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THE WEEKEND INTERVIEW

Elizabeth Holmes: The Breakthrough of Instant Diagnosis

A Stanford dropout is bidding to make tests more accurate, less painful—and at a fraction of the current price.

By Joseph Rago

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Palo Alto, Calif.

"The reality within our health-care system today is that when someone you care about gets really sick, by the time you find that out it's most often too late to do anything about it. It's heartbreaking. Because in those moments, there's nothing you wouldn't do to change it, and too often you're helpless," says Elizabeth Holmes. "We're finding cancer when you have a tumor, or heart disease by virtue of the fact that you're having a heart attack."

She wants to change that.

Ms. Holmes, a 29-year-old chemical and electrical engineer and entrepreneur, dropped out of Stanford as an undergraduate after founding a life sciences company called Theranos in 2003. Her inventions, which she is discussing in detail here for the first time, could upend the industry of laboratory testing and might change the way we detect and treat disease.

Ten years ago, Ms. Holmes was working out of the basement of a group college house, a world away from her current headquarters at a rambling industrial building in a research park just off campus. The company's real estate was one of the few Theranos facts known to Silicon Valley, but one suggestive of the closely held business's potential: The space was once home to Facebook, and before that Hewlett-Packard.

The secret that hundreds of employees are now refining involves devices that automate and miniaturize more than 1,000 laboratory tests, from routine blood work to advanced genetic analyses. Theranos's processes are faster, cheaper and more accurate than the conventional methods and require only microscopic blood volumes, not vial after vial of the stuff. The experience will be revelatory to anyone familiar with current practices, which often seem like medicine by Bram Stoker.

A Theranos technician first increases blood flow to your hand by applying a wrap similar to one of those skiing pocket warmers, then uses a fingerstick to draw a few droplets of blood from the capillaries at the end of your hand. The blood wicks into a tube in a cartridge that Ms. Holmes calls a "nanotainer," which holds microliters of a sample, or about the amount of a raindrop. The nanotainer is then run through the analyzers in a Theranos laboratory. Results are usually sent back to a physician, but a full blood work-up—metabolic and immune markers, cell count, etc.—was in my inbox by the time I walked out the door. (Phew: all clear.)

It's the kind of modern, painless service that consumers rarely receive in U.S. health care, though Ms. Holmes makes the point the other way around: "We're here in Silicon Valley inside the consumer technology world . . . and what we think we're building is the first consumer health-care technology company. Patients are empowered by having better access to their own health information, and then by owning their own data."

FRED HARPER

And a Theranos clinic may be coming soon to a pharmacy near you. On Monday the company is launching a partnership with Walgreens for in-store sample-collection centers, with the first one in Palo Alto and expanding throughout California and beyond. Ms. Holmes's long-term goal is to provide Theranos services "within five miles of virtually every American home."

Diagnostics is one of those corners of the health markets that is more irrational the closer you look. Tests account for between 2% and 2.5% of health spending, but Ms. Holmes notes that they drive an estimated seven or eight of every 10 clinical decisions by physicians, with 6.8 billion lab tests annually in the U.S.

"The art of phlebotomy originated with bloodletting in 1400 B.C. and the modern clinical lab emerged in the 1960s—and it has not fundamentally evolved since then," she says. The billions of tests generally follow the same ritual: In a hospital or clinic, "you go in, sit down, they put a tourniquet on your arm, stick you with a needle, take these tubes and tubes of blood," as Ms. Holmes describes it.

The specimens are then transported, via a courier or hospital pneumatic tube, to a centralized lab, where they are manually removed from the tubes with a pipette and mixed with a chemical reagent or sent through instruments like a centrifuge or mass spectrometer. After days or weeks of waiting, your doctor finally gets the results.

One major problem, Ms. Holmes says, is that physicians rarely have "the best actionable information to make the best possible diagnosis at the time it matters." She posits a hypothetical patient whose doctor orders a test and discovers that she has a dangerously low hemoglobin count, so he puts her on an anti-anemia drug. He must order another test to find out what kind of anemia she has, and days later it turns out to be merely an iron deficiency. The best final treatment was actually "take some iron pills or eat more spinach."

Theranos's technology eliminates multiple lab trips because it can "run any combination of tests, including sets of follow-on tests," at once, very quickly, all from a single microsample. Ms. Holmes estimates that patients and doctors will receive readouts in "as little as two hours" and can even do so before an office visit based on their physician's recommendation for better, or at least less ad hoc, consultations.

Only about 62% of tests that doctors order are ultimately carried out, according to health-policy researchers at the Lewin Group. One reason tests aren't performed: not enough blood. To ensure that labs don't reject samples, several studies have documented that medical institutions sometimes collect as much as *45 times* the amount of blood from patients that conventional tests actually require.

Luckily, blood is a renewable resource, though the small Theranos sample size is a particular advance for the elderly, for whom blood draws can be agony because of collapsed veins. It's also good news for children who fear needles, and for oncology patients, whose blood is being constantly tested.

Another Theranos advance is its testing's accuracy. Ms. Holmes believes the chain of conventional laboratory custody introduces too many opportunities for error, "which is basically wherever humans are involved." The integrity of lab specimens can be contaminated if they sit too long on the bench, or if they're mistakenly processed by a tech, or by temperature, and so forth.

A 2002 review in the journal Clinical Chemistry found error estimates ranging from one out of every 33-50 tests to one of every 8,300, though the rate has likely since improved. The same sample sent to two different labs can yield two varying results, and the same lab testing the same sample twice can yield different results too.

That's because the precision of lab instruments, and their reference ranges, vary from manufacturer to manufacturer. Labs buy from different vendors and often don't calibrate the machines to each other. Certain tests may be reported with fairly wide margins of error, such as a plus-or-minus 30% of allowable error for HDL cholesterol. Ms. Holmes notes that a measurement that is essentially a 60% error range isn't very useful, especially over time, since disease itself is a progression over time.

Theranos's technology is automated, standardized, and attempts to subtract human

error from the process. It can thus achieve much lower variance ranges for a given test. Ms. Holmes says its tests have margins of "allowable error" targets less than 10%.

The medical promise of this speed and better information means catching disease in its earliest stages before the onset of symptoms. The company's analytic tools might also help realize the possibilities of truly personalized medicine, as scientists gain a better understanding of the heterogeneity of disease and how to treat individuals based on their own bodies, not large averages.

Theranos's tools may also allow doctors to analyze data "longitudinally"—to see trends, clusters and rates of change that they can't now. Medicine would ask fewer on-off, do-you-have-this-disease-or-not questions, and instead "meaningfully and powerfully answer the question of how to detect and manage these diseases early on," says Ms. Holmes.

She first funded Theranos at age 19 by cashing out an education trust that her parents set up, which allowed her to hire her first employee and rent lab space. Later rounds of funding were raised from venture capital and private equity. Once Theranos was more established, it started to earn revenue from contracts conducting pharmaceutical testing in cancer drug and other clinical trials.

A word about costs and what that investment bought, which doesn't follow the usual rules about a new medical technology. Ms. Holmes says Theranos can conduct a battery of tests for "tens of dollars," a phrase that does not exist in U.S. health care. She calls it "a watershed opportunity to change the trajectory of health costs through price transparency."

Since 1984, the Medicare Clinical Laboratory Fee Schedule has set reimbursements for 1,140 unique lab tests across 57 U.S. jurisdictions. That's 64,980 different price controls. Meanwhile, the prices that private insurers negotiate with providers are virtually trade secrets.

Theranos is committing to a half-off discount on Medicare fees. "So a test that costs $100 now, we'll do $50 or less. The quote-unquote payer community I don't think has ever seen someone walk in and say we want to bill you at less than you're willing to reimburse," she says. If this strategy succeeds in squeezing down prices—say, lowering testing as a share of total health costs to 1.5% from 2.3% now—it could save Medicare $61 billion over 10 years and Medicaid $96.1 billion, according to what Theranos calls a conservative estimate.

Ms. Holmes says her larger goal is increasing access to testing, including among the uninsured, though she might also have a market-share land grab in mind. For instance, she says Theranos will publish all its retail prices on its website. The company's X-ray of self-transparency also includes reporting its margins-of-error variations online and on test results and order forms, which few if any labs do now.

This strategy may be inviting a hell of a battle with the health industry, where the incentives are rigged against startups and the empire usually finds a way of striking back. Witness the medical-practice regulations that make medicine a cartel against competitors. Pathologists, lab scientists and technicians won't be pleased if their jobs go the way of travel agents.

Ms. Holmes declines to discuss Theranos's future plans, though one may speculate. There could be military applications in the battlefield, especially given the numerous framed American flags across the Theranos office and the presence on its corporate board of retired Gens. Jim Mattis and Gary Roughead, former Defense Secretary Bill Perry and former Secretary of State George Shultz.

The other obvious tech reality is that the devices keep shrinking, and over the last several years Theranos has been granted several patents for portable diagnosis system at the point of care. One of them even invokes—forget the iWatch—a wearable diagnostic device that would attach to the body with silicon microneedles "about the size of a human hair."

The biggest question is whether Ms. Holmes has discovered one of those often promised, more often elusive disruptive innovations designed to cut costs while improving quality. In a conversation about a year ago, Secretary Shultz said Ms. Holmes could be "the next Steve Jobs or Bill Gates."

When I put it to him again on my recent visit, he smiles slyly. "This is not the last thing she's going to invent or create."

Mr. Rago is a member of the Journal's editorial board.