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OPINION | COMMENTARY

When Startups Put the Fab in Fabricate

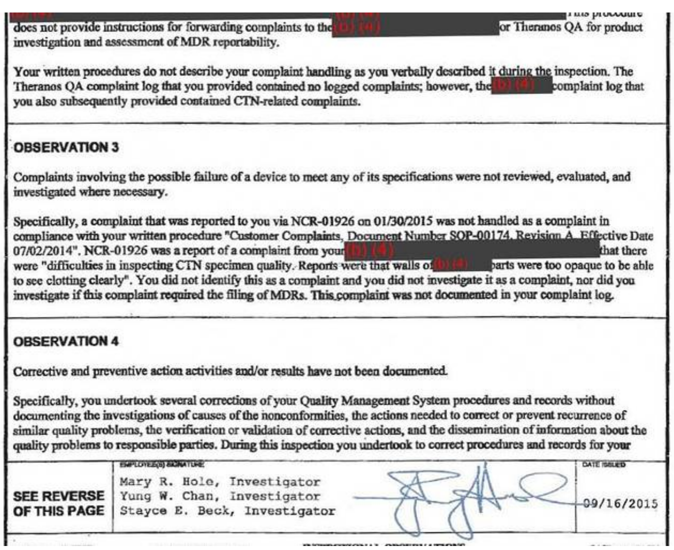
Shading the truth in Silicon Valley comes with the territory.

By ANDY KESSLER

July 8, 2016 6:02 p.m. ET

The stormy Theranos saga took another turn late Thursday when the company announced that federal regulators were banning founder Elizabeth Holmes for two years from operating a blood-testing laboratory. The Centers for Medicare and Medicaid Services also pulled approval of the company's California laboratory.

Theranos had already voided two years of results from its Edison blood-testing device. It is increasingly unclear whether the secretive company's microfluidics technology, which required only a finger prick instead of a needle jab, ever actually worked.



[redacted] This procedure does not provide instructions for forwarding complaints to the [redacted] or Theranos QA for product investigation and assessment of MDR reportability.

Your written procedures do not describe your complaint handling as you verbally described it during the inspection. The Theranos QA complaint log that you provided contained no logged complaints; however, the [redacted] complaint log that you also subsequently provided contained CTN-related complaints.

OBSERVATION 3

Complaints involving the possible failure of a device to meet any of its specifications were not reviewed, evaluated, and investigated where necessary.

Specifically, a complaint that was reported to you via NCR-01926 on 01/30/2015 was not handled as a complaint in compliance with your written procedure "Customer Complaints, Document Number SOP-00174, Revision A, Effective Date 07/02/2014". NCR-01926 was a report of a complaint from your [redacted] that there were "difficulties in inspecting CTN specimen quality. Reports were that walls of [redacted] parts were too opaque to be able to see clotting clearly". You did not identify this as a complaint and you did not investigate it as a complaint, nor did you investigate if this complaint required the filing of MDRs. This complaint was not documented in your complaint log.

OBSERVATION 4

Corrective and preventive action activities and/or results have not been documented.

Specifically, you undertook several corrections of your Quality Management System procedures and records without documenting the investigations of causes of the nonconformities, the actions needed to correct or prevent recurrence of similar quality problems, the verification or validation of corrective actions, and the dissemination of information about the quality problems to responsible parties. During this inspection you undertook to correct procedures and records for your

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Mary R. Hole, Investigator Yung W. Chan, Investigator Stayce E. Beck, Investigator	DATE ISSUED 09/16/2015

The FDA document declaring tiny vials used by Theranos Inc. an "uncleared medical device." *PHOTO: U.S. FOOD AND DRUG ADMINISTRATION*

I'm in no way surprised. After 25 years of tracking and investing in startups, I've learned that entrepreneurs will do anything to make their company successful: persuade, cajole and even put the fab in fabricate.

Entrepreneurs, it seems, all want to emulate the late Steve Jobs—even his fashion, given Ms. Holmes's penchant for black mock turtlenecks. At Apple and Next and Pixar, Jobs emanated what became known as a "reality distortion field." His overpowering charisma would convince workers, developers and investors to come around to his view of where the world was going.

There was only one Steve Jobs, but other entrepreneurs try their own Jedi mind tricks, attempting to use The Force to influence the weak. (In Silicon Valley, "Star Wars" is regarded as a documentary.) Sadly, the journey from charisma to coercion to lying is quick and often complete.

I've been lied to plenty. As an analyst, I once visited a still-prominent Silicon Valley CEO. His stock had taken a beating recently, but I liked the firm's prospects and had come to evaluate the opportunity. He looked me in the eye and said, as I recall, "I don't know why anyone would recommend our stock right now." Then he unloaded all the things that were about to go wrong. Within two months, on better revenue, the stock had almost doubled. It turned out that when I had visited, the company was pricing options for the CEO and other executives. Had I recommended the stock, the exercise price might have been higher, eating into their take.

During the dot-com frenzy, I recall sitting through an initial public offering presentation for eToys.com. A chart of projected e-commerce spending overall showed quarter-by-quarter growth. But the graph with revenue for eToys itself inexplicably switched to six-month numbers. I passed on the deal; they were hiding something. No matter, the public got duped and in May 1999 the stock quadrupled on the first day of trading to a $7.8 billion valuation. The company would file for bankruptcy 22 months later.

It's almost a rite of passage to be pitched an investment with a dodgy PowerPoint deck. There is some ambitious goal, a product road map and then overly precise revenue forecasts: $1 million after one year, $5 million after two, then $20 million. Uh huh. Sure.

After I figured out the game, I learned a few tricks of my own. At meetings with CEOs or CFOs, I started to notice whether they closed their office door. That might be a sign they didn't want to be overheard stretching the truth. Healthy skepticism is also advisable. This year I was pitched to invest in a Korean company. A billion in sales, multibillion valuation, they said. Can I see audited numbers? No. Can I talk to existing investors? No. Can I meet the CEO? No. Did I invest? Heck no.

If you talk to people who short stocks, the cause célèbre is Tesla. The firm's Model S is imperfect—no cupholders or armrest in the back seat?—but still a nice vehicle. Short sellers note, however, that the company's founder, Elon Musk, has his own battery-powered reality-distortion field. Two years ago, Tesla suggested that it might ship 100,000 vehicles in 2016. Now it has missed the numbers for both first and second quarter, and even 80,000 seems like a stretch.

Yet every time investors get nervous, Mr. Musk makes another outlandish announcement. In May he audaciously suggested that Tesla might have the capacity to ship 500,000 cars by 2018 and a million by 2020. Will he do it? Who knows? But as Morgan Stanley analyst Adam Jonas wrote in May: "Our delivery estimates are largely unchanged. By 2018, we forecast ~108k units, well below the updated target." Add the funky-smelling plan to merge Tesla and SolarCity, another of Mr. Musk's babies, and it might be enough to remind investors that hype is what entrepreneurs do best.

Theranos raised some $700 million and once sported a $9 billion valuation. Backed by a world-class board of investors and prominent politicians, it promised to completely transform a $50 billion market. I was rooting for it. Turned out we don't know if the machine works. When Ms. Holmes said that all was well, she was probably trying to buy time until she could get the technology right. But she wasn't selling toys online: People's health was involved.

Theranos has probably set back the tremendously promising field of microfluidics by a decade. That's a shame—speaking as more than an investor.

Mr. Kessler, a former hedge-fund manager, is the author of "Eat People" (Portfolio, 2011).