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COMPLIANCE CULTURE CASE STUDIES

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What is culture?

- **the set of shared attitudes, values, goals, and practices that characterizes an institution or organization**
Source: <https://www.merriam-webster.com/dictionary/culture>
- **Culture is “the way we do things around here” and becomes visible in the choices people make, how they interact with one another, and how they deliver against their objectives.**
Source: <https://action.deloitte.com/topic/25/culture>

What does the federal government say?

- **“...superficial efforts or programs that are hastily constructed and implemented without a long term commitment to a culture of compliance likely will be ineffective and may expose the nursing facility to greater liability than if it had no program at all.”**
—OIG Compliance Program Guidance for Nursing Facilities, 2000
- **“It is important for a nursing facility to have an organizational culture that promotes compliance.”**
—OIG Supplemental Compliance Guidance for Nursing Facilities, 2008

What does the federal government say?

§8B2.1. **Effective Compliance and Ethics Program**

(a) To have an effective compliance and ethics program... an organization shall—

- (1) exercise due diligence to prevent and detect criminal conduct; and
- (2) **otherwise promote an organizational culture that encourages ethical conduct and a commitment to compliance with the law.**

- Federal Sentencing Guidelines

Today's case studies:

- **Boeing**
- **Theranos**
- **Johnson & Johnson**



boeing

Background

- Boeing enjoyed a good reputation for decades.
- One pilot said: "If it isn't Boeing, I'm not going."
- Boeing did not have competitors until Airbus' growth in the 1990s.
- In 2010, Airbus introduced a new plane, the neo, which was a game-changer.
- To compete with the neo, Boeing decided to revamp its 737 plane, rather than design a new aircraft, which would take years longer.

The result: The 737 Max 8

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Issues building the 737 Max 8:

- **MCAS**
- **Did pilots need simulator training on the 737 Max?**

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The crashes:

- **Indonesia (Lion Air Flight 610)**
 - **October 29, 2018**
 - **All 189 people on board were killed.**
- **Ethiopia (Ethiopian Airlines Flight 302)**
 - **March 10, 2019**
 - **All 157 people on board were killed.**

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Boeing employees raised concerns:

“Are we vulnerable to single AOA sensor sensor failures with the MCAS implementation or is there some checking that occurs?”

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Boeing employees raised concerns:

“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.”

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Boeing employees raised concerns:

“catastrophe”

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FAA employees raised concerns

Former FAA employee Michael Collins said FAA senior managers sided with Boeing - rather than FAA employees - about safety concerns.

Once a senior FAA manager ignored the concerns of "13 engineers, one project pilot, and four managers" who had concerns about the plane's design.

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Whistleblowers

Seven whistleblowers contacted the U.S. Senate Committee on Commerce, Science, and Transportation with concerns about aircraft safety and certification at the FAA and within the industry.

Three former Boeing employees were among the whistleblowers.

The Committee conducted an investigation and a report, which found: "Boeing production staff experienced 'relentless' schedule pressure in the 737 MAX program as well, raising safety concerns."

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The House investigation

A House investigation revealed that Boeing employees had raised concerns about MCAS.

The investigation also revealed that production pressures trumped safety concerns.

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The fallout

- After the Ethiopia crash, the 737 Max was grounded.
- Boeing made changes to MCAS.
- Pilots now receive simulator training.

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The fallout: DOJ settlement

- In January 2021, Boeing entered a \$2.5 billion settlement to resolve a DOJ criminal investigation into two Boeing pilots' involvement in FAA approval of training for the 737 Max.
- The DOJ alleged the pilots conspired to deceive the FAA.
- Special Agent in Charge Andrea M. Kropf noted: "integrity and transparency may never be sacrificed for efficiency or profit."

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The fallout: DOJ settlement

- Boeing received credit for compliance.

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The fallout: Criminal charges

- In October 2021, former Chief Technical Pilot Mark Forkner was indicted for lying to the FAA when it was certifying the 737 Max.
- In internal email, Forkner said if regulators required simulator training, it would cost Boeing tens of millions of dollars.

“In an attempt to save Boeing money, Forkner allegedly withheld critical information from regulators”

– Acting U.S. Attorney Chad E. Meacham for the Northern District of Texas

In May 2022, Forkner was found not guilty.

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The culture lessons

If employees feel their internal complaints are not addressed, they might go to the government – as whistleblowers.

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The culture lessons

Competing interests are a compliance nightmare.

Here: Safety versus production timelines.

Strict adherence to safety protocols, and use of data to prove they are followed, can counteract the conflict.

boeing

Further watching:

- 20/20 Season 43, Episode 6: Falling from the Sky

Further reading:

- Aviation Safety Whistleblower Report, U.S. Senate Committee on Commerce, Science, and Transportation, Chair Maria Cantwell, December 2021



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Background

- In 2003, at age 19, Elizabeth Holmes dropped out of Stanford to found Theranos.
- Sunny Balwani, Elizabeth's boyfriend at the time, joined Theranos in 2009 as President and CEO.
- In 2014, Theranos was valued at more than \$10 billion.

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The mission

- "We believe it's wrong for people to pay \$10,000 for a lab test."
- "People have a fundamental right to their own health information."
- "We wanted to help people who were scared of needles."
- "Many of our tests require only a few drops of blood."
- "a world in which no one ever has to say goodbye too soon"
- "We were looking for a way to build a system that could help make early detection and prevention [of diseases] a reality in our health-care system."

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The concept

A finger prick would draw a few drops of blood.

The blood would be transferred to a cartridge the size of a credit card.

The cartridge would be put inside a box the size of a toaster, that would analyze the blood and produce a result - for 200+ tests.

Blood was kept in tiny containers called nanotainers.

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The problem:

It didn't always work. And it couldn't do that many tests.

- A few drops of blood weren't enough. So, Theranos diluted the blood to increase the quantity. This compromised the results.
- Nanotainers broke or exploded. Or, blood dried up in them and then the sample was lost.
- One employee reported that pieces would break off and spill blood throughout the device.
- Finger prick blood is less accurate because it is contaminated with "fluids from tissues and cells." Bad Blood p 231
- Patients went to Walgreens thinking they would get a finger prick, but they got a needle draw. And many patients received inaccurate results.

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The problem:
 Safeway, Walgreens, and Pfizer

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.

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Lies told to investors

- Theranos finger-stick technology can perform blood tests. corresponding to up to 1,300 CPT codes.
- Theranos technology is as accurate as traditional lab testing.
- Theranos had developed 300 blood tests. 98% of them could be done on a finger-prick's amount of blood. Theranos had submitted all of these tests to the FDA for approval.
- Theranos devices can conduct 70 tests simultaneously.
- Revenue projections:
 - 2014: gross profits of \$165 million on revenues of \$161 million
 - 2015: gross profits of \$1.08 billion on revenues of \$1.68 billion
 - Sunny made up these numbers. Theranos did not have a CFO.
- Theranos recorded a video of an accurate result, and played that for Theranos during demos - because the device might not work live.
- Investors did not question this information.

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"Holmes and her company had overpromised and then cut corners when they couldn't deliver."
 - Bad Blood by John Carreyrou, page 229

"The way Theranos is operating is like trying to build a bus while you're driving the bus. Someone is going to get killed."
 - Bad Blood, page 229

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Theranos ignored concerns from:

- Alan Beam
- Lina Castro
- Henry Mosley
- Ana Arriola
- Todd Surdey & Michael Esquivel
- Chelsea Burkett
- Anjali Laghari
- Avie Tevanian (board member)

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Theranos ignored concerns from:
Tyler Shultz

Concerns:

- Theranos discarded inaccurate data to force "good" data results. Theranos deleted some results as "outliers" until the ideal outcome was reached.

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Theranos ignored concerns from:
Tyler Shultz

"That reckless comment and accusation about the integrity of our company, its leadership and its core team members based on absolute ignorance is so insulting to me that had any other person made these statements, we would have held them accountable in the strongest way. The only reason I have taken so much time away from work to address this personally is because you are Mr. Shultz's grandson... I have now spent an extraordinary amount of time postponing critical business matters to investigate your assertions—the only email on this topic I want to see from you going forward is an apology that I'll pass on to other people...."

- Bad Blood, page 196

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**Theranos ignored concerns from:
Erika Cheung**

- Testified that she raised her concerns about the technology not working with Sunny - who responded by questioning why she was qualified to raise these concerns and questioned her loyalty to the company
- Testified that Theranos could only process 12 types of blood tests on its proprietary devices. The rest were processed on third-party, traditional lab machines. Theranos told investors its devices could process 200 tests.
- Testified that she noticed discrepancies between blood test results on the Theranos devices compared to the third-party devices
- Testified that Theranos deleted data points in order to get better results

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Blowing the whistle

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." He also talked with John Carreyrou.

Erika Cheung filed a complaint with CMS. CMS showed up at Theranos less than three days later for a surprise inspection. CMS found so many problems that they decided they had to come back to continue the inspection. CMS found deficiencies that posed "immediate jeopardy to patient health and safety."

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The fallout

In addition to the CMS inspection...

- The FDA did a surprise inspection and determined that the nanotainer was an uncleared medical device, and prohibited Theranos from using it.
- Elizabeth claimed she didn't know about lab issues until the CMS inspection. She blamed lab leadership. She had a duty to know about those issues.
- Theranos refunded every patient for their blood tests
- In 2018 Theranos dissolved. Elizabeth and Sunny were charged with fraud and conspiracy.
- Elizabeth fired Sunny and blamed him.
- Investors sued Holmes or settled. Theranos paid \$300M in legal fees and settling lawsuits from investors.
- Walgreens sued, and settled for 25 million
- Theranos settled with the AZ attorney general for \$4.65 million to reimburse Arizona residents who obtained blood tests from Theranos.
- Ten patients sued for medical battery and consumer fraud.

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The fallout: Criminal charges

Criminal fraud charges

- **January 3, 2022: Elizabeth Holmes was found guilty on four of eleven fraud charges.**
- **Sunny Balwani was convicted of 12 counts of wire fraud and conspiracy to commit wire fraud.**

The SEC charged Holmes and Balwani with fraud

- **Holmes settled the civil charges: She gave up voting control of Theranos; gave back significant stock; paid a \$500,000 penalty; and is barred from serving as officer or director of a public company for 10 years.**
- **Balwani wouldn't settle, so the SEC sued him.**

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The fallout: Update

- **Holmes' sentencing, scheduled for October 17, was delayed. Holmes requested a new trial after Adam Rosendorff, a witness for the prosecution, expressed regret over their role in the trial. At a hearing, Rosendorff stood by his prior testimony. Sentencing for Holmes is scheduled for November 18.**

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The culture lessons

Ignoring data to achieve a goal

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The culture lessons

Trust without verification

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The culture lessons

**Squelch a complaint,
create a whistleblower.**

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The culture lessons

"Fake it til you make it"

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The culture lessons

Conflict: Revenue before patient safety

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Further reading

- **WSJ Live Updates for the Elizabeth Holmes Trial**
- **Hot Startup Theranos Has Struggled With Its Blood-Test Technology, WSJ, October 16, 2015, John Carreyrou**
- **Bad Blood: Secrets and Lies in a Silicon Valley Startup, by John Carreyrou, published in 2018; republished in 2020 with a new afterword**

Further watching

- **The Inventor: Out for Blood in Silicon Valley (Hulu)**

Further listening

- **Bad Blood: The Final Chapter Podcast**

johnson & johnson

Getting it right

johnson & johnson

- In 1982, someone purchased Tylenol Extra-Strength capsules, injected cyanide into the capsules, resealed the packages, and put them on the shelves at half a dozen pharmacies and grocery stores in Chicago.
- Seven people died. The murderer was never identified or captured.
- Despite this tremendous disaster - J&J came out on top.

Why?

johnson & johnson

J&J's response:

- **FIRST: How do we protect the people**
- **SECOND: How do we save the product?**

<https://www.ou.edu/deptcomm/dodjcc/groups/02C2/Johnson%20%20Johnson.htm>

Your culture strategy

- **Compliance needs to be an expectation of all employees, including the leadership, and the Board.**
- **Prove you are supporting your mission by verifying it with data - regularly.**
- **Put patient safety first -ahead of the bottom line (or the bottom line will not last).**
- **Create transparency from top to bottom.**

Your culture strategy

- **Fill your board with industry experience.**
- **Use committees: Boeing could have benefited from a safety committee.**
- **Slow down and pay attention to the red flags.**
- **Welcome complaints and concerns. Vet them independently, every time.**

Culture change - Deloitte

- **Culture can be transformed by understanding current/future state and activating appropriate organizational levers.**

Source: <https://action.deloitte.com/topic/25/culture>

Culture change – Harvard Business Review

Implementation – Formal Interventions

- **Reporting structures**
- **Decision rules and rights**
- **Business processes and policies**
- **Training, leadership, and organizational development programs**
- **Internal communications**

Implementation – Informal Interventions

- **Behavior modeling by senior leaders**
- **Meaningful manager/employee connections**
- **Internal, cross-organizational networks**
- **Ad hoc gatherings**
- **Peer-to-peer interactions and storytelling**

Source: <https://hbr.org/2012/07/cultural-change-that-sticks>

Culture change – Harvard Business Review

“Whether formal or informal, interventions should do two things: reach people at an emotional level (invoking altruism, pride, and how they feel about the work itself) and tap rational self-interest (providing money, position, and external recognition to those who come on board).”

Source: <https://hbr.org/2012/07/cultural-change-that-sticks>

Culture change – practical tips

- **Assess your culture**
- **Identify problems, concerns and solicit suggestions for improvement**
- **Respond to each staff issues**
- **Fix as many problems and concerns**
- **Communicate fixes except for personnel issues**
- **Do not ignore “bad people”**

Culture change – assessment

Interviews

- **Interview managers – meet individually (confidential)**
- **Interview board members individually**
- **Interview staff**
 - **all staff meetings**
 - **meet individually**
- **Use open ended questions**
 - **What is good and bad with dept, supervisor, organization?**

Culture change – assessment

Staff survey

| Question | C-Suite & Board | Below C-Suite |
|--------------------------------------------------------------|-----------------|---------------|
| Our organization has a strong sense of purpose | 79% | 65% |
| I feel a personal connection to our organizations' purpose | 83% | 54% |
| Our organization walks the talk on purpose value and culture | 73% | 46% |
| My team inspires me to do my best work | 81% | 54% |

Source: <https://www.pwc.com/gx/en/issues/upskilling/global-culture-survey-2020/pwc-global-culture-survey-2021.pdf>

Culture change – problem list

Easy fixes

- Communication - Last minute notification about meetings to managers and too many memos
- Equipment - Beepers for call lights don't work a lot of the time
- Equipment - No automatic stop on elevator. Elevator doors are closing on patients.
- Equipment - Not enough wheelchairs and other equipment; only 5 new wheelchairs after relocation; equipment often does not work.
- Equipment - The spa room cannot be used because there is no lift into the tub.
- Equipment - There is a sarah lift patient, but no sarah lift.
- There is a need for more staff lockers
- Dining - Need food carts on units for the feeders. There is no benefit in bringing the feeders to the Dining Room (suggested several times)
- Dining - Need different serving times in the Dining Room; alternating times for different units. This has been tried, however it didn't work because of running out of food.

Culture change – problem list

Not so easy fixes

- Accountability - There are tons of call-ins; there doesn't seem to be a discipline process for the abusers. It's the same people calling-in and it is so short staffed that these people "can't afford to be disciplined"
- Accountability - Problems/complaints not being addressed
- Accountability - A lot of write-ups, but no one fired
- Accountability - Staff talk about residents in front of other residents family.
- Trust - If a suggestion box is used, who will open and read suggestions? The suggestions will be destroyed or management will give the "right" message and not do anything more with it.
- Retaliation/Trust - Nothing done when complaints are made to supervisor; when you go over their head, expect retaliation.
- Carrot not stick - More employee recognition and encouragement is needed; this may lead to better teamwork

Culture change – communicate fixes

- **Employee newsletter**
- **Get back directly to employee**
- **Personnel issues must remain confidential**
- **Implement communication channels**
 - **Suggestion box**
 - **Compliance hotline**
 - **Ask for suggestions**

Culture change – Examples

- **Enforce or reset policies - attendance**
- **Everyone in the organization is held to the same standards**
 - **Director of Nursing**
 - **Assistant Director of Nursing**
 - **Executive Director**

Culture change – bad people (negativity)

- **The 10 percenters**
- **Clearly establish expectations to everyone including non-retaliation policy**
- **Investigate and address**
- **Do not ignore**
- **Undermining vs. open communication**

Culture change – leadership

- **Ask for input – leaders do not have all of the answers**
- **Don't be afraid to make a decision**
- **Once a decision is made, support decision**
- **Accept negative communication; admit mistakes**

Southwest Airlines: What is culture?

- **Employee happiness even over customer satisfaction**
- **Customers even over stakeholders**
Source: <https://www.fearlessculture.design/blog-posts/southwest-airlines-culture-design-canvas>
- **Walk the walk:**
 - **Kelleher heard that an employee's son had been killed in a car crash.**
 - **The employee was in Baltimore and his family was in Dallas.**
 - **Kelleher had a plane that was about to be taken out of service for routine maintenance rerouted to land in Baltimore, pick up the employee, and get him back to his family immediately.**
Source: <https://www.carminegallos.com/southwest-airlines-founder-herb-kelleher-built-a-successful-culture-based-on-employees-first/>

Questions?



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