

Letter to the Editor

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Theranos phenomenon – part 3

DOI 10.1515/cclm-2016-0107

Received for publication February 10, 2016; previously published online March 11, 2016

Keywords: overdiagnosis; overtesting; overtreatment; self-interpretation; self-testing; Theranos.

To the Editor,

In our previous communications [1–3], we commented on the Theranos technology, its possible advantages and disadvantages and provided evidence that the perceived “revolutionary” approaches to new diagnostics have likely been overstated. We and others [4] have also drawn attention to the fact that the secrecy associated with the Theranos technology and the lack of peer-reviewed publications does not allow for detailed comments on the company’s claims regarding validity and quality of results.

We have also raised the related issue of the clinical value of patient self-testing and self-interpretation, and drew attention to the fact that these approaches may not serve the best interests of the patients [5]. We have also challenged Theranos to conduct a short-term prospective trial to establish the possible benefits and drawbacks of self-testing and self-interpretation [6].

In the last 12 months we witnessed new revelations on Theranos and its technology. The FDA has recently concluded that one of Theranos’ major testing components, the so-called nanotainer tube, used for finger-prick blood collection, is an uncleared medical device. Other reports reveal that Theranos is primarily using commercial analyzers (such as the one from Siemens) to carry out the vast

majority of their testing, in regular venipuncture blood [7]. The proprietary instrument of Theranos (Edison) seems to be used for only one test (the herpes test, which is the only one until now with FDA clearance).

On January 25th 2016, a letter from the Center for Medicare and Medical Services of USA describes serious deficiencies with Theranos testing, saying some results pose “immediate jeopardy” to patients. Immediate jeopardy is defined as “a situation likely to cause at any time, serious injury or harm, or death, to individuals served by the laboratory or to health and safety of the general public”. The agency gave Theranos 10 days to correct the problems [8].

The questionable quality of Theranos’ services was followed by an announcement from Walgreens, the major business partner of Theranos, that they are pulling out from the partnership in some laboratories and closing some wellness centers [9]. The large USA insurer Capital BlueCross has also suspended blood drawing and testing at the Theranos central facility until the deficiencies are corrected [10].

The new revelations confirm our previous skepticism on the Theranos technology and quality of results. It appears that technologies bypassing peer review and choosing secrecy over transparency, may be vulnerable in the long run. Theranos is a classic example of a business that thrived in secrecy but exposed its weaknesses in the marketplace. The final chapter is yet to be written.

Author contributions: All the authors have accepted responsibility for the entire content of this submitted manuscript and approved submission.

Research funding: None declared.

Employment or leadership: None declared.

Honorarium: None declared.

Competing interests: The funding organization(s) played no role in the study design; in the collection, analysis, and interpretation of data; in the writing of the report; or in the decision to submit the report for publication.

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