

Q&A

BY CAITLIN ROPER



ONE DROP, INFINITE DATA HOW ELIZABETH HOLMES BUILT A BETTER BLOOD TEST

PHLEBOTOMY. Even the word sounds archaic—and that's nothing compared to the slow, expensive, and inefficient reality of drawing blood and having it tested. As a college sophomore, Elizabeth Holmes envisioned a way to reinvent old-fashioned phlebotomy and, in the process, usher in an era of comprehensive superfast diagnosis and preventive medicine. ¶ That was a decade ago. Holmes, now 30, dropped out of Stanford and founded a company called Theranos with her tuition money. Last fall it finally introduced its radical blood-testing service in a Walgreens pharmacy near the company headquarters in Palo Alto, California. (The plan is to roll out testing centers nationwide.) Instead of vials of blood—one for every test needed—Theranos requires only a pinprick and a drop of blood. With that they can perform hundreds of tests, from standard cholesterol checks to sophisticated

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genetic analyses. The results are faster, more accurate, and far cheaper than conventional methods. ¶ The implications are mind-blowing. With inexpensive and easy access to the information running through their veins, people will have an unprecedented window on their own health. And a new generation of diagnostic tests could allow them to head off serious afflictions from cancer to diabetes to heart disease. ¶ None of this would work if Theranos hadn't figured out how to make testing transparent and inexpensive. The company plans to charge less than 50 percent of the standard Medicare and Medicaid reimbursement rates. And unlike the rest of the testing industry, Theranos lists its prices on its website: blood typing, \$2.05; cholesterol, \$2.99; iron, \$4.45. If all tests in the US were performed at those kinds of prices, the company says, it could save Medicare \$98 billion and Medicaid \$104 billion over the next decade.

What was your goal in starting a lab-testing company?

We wanted to make actionable health information accessible to people everywhere at the time it matters most. That means two things: being able to detect conditions in time to do something about them and providing access to information that can empower people to improve their lives.

There are a billion tests done every year in the United States, but too many of them are done in the emergency room. If you were able to do some of those tests before a person gets checked into the ER, you'd start to see problems earlier; you'd have time to intervene before a patient needed to go to the hospital. If you remove the biggest barriers to these tests, you'll see them used in smarter ways.

What was your motivation to launch Theranos at the age of 19? What set you on this road?

I definitely am afraid of needles. It's the only thing that actually scares me. But I started this company because I wanted to spend my life changing our health care system. When someone you love gets really sick, most of the time when you find out, it's too late to be able to do something about it. It's heartbreaking.

You're not alone in your fear of needles.

Phlebotomy is such a huge inhibitor to people getting tested. Some studies say

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that a substantive percentage of patients who get a lab requisition do not follow through because they're scared of needles or they're afraid of worrying, waiting to hear that something is wrong. We wanted to make this service convenient, to bring it to places close to people's homes, and to offer rapid results.

Why the focus on rapid results?

We can get results, on average, in less than four hours. And this can be very helpful for doctors and patients, because it means that someone could, for example, go to a Walgreens in the morning to get a routine test for something their doctor is tracking, and the physician can have the results that afternoon when they see the patient. And we're able to do all the testing using just a single microsample, rather than having to draw a dedicated tube for each type of test.

So if I got a blood test and my doctor saw the results and wanted other tests done, I wouldn't have to have more blood drawn?

Exactly. And on their lab form, the physician can write, "If a given result is out of range, run this follow-up test." And it can all be done immediately, using that same sample.

Some conventional tests, like pH assays, can be done quickly. Others, like those that require culturing bacteria or viruses, can take days or even weeks. Are there some tests that take Theranos longer? Can everything really be turned around in four hours?

Yes, we had to develop assays or test methodologies that would make it possible to accelerate results. So we do not do things like cultures. In the case of a virus or bacteria, traditionally tested using a culture, we measure the DNA of the pathogen instead so we can report results much faster.

Where do you see this making a big difference?

Fertility testing is a good example. Most people pay for it out of pocket, and it can cost as much as \$2,000. These tests provide the data you need to figure out someone's fertility, and some women can't afford them. Our new fertility panel is going to cost \$35. That means women will be able to afford the tests. They'll be able to better manage the process and take some of the stress out of trying to conceive.

What are you doing to ensure the accuracy of your testing?

The key is minimizing the variability that traditionally contributes to error in the lab process. Ninety-three percent of error is associated with what's called pre-analytic processing—generally the part of the process where humans do things.

Such as?

Manually centrifuging a sample or how much time elapses before you test the sample, which brings its decay rate into play.

So how do you avoid these potential errors?

There's no manual handling of the sample, no one is trying to pipette into a Nanotainer, no one is manually processing it. The blood is collected and put into a box that keeps it cold. The very next thing that happens is lab processing, and that's done with automated devices at our centralized facility with no manual intervention or operation.

How can improved processes actually save lives?

We've created a tool for physicians to look at lab-test data over time and see trends. We don't usually think about lab data this way today. It's "Are you in range, or are you out of range?" Instead, we like to think, "Where are you going?" If you showed me a single frame from a movie and asked me to tell you the story, I wouldn't be able to do it. But with many frames, you can start to see the movie unfold.

How else can you use this technology?

Many, many years of work went into making this possible. We started our business working with pharmaceutical companies. Because we made it possible to get data much faster, they could use our infrastructure to run clinical trials. They were also able to run what's called an adaptive clinical trial, where based on the data, they could change the dosing for a patient in real time or in a premeditated way, as opposed to waiting a long period and then deciding to change a dose.

In the long run, what impact will your technology have?

The dream is to be able to help contribute to the research that's going on to identify

THE DREAM IS TO HELP I.D. CANCER SIGNATURES AS THEY CHANGE OVER TIME SO WE CAN INTERVENE EARLY."

cancer signatures as they change over time, to help intervene early enough to do something about an illness.

Will people become more used to gathering and examining their own health data?

No one thinks of the lab-testing experience as positive. It should be! One way to create that is to help people engage with the data once their physicians release it. You can't do that if you don't really understand why you're getting certain tests done and when you don't know what the results mean when you get them back.

It drives me crazy when people talk about the scale as an indicator of health, because your weight doesn't tell you what's going on at a biochemical level. What's really exciting is when you can begin to see changes in your lifestyle appear in your blood data. With some diseases, like type 2 diabetes, if people get alerted early they can take steps to avert getting sick. By testing, you can start to understand your body, understand yourself, change your diet, change your lifestyle, and begin to change your life. ■

Theranos' Nanotainer holds just a drop of blood. As many as 30 lab tests can be done from this one tiny sample.

