

ANNALS OF INNOVATION DECEMBER 15, 2014 ISSUE

BLOOD, SIMPLER

One woman's drive to upend medical testing.



By Ken Auletta

December 8, 2014



Elizabeth Holmes says that her test can help detect ailments from just a few drops of blood. Photograph
by Jenny Hueston

One afternoon in early September, Elizabeth Holmes took the stage at TEDMED, at the Palace of Fine Arts, in San Francisco, to talk about blood. TEDMED, a part of the Technology, Entertainment, and Design enterprise, is an annual conference devoted to health care; its speakers span a range of inquiry from Craig Venter, the genomic scientist, discussing synthetic life, to Ozzy Osbourne discussing his decision to get his entire genome sequenced. The phrases “disruptive technology” and “the future of medicine” come up a lot.

Holmes, who is thirty, is the C.E.O. of Theranos, a Silicon Valley company that is working to upend the lucrative business of blood testing. Blood analysis is integral to medicine. When your physician wants to check some aspect of your health, such as your cholesterol or glucose levels, or look for indications of kidney or liver problems, a blood test is often required. This typically involves a long needle and several blood-filled vials, which are sent to a lab for analysis. Altogether, diagnostic lab testing, including testing done by the two dominant lab companies, Quest and Laboratory Corporation of America, generates seventy-five billion dollars a year in revenue.

Holmes told the audience that blood testing can be done more quickly, conveniently, and inexpensively, and that lives can be saved as a consequence. She was wearing her daily uniform—a black suit and a black cotton turtleneck, reminiscent of Steve Jobs—and had pinned her hair into an unruly bun. As she spoke, she paced slowly, her eyes rarely blinking, her hands clasped at her waist. Holmes started Theranos in 2003, when she was nineteen; she dropped out of Stanford the following year. Since then, she told the audience, the company has developed blood tests that can help detect dozens of medical conditions, from high cholesterol to cancer, based on a drop or two of blood drawn with a pinprick from your finger. Theranos is working to make its testing available to several hospital systems and is in advanced discussions with the Cleveland Clinic. It has also opened centers in forty-one Walgreens pharmacies, with plans to open thousands more. If you show the pharmacist your I.D., your insurance card, and a doctor’s note, you can have your blood drawn right there. (The sample is then sent to a Theranos lab.) From that one sample, Holmes said, several tests can be run—all less expensive than standard blood tests, sometimes as much as ninety per cent below the rates that Medicare sets. A typical lab test for cholesterol can cost fifty dollars or more; the Theranos test at Walgreens costs two dollars and ninety-nine cents.

In conversation, Holmes speaks in a near-whisper; onstage, her voice drops an octave and takes on a formal instructional cadence. The TEDMED crowd listened intently as she spelled out what she sees as

the shortcomings of the existing blood-testing business. The tests are too costly, are available at inconvenient times or places, and involve unpleasant syringes. Holmes has an aversion to needles, and her mother and her grandmother fainted at the sight of them and at the sight of blood. Recently, she told me, “I really believe that if we were from a foreign planet and we were sitting here and said, ‘O.K., let’s brainstorm on torture experiments,’ the concept of sticking a needle into someone and sucking blood out slowly, while the person watches, probably qualifies.”

Holmes thinks that getting a blood test should instead be a “wonderful” experience, and the aim of Theranos is to lower the barriers. She told the crowd that between forty and sixty per cent of people who are ordered by their doctor to get a blood test do not. Diabetes, sexually transmitted diseases, and other common medical conditions could be diagnosed and treated earlier if the tests were less onerous and more accessible, she said. “We see a world in which no one ever has to say, ‘If only I’d known sooner.’ A world in which no one ever has to say goodbye too soon.”

Theranos, which is privately held, is both a hardware company and a medical company, and for many years it has operated with a stealth common to many Silicon Valley startups. “For a long time, I couldn’t even tell my wife what I was working on,” Channing Robertson, a chemical-engineering professor at Stanford and the company’s first board member, told me. In recent months, Holmes has been giving similar versions of her TEDMED presentation in talks and interviews around the country. Investors have valued the company at more than nine billion dollars, comparable to the two major diagnostic labs. Holmes owns more than fifty per cent of the company; she was profiled last spring in *Fortune* and subsequently featured in *Forbes* as “the youngest self-made female billionaire in the world.” The board of her company is stocked with prominent former government officials, including George P. Shultz, Henry Kissinger, Sam Nunn, and William H. Foege, the former director of the Centers for Disease Control and Prevention. Dr. Delos M. Cosgrove, the C.E.O. and president of the Cleveland Clinic, is an avid supporter. “I think it’s potentially a breakthrough company,” he told me. “It represents a major change in how we deliver health care.”

The company’s rise comes at a time when consumers are increasingly eager for access to their personal data. The plummeting costs of DNA-sequencing technology have made it possible for companies such as 23andme to provide individuals with their genetic information directly, rather than through doctors, empowering nerdy customers and self-motivated patients. Smartphone apps let users track their heart rates, their sleep cycles, and the number of steps they’ve taken, and share the data with a

doctor or with friends. In her talk, Holmes said, “My own life’s work in building Theranos is to redefine the paradigm of diagnosis away from one in which people have to present with a symptom in order to get access to information about their bodies to one in which every person, no matter how much money they have or where they live, has access to actionable health information at the time it matters.” Cosgrove predicts that blood tests for many common health issues, including high cholesterol and diabetes, will be initiated by patients as well as by doctors. “The CVSs and the Walgreens and the Walmarts of the world are going to be taking a lot of things that currently go to primary-care physicians,” he said. “The impact of that on our industry will be enormous.”

But unfiltered medical data aren’t a pure virtue. Last year, the U.S. Food and Drug Administration barred 23andme from disseminating some information out of concern that consumers might misunderstand or misuse it. Some observers are troubled by Theranos’s secrecy; its blood tests may well turn out to be groundbreaking, but the company has published little data in peer-reviewed journals describing how its devices work or attesting to the quality of the results. “It’s trying to apply the Steve Jobs way of keeping everything secret until the iPhone was released,” Lakshman Ramamurthy, a molecular biologist and a former associate director at the F.D.A., told me. “But a health test is more consequential than a consumer product. It needs to be clinically valid and provide useful information.”

Holmes counters that Theranos is only trying to protect itself from competitors while it tries to do something unique. “There isn’t a company that does what we do,” she told me. “We’re creating a new space. We’re in a market for people who don’t like having a needle stuck in their arm.”

The day after her TEDMED talk, I met with Holmes in a conference room at the Theranos headquarters, a single-story building two blocks from the Stanford campus. (In November, Theranos moved its main offices to a larger space a few miles away.) Her home is a two-bedroom condo in Palo Alto, and she lives an austere life. Although she can quote Jane Austen by heart, she no longer devotes time to novels or friends, doesn’t date, doesn’t own a television, and hasn’t taken a vacation in ten years. Her refrigerator is all but empty, as she eats most of her meals at the office. She is a vegan, and several times a day she drinks a pulverized concoction of cucumber, parsley, kale, spinach, romaine lettuce, and celery.

Growing up, Holmes was in constant motion. Her father, Chris, worked for government agencies, including, for much of his career, the U.S. Agency for International Development and the State Department, often travelling abroad, overseeing relief and disease-eradication efforts in developing nations; today, he is the global water coordinator for U.S.A.I.D. Her mother, Noel, worked for nearly a decade as a foreign-policy and defense aide on Capitol Hill, until Elizabeth and her brother Christian, two years younger, were born. The family moved several times, which meant there was little opportunity to develop lasting friendships. Holmes describes herself as a happy loner, collecting insects and fishing with her father.

“I was probably, definitely, not normal,” she said. “I was reading ‘Moby-Dick’ from start to finish when I was about nine. I read a ton of books. I still have a notebook with a complete design for a time machine that I designed when I must have been, like, seven. The wonderful thing about the way I was raised is that no one ever told me that I couldn’t do those things.”

Chris Holmes’s great-grandfather Christian Holmes emigrated from Denmark, studied engineering, settled in Cincinnati, and became a physician. When Elizabeth was eight, she was given a tour of the local hospital where he worked and which was named in his honor. He had married the daughter of a patient, Charles Fleischmann, who pioneered packaged yeast and built a baking empire around it. (A nephew, Raoul Fleischmann, started this magazine in 1925, with Harold Ross.) Not all of Fleischmann’s children shared his entrepreneurial drive, and this was a common subject of conversation in the Holmes household. “I grew up with those stories about greatness,” she said, “and about people deciding not to spend their lives on something purposeful, and what happens to them when they make that choice—the impact on character and quality of life.”

In 1993, when Elizabeth was nine, her father took a job in Houston, as executive assistant to the C.E.O. of Tenneco, which was then a manufacturing and energy conglomerate. She knew that her father felt guilty for uprooting the family, so she wrote a letter to console him: “What I really want out of life is to discover something new, something that mankind didn’t know was possible to do.” She reassured him that Texas suited her, because “it’s big on science.”

For several years in the nineteen-eighties, Chris Holmes spent two weeks a month in China, helping American companies invest in large-scale development projects. Soon after the family moved to Houston, Elizabeth started studying Mandarin; by the summer following her sophomore year of high

school, she was intent on taking summer classes in Mandarin at Stanford. She repeatedly called the admissions office for information, only to be told, each time, that the program did not enroll high-school students. One day, her father recalls, the head of the program became so annoyed that he grabbed the phone from the employee who was talking to Holmes. "You've been calling constantly," he told her. "I just can't take it anymore. I'm going to give you the test right now!" He asked questions in Mandarin; she answered fluently, and he accepted her on the spot. She completed three years of college Mandarin while still in high school.

In 2001, in her senior year, Holmes applied to Stanford, was accepted, and then was named a President's Scholar, which came with a small stipend to select her own research project. Her parents sent her off with a copy of Marcus Aurelius' "Meditations," her father said, "to convey to her: Live a purposeful life." Holmes elected to study chemical engineering. She was drawn to the work of Channing Robertson, the chemical engineer and, at the time, a dean at the engineering school. Robertson is seventy-one and fit, with thinning hair and a relaxed smile; I visited him in his home on campus. Holmes's first class with him was a seminar on devices designed to control the release of drugs into the human body. One day, in her freshman year, Robertson said, she came to his office to ask if she could work in his lab with the Ph.D. students. He hesitated, but she persisted and he gave in. At the end of the spring term, she told him that she planned to spend the summer working at the Genome Institute, in Singapore. He warned her that prospective students had to speak Mandarin.

"I'm fluent in Mandarin," she said.

"I'm thinking, What's next? She's already coming into the research group meetings at the end of her freshman year with my Ph.D. students. I find myself listening to her more than to them about the next experiments to be done and the progress that's been made. I realized she's different."

That summer, at the Genome Institute, Holmes worked on testing for severe acute respiratory syndrome, or SARS, an often fatal virus that had broken out in China. Testing was done in the traditional manner, by collecting blood samples with syringes and mucus with nasal swabs. These methods could detect who was infected, but a separate system was needed to dispense medication, and still another system to monitor results. Holmes questioned the approach. At Stanford, she had been exploring what has become known as lab-on-a-chip technology, which allows multiple measurements

to be taken from tiny amounts of liquid on a single microchip. “With the type of engineering work and systems I had been focussing on at Stanford, it was quite clear that there were much better ways to do it,” she said.

Before returning to Stanford, Holmes conceived of a way to perform multiple tests at once, using the same drop of blood, and to wirelessly deliver the resulting information to a doctor. That summer, she filed a patent for the idea; it was ultimately approved, in November of 2007. Once back on campus, she went to see Robertson in his office and announced that she wanted to start a company. Robertson was impressed by the idea but urged her to at least consider finishing her degree first.

“Why?” she responded. “I know what I want to do.”

Holmes was consumed by the idea of developing a company. “I got to a point where I was enrolled in all these courses, and my parents were spending all this money, and I wasn’t going to any of them,” she said. “I was doing this full time.” Her parents allowed her to take the money they had set aside for tuition and use it to seed her company. In March, 2004, she dropped out of Stanford; one month later, she incorporated Theranos (the name is a combination of “therapy” and “diagnosis”). She persuaded Robertson to spend one day a week as a technical adviser to the company and to serve as her first board member. Eventually, he retired from his tenured position, and began working at Theranos full time.

Robertson introduced Holmes to several venture capitalists. She insisted that they abide by her terms, which included an understanding that she would retain control and pour the profits back into the company. By December of 2004, she had raised six million dollars from an assortment of investors. As she and the chemists and engineers dug deeper, she became convinced that they could accomplish five objectives: extract blood without syringes, make a diagnosis from a few drops of blood, automate the tests to minimize human error, do the test and get the results more quickly, and do this more economically.

A key to the company’s success was the hiring of Sunny Balwani, a software engineer, now forty-nine, whom Holmes had met in Beijing the summer after her senior year of high school. At the time, he was getting an M.B.A. from Berkeley. He had worked at Lotus and at Microsoft and been a successful entrepreneur, and in 2004 he began graduate studies in computer science at Stanford. He and Holmes

spoke often, and they shared a belief that software, not just chemistry or biology, mattered. If Theranos was going to be able to analyze a few drops of blood, engineers would have to develop the software to do it. In 2009, Balwani joined as C.O.O. and president. “Our platform is about automation,” he says. “We have automated the process from start to finish.”

Theranos has managed to keep its technology a secret for much of its decade of existence in part because it occupies a regulatory gray area. Most other diagnostic labs, including Quest and Laboratory Corporation of America, perform blood tests on equipment that they buy from outside manufacturers, like Siemens and Roche Diagnostics. Before those devices can be sold, they must be approved by the F.D.A., a process that makes their tests’ performances more visible to the public. But, since Theranos manufactures its own testing equipment, the F.D.A. doesn’t need to approve it, as long as the company doesn’t sell it or move it out of its labs. Holmes said that the company has long resisted discussing how its technology works or how it makes money in order to avoid tipping off potential competitors.

The company employs seven hundred people and, in addition to its headquarters, has a two-hundred-and-sixty-five-thousand-square-foot facility, in Newark, California, that manufactures the blood-testing devices. Holmes says that Theranos has a positive cash flow; it is clearly expanding. For many years, it has earned income from large pharmaceutical companies, including Pfizer and GlaxoSmithKline, which use its tests when they are conducting clinical trials on new drugs. It also earns revenue from the “wellness centers” that it has set up in Walgreens stores, its hospital work, and the U.S. military, although Holmes would not discuss the company’s arrangements with the latter.

In 2013, Theranos announced a “long-term partnership” with Walgreens that will eventually establish its wellness centers in most of the eighty-two hundred Walgreens stores. The Walgreens in Palo Alto has one, as do forty Walgreens pharmacies in Phoenix. Holmes envisages wellness centers in most Walgreens and Duane Reade stores, which would put Theranos “within five miles of every American.” Theranos also could sign up the rival drugstore chain CVS, which has seventy-eight hundred outlets.

One morning, I went to the Palo Alto Walgreens to get my blood tested. A trained phlebotomist wrapped my finger in a warming sleeve to help the blood flow and then swabbed it with alcohol.

Then, with a slight pinch from a small, square lancet containing a pricking pin, she drew two drops of blood, which she siphoned into a dime-size container. This took about two minutes. The container, marked with a bar code, was placed in a refrigerated box to be picked up and delivered to a Theranos lab a couple of miles away; the box pickup and return takes place three times a day.

The lab is a large, labyrinthine place bustling with chemists and technicians, and housing rows of machines, each easy for a single person to lift, in which the containers of blood are placed. What exactly happens in the machines is treated as a state secret, and Holmes's description of the process was comically vague: "A chemistry is performed so that a chemical reaction occurs and generates a signal from the chemical interaction with the sample, which is translated into a result, which is then reviewed by certified laboratory personnel." She added that, thanks to "miniaturization and automation, we are able to handle these tiny samples."

Theranos owes its success in part to its high-powered board, which Holmes corralled with the help of George Shultz, a Palo Alto resident, who, in his long career, has held four Cabinet positions, including Secretary of the Treasury and Secretary of State. Shultz is ninety-three and a fellow at Stanford's Hoover Institution; Holmes first met him in 2011. "It was one of those scheduled ten-minute meetings that turn into a two-hour meeting," she said.

Shultz agreed to join the board, and he meets with Holmes weekly. He introduced her to several other current board members: Bill Frist, a trained cardiac surgeon and former Senate Republican Majority Leader; Henry Kissinger, the former Secretary of State; Sam Nunn, a former Democratic senator and chairman of the Armed Services Committee; William J. Perry, the former Defense Secretary; and Richard Kovacevich, a former C.E.O. and chairman of Wells Fargo. All receive stock options from the company, among other forms of compensation. Kissinger, who is ninety-one, told me that Holmes "has a sort of ethereal quality—that is to say, she looks like nineteen. And you say to yourself, 'How is she ever going to run this?'" She does so, he said, "by intellectual dominance; she knows the subject."

Board members are clearly charmed by Holmes. She is a careful listener, and she is unnervingly serene; employees say that they can't remember an instance when she raised her voice. "She has sometimes been called another Steve Jobs, but I think that's an inadequate comparison," Perry, who knew Jobs, said. "She has a social consciousness that Steve never had. He was a genius; she's one with a big heart."

Holmes said that she had looked for “different kinds of people” for her twelve-member board. I pointed out that the membership includes no women. “Hopefully, I qualify,” she said. Equally notable is the fact that eight members are former elected, federal, or military officials. Aside from Frist, the one other board member with a medical license is William Foege, the former C.D.C. director. Holmes has established a medical task force, chaired by her and Dr. David Helfet, the director of the orthopaedic trauma service at New York’s Hospital for Special Surgery and New York-Presbyterian Hospital. I asked Holmes if the board was designed to attract government contracts.

“We don’t have any government contracts,” she said. “I’ve never applied for one, and I don’t plan to.” Theranos has conceded that it does earn revenue from the military, which Holmes calls “a really important area in terms of potential” for saving lives. But she said that the company’s policy has been to make its testing available “for far less than the government is willing to pay us.” She added that it would be “insulting” to suggest that her board members function as lobbyists. She views them as partners who are helping her to chart strategy. Kovacevich said that he brings business experience to the board. “I know most of the major retail-company C.E.O.s,” he told me, including Gregory D. Wasson, the C.E.O. of Walgreens. Kissinger advised Holmes to concentrate on building up Theranos in the U.S. before launching it in developing nations, he said, so that “it would not look like we were experimenting on them.”

Holmes and her board members like to emphasize how technologically advanced Theranos is; the implicit comparison is with the existing diagnostic behemoths such as Quest Diagnostics. The blood-test business is “dictated by the people who make the big machines,” Frist said, and they “obviously have a vested interest in keeping their technology out there.” He added, “You don’t need four tubes of blood” for a range of tests, or “this 1940 technology.”

Nigel Clarke, Quest’s senior scientific director for mass spectrometry, immunology, and automation, disagreed. I met Clarke in late September during a visit to Quest’s main lab center, near Teterboro Airport, in New Jersey. Quest runs about thirty full-service laboratories around the country; it performs six hundred million tests of all kinds annually—Theranos’s aim is to hit one million blood tests in 2015—and owns four thousand vehicles for picking up samples. The samples are delivered to an assembly line of machines, some larger than an S.U.V., that process vials of blood as they move along on conveyor belts. Instruments on the machines then identify the amount and the characteristics

of chemicals present in a blood sample, using a technique called mass spectrometry. Clarke maintains that these blood tests are as comparable to those of 1940 as a Lamborghini is to the Model T. He says that, over the past decade or so, the amount of blood needed has been reduced from two full vials to one-fifth of one vial.

The process is more automated than Frist suggests, but it is labor-intensive. Samples from hospitals and doctors' offices are labelled and packed in sealed plastic bags by phlebotomists. The samples are then picked up and delivered by drivers to a central lab, where they are manually sorted into various bins and then placed on the conveyor belts by hand. Holmes says that Theranos's operation is more automated, but it doesn't run itself. The partnership with pharmacies and hospitals will entail opening labs within easy distance of participating centers. The blood samples are much smaller than what Quest requires and are labelled digitally, but they still need to be picked up, and delivered, and handled by a technician—no small logistical task, and not free of the potential for human error.

Quest takes issue with several other of Theranos's claims. Holmes has argued that people want their blood tests to be more convenient; as evidence, she often states that between forty and sixty per cent of patients who are asked to get blood tests fail to do so. Theranos has developed these numbers internally, in part, Holmes said, through consumer surveys. Dermot V. Shorten, Quest's vice-president of strategy and ventures, told me the figure is lower. "The number is thirty per cent," he said, citing Quest's own figures. He added, "It is a huge number." He also said, less plausibly, "I don't think we've ever heard that fear of needles was a reason."

Clarke argues that finger-stick blood tests aren't reliable for clinical diagnostic tests; because the blood isn't drawn from a vein, the sample can be contaminated by lanced capillaries or damaged tissue. Holmes strongly disagrees: "We have data that show you can get a perfect correlation between a finger stick and a venipuncture for every test that we run." When I asked for evidence, I was sent a document by Daniel P. Edlin, Theranos's senior product manager, titled "Select Data." It purported to show favorable results from numerous comparison tests. I asked Edlin if the tests had been conducted by an independent third party. He replied by e-mail: "The clinical tests were conducted by a combination of Theranos and external labs," but he wouldn't say which ones.

When I asked Holmes for evidence that her tests were independently audited, she said that there have been "tens" of audits and "external third-party comparisons" of Theranos's tests, including those done

by the hospital groups that are adopting its finger-prick tests and the pharmaceutical companies that have contracted with Theranos for testing their products. Holmes says that Theranos is certified in forty-eight states, with two more applications pending, under the federal Clinical Laboratory Improvement Amendments of 1988. Under the amendments, laboratories like hers must be certified before they can perform tests for the general public, and their performance is evaluated three times a year by the College of American Pathologists. Holmes also pointed me to a pilot study published by *Hematology Reports*, an online-only peer-reviewed journal; she is listed as a co-author. The report, released in April, concluded that Theranos tests “correlated highly with values obtained” from standard lab tests.

The company’s reluctance to share its results or display its devices has prompted wariness among some physicians and medical officials. Lakshman Ramamurthy, the former associate director at the F.D.A., is concerned. “The technology should have peer review,” he said. To claim, as Theranos does, “that with a finger stick you can do hundreds of tests, your technology has to be different.” He added, “Does that not need some peer review?”

Technically, it doesn’t. “Typically, laboratories are not required to disclose data on how their tests work,” Alberto Gutierrez, the director of the F.D.A.’s office of in-vitro diagnostics and radiological health, told me. The F.D.A. imposes rigorous standards on companies seeking approval to sell new drugs. But most blood tests aren’t monitored by the F.D.A. and don’t receive the same level of pre-approval scrutiny. The labs are effectively left to police themselves. Gutierrez said that the F.D.A. is in the process of developing new guidelines for oversight of tests that labs develop for their own use in-house.

Holmes says that she welcomes government monitoring. She says that Theranos has submitted all its lab-developed tests for F.D.A. approval—a step that isn’t required and that no other diagnostic company has taken. “We believe that to realize our vision we must operate at the highest levels of excellence,” she told me. “And the F.D.A.’s stamp of approval is seen as an indicator of the quality of a product.” However, it’s unclear whether the F.D.A. has a mechanism for responding to the company’s request. The agency did not indicate if or when any kind of approval might be granted.

“When Theranos tells the story about what the technology is, that will be a welcome thing in the medical community,” Eric Topol, a cardiologist and geneticist and the director of the Scripps

Translational Science Institute, in La Jolla, California, said. “Until it does that, it can have the big labs saying Theranos is not real, or is not a threat. I tend to believe that Theranos is a threat. But if I saw data in a journal, head to head, I would feel a lot more comfortable.”

Theranos has raised more than four hundred million dollars from numerous investors, including the founder of Oracle, Larry Ellison. Holmes believes that the seventy-five-billion-dollar testing marketplace could grow to two hundred billion dollars, as more people take it upon themselves to go to a pharmacy and request blood tests for pregnancy, high cholesterol, and other common medical issues. At the moment, most such blood tests require a doctor’s note; Holmes says that this would have to change, and could. “There are states in the U.S. where citizens can order tests directly,” she said. “The fact that in some states it’s illegal for someone to be able to get basic data about their body—for example, you’re pregnant or you’re not, you have an allergy or you don’t. Not a lot of sophistication has to go into the interpretation of that test.”

For all of her practice at presentation, Holmes still sometimes has an engineer’s difficulty in clearly articulating how Theranos will advance the cause of preventive medicine. At TEDMED, she noted that diabetes, which is a major source of health-care costs, can be reversed through changes in life style. “Yet today there are eighty million Americans who are pre-diabetic,” she told the crowd, “and ninety per cent of them don’t know that they are.” Holmes figures that pre-diabetics aren’t gaining this knowledge either because they don’t visit the doctor or because they avoid the blood test, or both. Instead, she assumes that Theranos will make getting a blood test so simple and painless that it will become something that we do before visiting the doctor, or that we think to do on our own; the results would be forwarded to the physician, as a basis for further discussion.

Holmes insists that Theranos would be serving doctors, not replacing them. “If a test is abnormal, most people will want to have some type of treatment,” she told me. “People say, ‘What does Theranos mean?’ The simplest way to explain it is detection at the onset of disease in time for therapy to be effective. The detection piece”—Theranos’s role—“is half of the equation. The therapy piece is the other half.”

Prescriptionless blood tests raise a host of questions. “Will insurance be willing to pay for patient-ordered blood tests?” Bruce Deitchman, a dermatologist and pathologist, said. Deitchman has served as an alternate member of the American Medical Association’s expert panel that recommends

reimbursement rates to Medicare. “Will Theranos insist that test results be sent to physicians, and will patients want their doctors to know?” He noted that doctors are legally obligated to follow up and address abnormal blood tests with patients. In the absence of a doctor, will Theranos be held to that standard? Still, Deitchman added, getting patients involved in their own care “can lead to better health outcomes.”

Some experts see the changes to health care such as those envisaged by Theranos as inevitable, and mostly for the good. “Regardless of how doctors or anyone else may feel about it, this type of innovation is going to happen, and probably needs to happen,” Andy Ellner, a physician and the co-director of the Harvard Medical School Center for Primary Care, said. “There is going to be a big shift in power, control, and authority of health data from doctors to patients.” But Ellner added that there is “very little evidence” that paying more attention to blood tests, or doing more tests over all, will have an impact on people’s health. Of diabetes, in particular, he said that there is only “modest evidence that screening for it in particular populations helps us intervene earlier in a way that benefits people. The main value of knowing that someone is pre-diabetic is that it confirms what we already know: that people should be eating a better diet and exercising more.”

Holmes faces a number of challenges as she pursues her vision for Theranos. One is logistical. Holmes’s brother, Christian, a Duke graduate and former management consultant who joined the company three years ago and is now the director of product management, says, “You’ve got to be able to scale this. If we can’t, we’ll get killed.” Another challenge is the competition. As miniaturization becomes the standard, researchers are finding ways to bring medical tests directly to patients. Many companies are exploring a range of tests that don’t require needles, relying instead on lasers, oximetry, biosensors, and medical imaging, such as MRIs.

Holmes says she is acutely aware that technology could disrupt Theranos. “We focus all the time on disrupting ourselves, and that’s one of the core tenets in the way we operate,” she said. “Silicon Valley is a great symbol of disruptive technology being able to, one, change the world, and, two, obsolete itself.”

Late one afternoon in September, Holmes was driven from Palo Alto to the San Francisco airport, where she boarded a seven-seat Gulfstream 150 for a flight to Chicago. She would be

speaking at a panel; from there she would fly to Cleveland to attend meetings at the Cleveland Clinic. She was travelling alone. Members of the Theranos board sometimes worry about Holmes. “My wife and I feel that one of our jobs is to bring her out,” George Shultz told me. They invite her to the theatre, and this year threw her a thirtieth-birthday party at their home, which was attended by her parents, her brother, Balwani, Robertson, and several members of the board and their spouses. Henry Kissinger and his wife, Nancy, have tried, without success, to fix her up on dates. Her mother told me, “As a parent, I do hope that at some point she will have time for herself.”

This concern is lost on Holmes. The plane had reached cruising altitude, far above a bank of clouds, and another green vegetable drink had materialized in her hand. “I have done something, and we have done something, that has changed people’s lives,” she told me. “I would much rather live a life of purpose than one in which I might have other things but not that.” Also, she said, with a smile, “I think I’m very young. Still.” ♦

Published in the print edition of the December 15, 2014, issue.



*Ken Auletta began contributing to *The New Yorker* in 1977 and has written the *Annals of Communications* column since 1993.*

More: [Chief Executive Officers \(C.E.O.s\)](#) [Elizabeth Holmes](#) [Entrepreneurs](#) [Patents](#) [Silicon Valley](#)

[Stanford University](#) [TED Talks](#) [Theranos](#)
