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Theranos' Blatant Disregard for Patient Safety

By Lila Abassi — March 11, 2016

Laboratory equipment via Shutterstock [1]

I'm not sure if it is appropriate to laugh at this company's chutzpah because endangering a patient's life is no laughing matter. That said, it's a little hard not to be amused by what's going on at Theranos right now. They earned it.

What started off as a company which gleefully offered revolutionary technology and promises of breakthrough performance, Theranos seems to have failed miserably. The company's website alleges [2] that they are, "working to facilitate the early detection and prevention of disease, and empower people everywhere to live their best possible lives," and that they "lead the industry in transparency and quality."

Except, sorry folks, these guys are doing anything but. An article [3], recently published in the *Wall Street Journal*, discusses the time that the Feds swung by Theranos labs (the report is not publicly available yet) and found that blood tests were performed on 81 patients within a span of six months on lab equipment that had not passed quality control assessments and provided inconsistent lab results.

The federal regulators from the Centers for Medicare and Medicaid Services (CMS), which is part of the Department of Health and Human Services, sent a letter to Theranos' medical director, Sunil Dhawan, MD. The letter [4] contained some feedback - all of it bad:

- To perform lab tests they must comply with CLIA (clinical laboratory improvement amendments) requirements
- Based on recertification survey, they are not in compliance with CLIA
- With regard to hematology labs "deficient practices of the laboratory pose *immediate* jeopardy to patient health and safety" (requiring immediate corrective action) because it has "already caused, is causing, or is likely to cause, at any time, serious injury or *harm, or death*"
- There were five conditions not met by the lab (based on random sampling and not all the

faulty practices of the lab were assessed)

This is both upsetting and instructive at the same time. In the WSJ article, it was noted that the company was not even using their own proprietary equipment to run a blood test that checks the blood's coagulation panel (ability of blood to clot), which is critically important for anyone taking blood thinning medication. If not carefully monitored they are at risk of having a stroke or life-threatening bleeding.

"We have conducted assessments to identify any patients affected or having the potential to be affected by the issues identified by CMS and we have no reason to believe that these issues have affected patients' health," as per a California lab director, Kingshuk Das, who has since taken over for their previous director, Dr. Dhawan. Seems like a bunch of empty words, no? That is unless you're an attorney hoping to get in on the inevitable lawsuits.

Theranos was a nine-billion-dollar startup that promised [5] to offer diagnostic testing at ten percent of the cost of centralized laboratories and the company was touted as being "one of the top 10 medical and technological innovations in 2013," and an example of disruptive technology (one that shakes up the industry with a ground-breaking product). Add to that, an attractive, young, female CEO and it is the recipe for success.

But the sad truth about Theranos is that it overpromised and underdelivered – consistently – and it has been found repeatedly that most of this company's claims have been exaggerated. We hope that this mess will not cost any patients' their lives. But there is a lesson here - technology is not the answer to everything, especially in a field as unpredictable as medicine. Also, hype doesn't make something work. Did the young, attractive female CEO angle drive this company to a place where it did not belong? Investors are likely asking themselves this question right now.
