

Case Study

The author retracts his story almost 18 months later.....

How Theranos Misled Me

By **Roger Parloff**

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In a June 2014 cover story for *Fortune*, I helped raise to prominence the inventor-entrepreneur Elizabeth Holmes and her remarkable—I think everyone will still go along with that adjective—diagnostics company Theranos.

Fairly high up in my story there is a whopping false statement. After explaining that Theranos’s tests could be performed with a finger-stick, rather than using traditional venipuncture (a syringe in the crook of the arm), I wrote that the company “currently offers 200—and is ramping up to offer more than 1000—of the most commonly ordered blood diagnostic tests, all without the need of a syringe.”

Sixteen months later, John Carreyrou of the *Wall Street Journal* published a now famous front-page story containing a wide range of unflattering accusations about Theranos. Among them, he reported that one “former senior employee” had told him—in an account generally corroborated by three other former employees—that as of December 2014, the company was actually performing only about 15 finger-stick tests using its proprietary technology; the remainder were being performed using conventional, third-party analyzer machines, made by companies like Siemens—i.e., the same machines used by conventional labs like Quest Diagnostics (dgx, +0.34%) and LabCorp (lh, +1.10%).

In that *Journal* article, a Theranos spokesperson was quoted flatly denying the newspaper’s allegations in a blanket manner, but refusing to be specific, citing trade secrets. Notably, from my perspective, she did not say how many tests the company had, in fact, been performing by proprietary methods in December 2014.

In a longer statement issued the same day on its website, Theranos further blasted the *Journal* for, among other things, relying on the accounts of “anonymous, disgruntled former employees,” but still declined to state how many proprietary tests it had really been performing.

It wasn't until a week later—on Oct. 22—that Theranos, after stonewalling and threats of legal action failed to quell the furor, offered a serious, 14-page response to the *Journal* article, addressing the full panoply of its accusations. Among other things the company asserted that, as of December 2014, it had in fact been performing “more than 80 of the tests on our online test menu via finger-stick,” and that all but “a few” of those “ran using proprietary technologies.” It also asserted that in the fourth quarter of 2014, 57% of all tests ordered had been performed by finger-stick.

Those figures, if accurate, would suggest that the company might well be accomplishing, as it has claimed, something genuinely innovative and beneficial to society. I should add that the company's extremely low prices and price-transparency would also be of unquestionable benefit to society, even if the company weren't doing *anything* technologically innovative. On the other hand, all these advances matter only if Theranos's tests are also reliable, which the *Journal* article also cast doubt upon. In my opinion, the evidence for this was weaker than its evidence that the company was misrepresenting its accomplishments.

After Theranos's Oct. 22 statement, I contacted officials there to inquire how many tests it had actually been commercially performing by proprietary means in June 2014, when I had reported that it was offering more than 200. A spokesperson acknowledged to me that it was fewer than 200, but declined to specify how many. She said she'd send a statement.

The company's statement arrived Nov. 3. “As discussed when you visited Theranos,” it said, “Theranos could perform hundreds of tests (more than 200) using its proprietary

technologies. The reports you reviewed at Theranos covered many of those tests Theranos developed for use with finger-stick samples.”

(The company had, indeed, provided me in the Spring of 2014 with what it said were—and what looked to be—validation studies for scores of different diagnostic tests, though, in truth, I lacked the expertise to assess their significance.)

The statement then went on to address my followup question, which was basically: *If you were capable of doing 200-plus tests using your proprietary methods, why weren't you in fact doing them?*

Here, with trademark, Theranos-ian opacity, is the reply:

Over time, we've been optimizing our clinical lab to bring up tests that are more commonly ordered, and in some cases move resources off the proprietary tests that are less commonly ordered to get to a point where the ordering patterns we are seeing can all be accommodated through our finger-stick technology.

Got that?

I then started looking back at my research for the original story—which had been conducted, by then, 17-19 months earlier—to try to reconstruct how I made the error.

As much as I'd like to say that Holmes lied to me, I don't think she did. I do believe I was misled—intentionally—but I was also culpable, in that I failed to probe certain exasperatingly opaque answers that I repeatedly received.

“We do routine, specialty, and esoteric tests,” Holmes told me in May 2014. “What we've done is take those, and develop the chemistry and analytic systems that made it possible to run them on a microsystem.”

When I started my research in March 2014, there were maybe something like 100 tests listed on Theranos’s online test menu. The number was gradually climbing as my work continued. By the time I was ready to publish there were 214 tests listed. I assumed that meant they had now adapted 214 tests to run on their microsystem.

In fact, at the time I didn’t know what else it could have meant. That’s because, so far as I can tell, at the time of my research the company had never revealed that it ever used conventional, nonproprietary analyzers to perform the tests it listed on its menu other than for research purposes.

About a year later—in May 2015—Holmes did explain to me, as I reported then, that the company had begun using such third-party analyzers, analyzing blood drawn by venipuncture. It had begun doing so, she explained, in order to be able to perform less commonly ordered tests, which she referred to as “esoteric” tests, thereby providing customers with one-stop shopping. This was presented to me as a new development, however—a departure from prior practice.

In mid-September 2015—after an inspection at which an FDA official opined that the company’s tiny blood collection device, known as a nanotainer, was an “uncleared” medical device—Theranos discontinued using its proprietary methods for all but at most one test, for which it had already received full FDA approval. This fact didn’t come to light until a month later, about a day after Carreyrou’s first article, and just a few hours before his second.

Back in early 2014, on both its website and in press releases of that time, Theranos did disclose that “we can use a tiny finger-stick or collect a *micro-sample* from a venous draw” (emphasis added). It thereby acknowledged that it was capable of doing venipuncture, but stressed that even then it strived to take only *micro-samples*. In our conversations, Holmes defined the word “micro-sample” as referring to the “tiny samples” or “these tiny droplets we take.”

Thus, “micro-samples”—whether from finger-stick or venipuncture—were what the company was about, and my assumption was that in either case they were being analyzed by the same proprietary devices, which were designed specifically to read tiny samples.

The company’s ads, promotional materials, and posters hanging on the headquarter walls, all seemed to hammer home this point. They featured slogans like “One tiny drop changes everything”; “All the same tests. One tiny sample”; and “1/1000th the size of a typical blood draw; Theranos runs any test available in central laboratories.”

My interviews with Holmes in 2014 seemed to further reenforce the point. “When we do collect venipuncture,” Holmes explained to me back then, “we take a smaller sample than traditionally required and we also use the smallest needle. It’s a tiny butterfly needle. The least painful. So it is a smaller volume.”

Surely this meant they were still analyzing these tiny draws with their proprietary devices—the ones uniquely designed to do so, I thought.

Nevertheless, the truth is that there was at least one great, flapping red flag that I missed. By May of 2014, I had already heard about anecdotes in which people had shown up at one of Theranos’s Wellness Centers and had been disappointed to learn that the test they ordered would require a venipuncture draw.

So I asked why that sometimes happened.

“The biggest reason,” Holmes told me in May 2014, “is we’re scaling. As we’re building out this infrastructure, we’re also building out our inventory and our capacity in terms of the number of samples that we can handle at any given point in time. . . . We’ll use venipuncture in addition to the micro-samples just to handle the volume of sample that we’re processing.”

I couldn't understand why venipuncture would help cope with volume. *Were they running out of nanotainers or some other specialized piece of equipment needed for fingerstick draws at some of the Wellness Centers? Running short of some reagent? Or was it just that they hadn't yet adapted certain tests for their proprietary platform?*

"It's more how we configure our own analytical systems," she said, "and the capacity that we have in those systems at any given point in time. And it evolves and it's changing. Every week we have more and more capacity."

I remember coming back to this point again later: *How exactly would venipuncture help them cope with volume?*

I was told that my question was getting into the realm of trade secret.

A secret, for sure. But maybe a different kind of secret.

So I blew it. And I should have included all these colloquies in the original story. I regret the error.

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Theranos founder Elizabeth Holmes, who promised to revolutionize blood testing, has been charged by the SEC with a "massive fraud" involving more than \$700 million.

Former president Ramesh "Sunny" Balwani was also charged. The two raised money from investors "through an elaborate, years-long fraud in which they exaggerated or made false statements about the company's technology, business, and financial performance," the SEC said Wednesday.

Theranos and Holmes agreed to resolve the claims against them, the SEC said. Holmes will give up control of the company and much of her stake in it. The SEC said it would take its case against Balwani to federal court in San Francisco.

Theranos is a Silicon Valley startup once valued at as much as \$9 billion. It was formed in 2003 by then 19-year-old Elizabeth Holmes, who dropped out of Stanford University to launch the company. It was considered an industry disruptor that aimed to create cheaper, more efficient alternatives to traditional medical tests.

But it's been rattled by controversy following a 2015 Wall Street Journal report that questioned its technology and testing methods. The company has since voided two years of blood tests, faced federal probes and pivoted away from blood testing.

Elizabeth Holmes declined to comment through her attorney.

Jeffrey B. Coopersmith, a partner at Davis Wright Tremaine who represents Balwani, called the SEC action against his client "unwarranted."

"Sunny Balwani accurately represented Theranos to investors to the best of his ability," Coopersmith said in a statement.

Coopersmith said Balwani invested millions of his own dollars into Theranos and "never benefited financially from his work at the company."

Theranos' independent directors issued a statement, saying "the company is pleased to be bringing this matter to a close and looks forward to advancing its technology."

According to the complaint against Theranos and Holmes, she and Balwani knew that its proprietary analyzer could perform only 12 of the 200 tests it published on its patient testing menu, something the Wall Street Journal hinted at in its first expose on the company.

Related: Former Equifax chairman charged with insider trading

The SEC said Theranos misled partners about its technology, and it allegedly used modified third-party machinery instead of its own to process some tests. The SEC also said it lied about revenue projections and claimed to investors that regulatory approval for its testing technology was voluntary when it wasn't.

Theranos compiled a binder for investors that included reports on clinical trials it said it had performed with pharmaceutical companies. But only one of the reports was co-written with a pharmaceutical client, according to the complaint. Two were written by Theranos employees.

Moreover, Theranos and Holmes made "false and misleading statements" in press accounts to bolster the startup's profile.

It then allegedly used those articles to generate financial interest. "In some instances, she and Theranos provided some of the articles containing untrue or misleading statements to potential investors," the complaint states.

The company was also said to be "on the verge of bankruptcy" in late 2017.

Theranos' reputation was inflated over the years with the help of some profile figures, including former secretary of states, Henry Kissinger and George Schultz, former secretary of defense William Perry, and senators Bill Frist and Sam Nunn -- all were once board members.

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Current secretary of Defense James Mattis, a former Theranos board member, cut ties with the startup ahead of his 2017 confirmation hearing.

Their ties with the company could have helped Holmes make it seem plausible that Theranos had a history of working with the Department of Defense -- something touted to mislead investors, according to the SEC.

In 2016, The Wall Street Journal reported Rupert Murdoch, the executive chairman of the publication's parent company 21st Century Fox, had invested \$100 million in Theranos. But he'd never been publicly linked to the startup.

One of the Therano's investors sued the company the same year for its \$96.1 million in funding money back after alleging securities fraud. The investment firm invested in the startup in February 2014.

At the time, Theranos released a statement: "The suit is without merit, the assertions are baseless, and the plaintiff is engaging in revisionist history."

The lawsuit between Theranos and Partner Fund Management was settled last year.

CNNMoney (New York) First published March 14, 2018: 12:58 PM ET

Huge employee turnover, Walgreens revealed the problems of Theranos tests—risking people's life.

Required Reading

If you're not familiar with all the details of this ever developing story, take a look at these articles for additional information. The first link is responsible for much of the news that's resulted from this situation.

- * Hot Startup Theranos Has Struggled With Its Blood-Test Technology
- * Walgreens Scrutinizes Theranos Testing
- * FDA Inspectors Call Theranos Blood Vial 'Uncleared Medical Device'
- * FDA's inspection report of Theranos (PDF)
- * Theranos Fires Back at Wall Street Journal Stories
- * Theranos' counter to the WSJ accusations

So what's the story behind this story? Is this a deliberate attempt to deceive on the part of Theranos or is it an example of what can happen when an "outsider" gets involved in the highly regulated medical device industry and faces off with the FDA without the proper experience in place to address potential areas of concern?

In a recent blog, I looked at the crowdfunding of medical devices and what can happen when claims made don't live up to the reality of the product that's actually developed. Once enthusiastic investors can quickly (and loudly) turn on a company or project, venting their frustration even directly on the crowdfunding page for all to see. Unfortunately, with the way these sites seem to be set-up, the money is still provided to the company that produces a product, albeit one that does not live up to the initial concept.

Is that what Theranos ultimately is? Were the technology claims taken at face value by significant investment backers? It would seem very unlikely, but given some of the accusations of former Theranos employees in the WSJ articles, it wouldn't be the only instance of Theranos trying to manipulate testing protocols for the sake of appearing more impressive. Theranos counters those claims by saying the former employees were actually unfamiliar with the actual testing the company performs. Whether or not you believe that is entirely up to you.

Another alternative to blatant deceit on the part of Theranos is the possibility that the company was simply playing in an industry it wasn't truly experienced enough to handle. In other words, how many FDA savvy employees work for Theranos? Did they seek consultants to help with the regulatory processes? Or were they simply naïve to the ways of the regulated industry in which they were entering?

Again, this scenario too seems unlikely, but it also brings in the debate over lab-developed tests and the FDA's regulation of them. If Theranos testing protocols fall under the realm of LDTs, then they aren't necessary under the oversight of the FDA. Sure, the blood collection device is (and that's why changes are currently occurring at the company), but does the FDA have the authority to inspect the company's tests if they are LDTs?

Ultimately, I think everyone (with the exception of competitors to Theranos perhaps) wants the company to be successful. The ideas and hope embedded within the original claims the company made will only enhance the quality of care that we are able to achieve within our healthcare system. Further, empowering patients to make decisions and get involved with their own healthcare management would likely improve their overall health.

Unfortunately, before any of that will be possible, Theranos is going to have an uphill battle in defending itself, its technology, and its CEO in this very public debate over the realistic capabilities it can provide. Hopefully, it learns from this experience and if the technology truly functions the way they've claimed, they'll bring on the necessary regulatory experts and better navigate the troubled waters in which they currently find themselves.

Credit: by Sean Fenske