

To: Elizabeth Holmes[eholmes@theranos.com]
Cc: Sunny Balwani[sbalwani@theranos.com]; Christian Holmes[cholmes@theranos.com]; Daniel Edlin[dedlin@theranos.com]
From: Jeffrey Blickman
Sent: Fri 9/6/2013 9:49:11 AM
Importance: High
Subject: RE: Readback.
Received: Fri 9/6/2013 9:49:12 AM

Went thru this and highlighted a few things in **yellow** directly in his email, and summarized below. There are a fair amount of issues that I've noted, some more concerning than others, please take a look.

Quote #1: use of the word "We're..." in the second part of quote is meant to imply the current health-care system", but without context the "we" might be confused with Theranos, hard to tell without add'l context

Quote #2: he called you a 30-something chemical engineer...inaccurate

Quote #3: "group college-kid house" – poorly worded

Main Copy:

- Says "nearly 500 employees" – overstatement
- Is his use of "microscopic" in reference to our blood samples accurate? Not a scientist but when I hear microscopic, think of things that can only be seen under microscope
- Describing the BCD, he says "into a tube in a cartridge..." – using the word cartridge might confuse an informed reader, suggest replacing
- I've always considered the volume of our BCD a trade secret, something we would share with him?
- Says "in the certified Theranos laboratory" but would be good to add "CLIA-certified"
- Calls our wellness centers "a Theranos unit" – would replace word unit
- He calls out "improved accuracy" when talking about reduction of human error thru automation
- His stat on Medicare/Medicaid savings is stated differently than the numbers we gave him. Our savings estimates are based on reducing lab test rates by 50% across the board not changing % of lab spend. The way his statement is made (reducing lab spend from 2.3% to 1.5% for both Medicare/Medicaid, these savings numbers would be \$64B Medicare/\$61B Medicaid. Think he either needs to reword his statement or we can provide him with these other numbers and clarify.
- Makes statement about "margins of error variations" (assume he means CV) being posted online, on test results, and on lab order forms...since that's a future happening and not accurate on 9/9, should we ask him to remove this?
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From: Joe Rago

Sent: Friday, September 06, 2013 1:48 AM

To: Elizabeth Holmes; Jeffrey Blickman

Cc: Joe Rago

Subject: Readback.

Elizabeth, Jeff,---

Deeply sorry for the delay, couldn't be helped on my end, but please find below all the quotes we plan to use in the interview, my paraphrases and all factual statements about Theranos. It will read somewhat disjointedly because its missing some exposition and transitions but journalistic ethics preclude me from just dumping the whole thing, though this will give you a sense of the shape and tone of the piece. I'm sure my editors will catch some typos tomorrow but wanted to get you copy for review as soon as I had it available.

If any points need to be clarified, if I've explained something incompletely or left out something important, or of course if there's an out and out error please let me know and we'll correct. Sometimes people explain something out loud in a wrong or imprecise way, so if any quotes ought to be refined we are open to that as well. There's a brief exchange with George Shultz in there if you'd like to run that by him, or else I will put in a call to his office.

Also one outstanding factual questions: What is the specific volume of a nanotainer?

Look forward to hearing from you, and I am available at any time via email or at 212.416.3175. We go to press at about 6pm EST.

With highest regards,---

Joe

Confidential

THPFM0000806157

“The reality within our health-care system now 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,” 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 30-something chemical engineer and entrepreneur, dropped out of Stanford as an undergraduate in 2003 to found a medical technology and life sciences company called Theranos. Her inventions, which she is discussing in detail here publicly for the first time, may upend the industry of laboratory testing and could even start to change the way we think about health and detect and treat disease.

Ten years ago she was working out of the basement of a group college-kid house, which seems far off from her current headquarters at a rambling industrial building in a research park just off campus.

The secret a decade in the making, which nearly 500 employees are now refining, are devices that automate and miniaturize more than 2,000 laboratory tests, from routine blood work to advanced genetic analyses. Theranos’s process is faster, cheaper and more accurate than the conventional methods and requires only microscopic blood volumes, not vials and vials of the stuff.

A technician uses a wrap similar to skiing pocket warmers to increase blood flow in your finger and then uses a fingerstick to draw a few droplets of blood from the capillaries at the end of your hand—almost unnoticeable. The blood is instantly wicked into a tube in a cartridge Ms. Holmes calls a “nanotainer,” which holds xxx milliliters, or about the amount of xxx. The nanotainer is run through the analyzers in the certified Theranos laboratory. A full blood workup—metabolic and immune markers, cell count, etc.—was in my inbox by the time I walked out the door. (Phew: all clear.)

“We’re here in Silicon Valley inside the consumer technology world and we think it’s possible to build, and what we think we’re building, is the first consumer health-care technology. Patients are empowered by having access to their own health information, by owning their own data.” Who knows, she adds, “people might even enjoy the process. People don’t think about enjoying lab tests.”

a Theranos clinic may be coming soon to a pharmacy near you. On Monday the company is launching a national partnership with Walgreens for in-store sample collection centers, with the first one opening in Palo Alto. Ms. Holmes’s long-term goal is a Theranos unit “within five miles of virtually every American home.”

Tests account for about 2% or 2.5% of spending but as Ms. Holmes points out they drive an estimated seven or eight of every 10 clinical decisions by physicians. The industry is not well structured to do so much work. “There has not been a lot of change in that space for a very long time. 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.”

The 6.8 billion lab tests that are conducted each year begin 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 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 sometimes weeks of waiting, your doctor will get your results.

One major problem with “the sheer logistics of the phlebotomy process” is that physicians don’t have “the best actionable information to make the best possible diagnosis at the time it matters.” Ms. Holmes posits a hypothetical patient whose doctor orders a test and discovers 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 an iron deficiency. The best treatment was actually “take some iron pills or eat more spinach.”

Theranos’s proprietary 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 patients and doctors

will receive read-outs in “as little as two hours” and can even do so prior to an office visit based on their physician’s recommendation for better, or least less ad hoc, consultations.

Only about 62% tests doctors order are carried out, according to the Lewin Group, and one reason is the amount of blood required. The small Theranos sample size is a particular advance for elderly: often with collapsed veins; children: the fear and pain of needles; and oncology patients: where samples must be taken so frequently that often more can’t be drawn without new health risks.

Theranos’s other advance is **improved accuracy**. The chain of conventional laboratory custody, Ms. Holmes believes, introduces too many opportunities for error, “which is basically wherever humans are involved.” The integrity of lab specimens can be contaminated by sitting too long on the bench, how they’re processed by a tech, temperature, and so forth. Patients might be shocked by how much. The same sample sent to two different labs could yield two different results. The same lab testing the same sample twice could yield different results too.

Another problem is the precision and sensitivity of lab instruments and their reference ranges vary from manufacturer to manufacturer, and labs buy from different vendors and often don’t calibrate the machines to each other. The federal body that regulates labs also pretty pretty wide margins of error for tests, or the degree to which they underestimate or overestimate the true value, like a plus or minus of 30% for HDL cholesterol levels. Ms. Holmes pointedly notes that a measurement that is essentially a 60% educated guess isn’t very useful, especially over time--when in fact disease itself is a progression over time.

Because Theranos’s process is automated and miniaturized it can achieve much lower technical variance ranges when measured against the clinical gold standard for a given test. Ms. Holmes says all its tests are less than 10% and often “significantly less.”

The speed and ease of what Ms. Holmes calls “better information, more often, faster” means catching disease in its earliest stages before the onset of symptoms when there is a better chance for recovery and better manage the chronic diseases ultimately kill seven of 10 Americans. The company’s analytic tools might also help might help realize the possibilities of truly personalized medicine.

Current testing, she says, is like “a movie I’ve never seen and you take one frame out and say, okay, Elizabeth, tell me the story. I’m going to have a really difficult time unless you give me a series of slides and then maybe I can start.” Theranos can deliver consistent data points in something approaching real time, building off “a standardized platform all around, with very low variation.” That means doctors can surveil consistent data “longitudinally” and see trends and clusters and rates of change that they can’t now in static test values. 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.”

Theranos has been investigating these questions for years as it has quietly brought in revenue and improved its technology by running testing for clinical pharmaceutical trials, in cancer at first and then expanding to other conditions. Instead of carpet bombing a tumor with a new drug and waiting six months to see what happened, Ms. Holmes explains, Theranos’s methods allowed for so-called adaptive trials that “tailored therapies on an individual basis” and “refit and retune the model to shift doses in a premeditated way.

Ms. Holmes says Theranos can conduct a battery of tests for “tens of dollars,” which is not often a phrase heard in health care. She calls it “a watershed opportunity to change the trajectory of health costs through price transparency.”

Theranos is committing to a half-off discount on the Medicare fees. “So a test that costs \$100 now, we’ll do for \$50 or less. The quote-unquote payer community I don’t think has ever seen someone walk in say we want to bill you at less than you’re willing to reimburse,” she says. If this strategy succeeds in marginally squeezing down test prices--to 1.5% of total health spending 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.

Theranos will publish all its retail prices on its web site. The company's x-ray transparency also includes reporting its margins-of-error variations online and on test results and order forms, which few if any incumbent labs now do.

For now, Ms. Holmes may have discovered one of those often promised, more often elusive disruptive innovations that is designed to take costs out of the health system while also improving quality. In a conversation about a year ago Secretary Shultz called Ms. Holmes "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," is all he'd say.