report, which said the committee received information from 50 whistleblowers.^[6] The report also said the committee "found a persistent culture of whistleblower retaliation in the FAA."

Safety Committee Is Now at the Board Level

DOJ reached its resolution with Boeing partly based on its "failure to timely and voluntarily self-disclose the offense conduct to the department; and Boeing's prior history, including a civil FAA settlement agreement from 2015 related to safety and quality issues concerning the Boeing's Commercial Airplanes (BCA) business unit." Boeing was required to create a board-level aerospace safety committee and reorganize its engineering functions so that all Boeing engineers and its flight technical team report through Boeing's chief engineer, not the business units.

One Boeing former chief technical pilot, Mark Forkner, was indicted in October for deceiving the FAA. He has pleaded not guilty.^[7]

The Boeing case is a compliance classic in terms of employees turning to outside authorities when they feel their concerns aren't addressed, Scavotto said.

"We saw the government characterize the conflict of interest between profits and safety."

Contact Scavotto at mcs@healthcareperformance.com.

¹ Margaret Scavotto, "Compliance Culture Case Studies," webinar, Health Care Compliance Association, January 10, 2022, <https://bit.ly/3KwUlfO>.

² Rachel Lerman, "Ex-Theranos lab director testifies in tense exchange during Elizabeth Holmes trial," *The Washington Post*, September 29, 2021, <https://wapo.st/3AlMttN>.

³ John Carreyrou (@JohnCarreyrou), "I'll add this: Adam was my first and most important source. Without him, I wouldn't have been able to break the Theranos story. Hats off to his courage and integrity. He's one of the real heroes of this story," Twitter, September 28, 2021, 5:50 pm, <https://bit.ly/3GLcaWG>.

⁴ Edward F. Pierson, "Statement of Edward F. Pierson Before the House Transportation and Infrastructure Committee," December 11, 2019, <https://bit.ly/3G1sDVL>.

⁵ Department of Justice, "Boeing Charged with 737 Max Fraud Conspiracy and Agrees to Pay over \$2.5 Billion," news release, January 7, 2021, <https://bit.ly/354WAHr>.

⁶ U.S. Senate Committee on Commerce, Science, and Transportation, *Committee Investigation Report: Aviation Safety Oversight*, December 2020, <https://bit.ly/3rGoGNM>.

⁷ Department of Justice, "Former Boeing 737 MAX Chief Technical Pilot Indicted for Fraud," news release, October 14, 2021, <https://bit.ly/3nLooWa>.

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