

Letter to the Editor

Eleftherios P. Diamandis*

Theranos phenomenon – part 4: Theranos at an International Conference

DOI 10.1515/cclm-2016-0389

Received May 3, 2016; accepted May 14, 2016; previously published online June 3, 2016

Keywords: diagnostic technology; overdiagnosis; over-testing; overtreatment.

To the Editor,

It seems these days that Theranos is the talk of the town among clinical chemists. The interest of clinical laboratory professionals in Theranos originates from the fact that the company has promised to revolutionize and democratize laboratory testing outside of its traditional settings, such as in pharmacies, thus empowering patients to test themselves and even interpret their results. After Theranos commercialized its technology about a year ago, numerous reports provided mostly negative publicity, mentioning poor quality of results, non-compliance with quality assurance, non-transparency, etc. [1–3]. There is even an ongoing criminal investigation of the company's CEO, Elizabeth Holmes. These events have led clinical chemists to wonder if Theranos is indeed a company with “disruptive diagnostic technology” or an outlet which is trying some new concepts but with at least initial, startling failures. This author scrutinized first the Theranos technology in the peer review literature with a series of publications [1–5]. Additionally, the concept of self-testing and self-diagnosis for preventing various diseases was reviewed by this author, who emphasized not only the benefits of such practices but also the dangers of overtesting, overdiagnosis and overtreatment [6].

*Corresponding author: Eleftherios P. Diamandis, MD, PhD, FRCP(C), FRSC, Head of Clinical Biochemistry, Mount Sinai Hospital and University Health Network, 60 Murray St. Box 32, Floor 6, Rm L6-201, Toronto, ON, M5T 3L9, Canada, Phone: +(416) 586-8443, E-mail: ediamandis@mtsina.on.ca; Department of Pathology and Laboratory Medicine, Mount Sinai Hospital, Toronto, Ontario, Canada; Department of Clinical Biochemistry, University Health Network, Toronto, Ontario, Canada; and Department of Laboratory Medicine and Pathobiology, University of Toronto, Toronto, Ontario, Canada

Many clinical biochemists drew attention to the fact that the initial failures of Theranos should not deter us from seeking and applying new and revolutionary technologies in laboratory medicine. This author fully agrees with this position and my past experience shows that I already participated in many new technological innovations in laboratory medicine [7]. Recently, I co-authored a review describing new and potentially revolutionary technologies in laboratory medicine [8].

Theranos' difficulties were recently addressed in a number of ways. The company announced the appointment to their Scientific Advisory Board of four stellar clinical chemists, all of them ex-presidents of the American Association for Clinical Chemistry (AACC). I applaud the appointments since there is no question that these professionals can help Theranos move forward.

Over the approximately 10 years of their operation, Theranos has maintained strict secrecy on their technology and practices, and they did not publish either their technology or its evaluation in the peer reviewed literature [9]. The only independent evaluation of the technology was published recently, with the general conclusion that the Theranos technology is in many respects inferior to standard laboratory techniques and in some instances the differences of results could have led to inappropriate patient therapies [10]. All in all, it is clear that these are not good times for Theranos but it seems that they are taking steps towards the right direction.

This communication wishes to comment on the recent, and somewhat unprecedented, decision of the AACC Leadership to offer a plenary lecture to Mrs. Elizabeth Holmes, to present the Theranos technology at the AACC Annual Conference in Philadelphia, July 31–August 4, 2016. The rationale of this invitation was that clinical chemists in the United States and elsewhere are keen to listen about the until now secretive Theranos technology and ask questions. However, this author disagrees with the decision for several reasons, as outlined below.

AACC has various forums for any diagnostic company to present their technologies to its members and its conference participants. For example, companies with new

technologies submit abstracts at the annual meeting, participate in symposia presentations (after review and approval) or organize commercial workshops. The last 10 years, Theranos ignored the AACC Annual Conference and never submitted an abstract, or any other presentation, did not organize a commercial workshop or had a booth. Additionally, Theranos did not submit any of their “revolutionary” technology for consideration by our peer reviewed journal *Clinical Chemistry*. AACC has other forums for companies with innovative diagnostics to present their technologies and their evaluations. For example, AACC is organizing an annual conference “Emerging Clinical and Laboratory Diagnostics” which is the sequel to the legendary Oak Ridge conference, devoted to presenting new technologies to its attendees. Theranos disregarded this forum as well. It is clear that Theranos, despite having lots of opportunities to reach AACC members in the appropriate way (as mentioned above) they chose secrecy instead. Consequently, the current offering of AACC to Theranos, to present at the AACC annual meeting, is, in my opinion, inappropriate. Let us not forget that a podium presentation at AACC is not peer-reviewed and everything that we will hear about Theranos technology will remain speculative, until scrutinized by expert reviewers.

At the annual AACC conference, hundreds of companies participate under the same rules and regulations and many of these companies are longtime sponsors of AACC and its conference. I suspect that the preferential treatment of Theranos at the next AACC conference will annoy many current sponsors, and there is a danger that some could withdraw sponsorship.

One then wonders as to why AACC decided to portray Theranos at the annual conference, if the presented information will not be peer-reviewed material. Members could speculate on other explanations. One could be that the intention will be to moderate the negative opinions on Theranos technology, due to their recent regulatory and other troubles. Theranos is known for hiring influential public opinion leaders such as Secretaries of State, Generals, Admirals etc. on their scientific advisory board. Now, there is a perception that they may follow a similar strategy by hiring influential clinical chemists and by securing podium presentations from our organization. While these speculations may not be accurate, no doubt, they will percolate in the minds of most of the participants of the next AACC meeting, while listening to the presentation of the Theranos executive.

I conclude that AACC should have a firm policy of treating all industrial participants at the annual conference the same way and offer no favors to any companies, even if such companies have tremendous financial strength or political influence.

At the end of the day, the success of Theranos, or any other company for that matter, will depend on the quality of their products and their proven value in patient care. These attributes can only be properly assessed through peer review, transparency and publication of results in respected journals. Any other strategy is destined to fail.

Author contributions: The author has 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.

References

1. Diamandis EP. Theranos phenomenon: promises and fallacies. *Clin Chem Lab Med* 2015;53:989–93.
2. Li M, Diamandis EP. Theranos phenomenon – part 2. *Clin Chem Lab Med* 2015;53:1911–2.
3. Li M, Diamandis EP. Theranos phenomenon – part 3. *Clin Chem Lab Med* 2016;54:e145–6.
4. Li M, Diamandis EP. Theranos promises a new era of preventive health care – but where’s the physician? *Clin Biochem* 2015;48:1027.
5. Li M, Diamandis EP. Will Theranos take the challenge of performing a pilot study and publishing their results? *Can J Pathol* 2015;7:4.
6. Diamandis EP, Li M. The side effects of translational omics: overtesting, overdiagnosis, overtreatment. *Clin Chem Lab Med* 2016;54:389–96.
7. Rifai N, Diamandis EP, Lo YM, Kricka LJ, Wilding P, Ladenson JH, et al. Advancing laboratory medicine through innovation: a tale of six inventors. *Clin Chem* 2012;58:502–10.
8. Li M, Diamandis EP. Technology-driven diagnostics: from smart doctor to smartphone. *Crit Rev Clin Lab Sci* 2016;53:268–76.
9. Ioannidis JP. Stealth research: is biomedical innovation happening outside the peer-reviewed literature? *J Am Med Assoc* 2015;313:663–4.
10. Kidd BA, Hoffman G, Zimmerman N, Li L, Morgan JW, Glowe PK, et al. Evaluation of direct-to-consumer low-volume lab tests in healthy adults. *J Clin Invest* 2016;126:1734–44.