

# Governance basics for the physician-scientist considering business ventures. Lessons from Theranos

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## Abstract

The prospect of an innovative laboratory device capable of an array of testing from a tiny amount of blood caught the intense attention of both the medical and investment community. The device, however, was never properly validated, with several false and misleading claims made by its founder. This venture in the business of science went very badly for the firm Theranos with ensuing criminal convictions. Using public domain reports from trial testimony provided a unique opportunity to distill facts for key learnings for future stakeholders in the business of science. Several lessons related to basic governance unfolded during the trial's testimony and are the basis for this brief case study. These include (1) a board make-up that had a suboptimal understanding of the technology, (2) advisors that did not sufficiently engage, (3) management/employee trust was tarnished and (4) investors failing to perform optimal diligence prior to funding. These lessons are particularly important for the physician-scientist and health executive who may find themselves at the interface of health and commerce. Points to consider in such ventures are discussed toward fostering the avoidance of these breakdowns.

**Keywords** Governance · Medical devices · Theranos · Advisories · Laboratory tests

## 1 Introduction

The prospect of an array of clinical laboratory tests performed on a tiny sample of blood collected in a “nanotainer” and analyzed in a compact device caught the attention of both the medical and investment community [1]. The company was Theranos, its founder was Elizabeth Holmes and its device was Edison. This was a venture in the business of science, and it went very badly.

In 2015, during the development of this technology, Diamandis [2] published an opinion paper noting that most of the company's claims were exaggerated. He was correct.

The device was never properly validated, with false and misleading claims by executives leading to criminal charges against Holmes and the firm's Chief Operating Officer (COO) Ramesh “Sunny” Balwani. Both were charged, convicted [3] and sentenced.

A subsequent editorial by Diamandis [4], 7 years later, reinforced to laboratory medicine colleagues how the development of such systems must follow stringent and accurate pathways before adoption to clinical practice.

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Several lessons came to light during the trial's testimony and form the basis of this brief case study. These are particularly important for those in the healthcare sector, including the physician-scientist who may find themselves at the interface of health and commerce. This involvement is typically in the context of innovator, investor, company advisor or board member.

While books and documentaries remain a source of understanding this fateful Theranos business journey, this report will briefly review important neglected governance areas uncovered during trial testimony and examination. Thus, investigative trial reporting of Theranos stakeholders under oath provided a unique approach to our methodology. This afforded details that anyone involved in the business of health sciences should be knowledgeable of to better function in the healthcare business world (Table 1).

## 2 Board of directors (BoD) make-up

Two important issues provide valuable lessons with respect to optimal BoD governance. First is composition. As pointed out by Clearfield and Tilcsik, the Theranos Board was made up of "formers", i.e., former senators, chief executive officers, and federal cabinet officials [5]. Essentially white men approaching their 9<sup>th</sup> decade. While the experiences of such individuals are unquestionably valuable, the homogeneity of the group may contribute to being less likely to probe topics and uncover potential issues. The concept of avoiding "Group Think" or the need to avoid "rubber stamping" is applicable to evaluate all boards. Many modern boards utilize a skills matrix and board composition is regularly scrutinized for diversity of skills and backgrounds by entities such as Institutional Shareholder Services (ISS).

Apart from lacking social diversity, Theranos' BoD was short on biotechnology and medical expertise. Diversity of relevant disciplines must be considered in Board make-up.

This was illustrated in the testimony of former US Defense Secretary, one such prominent board member serving from April 2013 to December 2016. He noted he was not a medical expert but described the Theranos platform as "pretty breathtaking", with potential in the triage and care of military zone casualties. While never serving on a board and noting rudimentary knowledge of the device, he was impressed with company founder Holmes. He believed, however, that was no substitute for having the device prove itself. He then learned that Theranos was performing test results on non-Theranos devices and fraudulently reporting their source as from Edison and lost hope for the company [6].

It is important to note that issues can go astray despite a competent board. The lesson is to speak up when uncomfortable, involve one's board colleagues in critical debate, and frequently apply the 'New York Times Rule' when evaluating a sensitive situation, i.e., would you be comfortable if your decision appeared on the front cover of the newspaper.

"In camera" sessions of the board, i.e., board sessions without officers and then without CEO is best practice as it fosters critical discussion. There are many best practices for company Boards to provide oversight in the best interest of the company and its shareholders [7]. The major learning, in this case, is the need for both social diversity as well as sufficient subject matter expertise. For example, the aforementioned editorial [2] in the laboratory medicine literature should have been openly discussed in a board meeting to allow critical discussion and risk mitigation and management.

Board involvement in strategy is an essential function with member expertise and engagement crucial for optimal results [8]. In the case of Theranos, its leader held total control and was focused on the company's economic value rather than its sustainability [9]. By ignoring stakeholder forces, political realities, and laws, she "willed an organisation into existence and to enormous growth based on an idea, not a tangible technology breakthrough or reasonable hope for their appearance." [9]. Strake and colleagues [9] take the Theranos case through a Design Innovation (DI) lens, which if followed would have shed light on a faulty pathway independent of the character findings and criminal activity. The DI framework exercise is another example of a framework that can be useful to board members and advisors to achieve sustainable innovation.

## 3 Trustful employee engagement and suboptimal involvement of advisors

Trust is a key component of character-based leadership with several examples of its absence at Theranos. For example, trial testimony uncovered that a company whistleblower approached Balwani around erroneous test results; she was not taken seriously rather her competence put into question [10]. Additionally, a former lab director testified there was failure of the firm's quality-control program with possible patient impact. He was unsatisfied with Holmes' alternative explanations of data, referring to them as implausible. Another part-time director who never met Holmes or visited the

**Table 1** Summary of governance issues uncovered in Theranos case with potential remedies

Category	Observation	Potential remedies
Board of Directors (BoD) Make-up	Board primarily consisted of 'celebrity' members who had high profile in politics, military, and finance. Suboptimal scientific representation and social diversity	Board composition should not only be socially diverse but have expertise in the area of business at hand. In this case, laboratory medicine, biochemistry, regulatory, and medical device expertise was not represented optimally
Trustful Employee Engagement	Employees raising concerns were not valued with employee complaints of not being aware of key information to perform one's function	Respect employee technical concerns. Front-line workers / supervisors should be given opportunity to present to board. While agenda's often busy, it allows for a critical assessment of engagement
Sub-optimal Utility of Advisors	Lack of engagement of critical advisors. Employees input minimized. One physician with title of Laboratory Co-Director testified to having minimal engagement	Align on clear responsibilities, key result areas, and objectives
Due Diligence and Investors' Fear of missing out (FOMO)	The degree of diligence of some investors was not optimal, perhaps for fear of missing out (FOMO) on opportunity	Diligence is the foundation of investment with no stones left unturned. If risks exist, they are at least identified in order to mitigate
Romantic relationships in the office	Holmes and Balwani, who has 20 years her elder were having a romantic relationship that was not disclosed. There were claims of abuse	Transparency to BoD is optimal to avoid misunderstandings of governance

laboratory left the firm with concerns related to lack of clarity about the lab and her inability to edit documents she was to sign [11]. Related to such learnings from these employee testimonies is the optimal practice of having various departmental leads presenting directly to the Board.

In our collective experience, most firms use clinician-scientists as advisors and are proud to display members of their scientific advisory group (SAG) on company media; however, often without context as to what extent these experts are involved. Some members are deeply involved while others might be listed for ‘celebrity status’ reflecting their prior work and/or institution. Investors and venture experts must ask how deeply these experts are involved and a physician-scientist involved on such boards should be aware of how their involvement is positioned externally. Most times, it is accurate and not misleading; other times this may not be the case.

Given the critical nature of biochemistry and laboratory science to Theranos’ platform, professional staffing with clear performance objectives were in order. Following the abrupt resignation of the firm’s lab director in November 2014, the CEO’s dermatologist was hired as one of two co-directors of the lab. In testimony, it was noted that the Co-Director spent less than 10 h working on the company, had never reviewed the lab policy, and considered the role part-time work [12]. A basic fundament in industry is clear performance objectives with periodic reviews of such. Furthermore, The Sunshine Act transparency reports provide the public with information on the financial interactions of physicians and industry [13] and do come into play with such roles. These are publicly available and should be scrutinized by both outside investors and board members regularly.

## 4 Diligence and fomo

Diligence of an asset is fundamental to sound investment whether it be personal or funds entrusted to a venture firm. “Deep dive” assessments of several disciplines are conducted by experts, including, but not limited to, the soundness of science and working hypothesis, identification of realistic development plans and their milestones, asset (e.g., drug/device) procurement (cost of goods) and delivery methods (e.g., formulation), and intellectual property strength. Among the most important assessments in due diligence are management systems and depth of management [14]. Additionally, team functionality and leadership should not be overlooked. Such a process greatly improves the chances of identifying risks and approaches to their mitigation. Both the company and the investors mutually benefit from strong diligence. All investment opportunities and third-party collaborations need to tackle due diligence with a fresh lens [15] allowing risks to be minimized without sacrificing true innovation.

Theranos investors received significant scrutiny related to suboptimal diligence; often driven by fear by investors of missing out on a celebrated opportunity. This fear of missing out (FOMO) was frequently discussed in the context of investment by the family office of the former Secretary of Education (RDV Corporation). Testimony provided by the office’s lead of due diligence, detailed by Wetsman [16], highlighted several aspects of the suboptimal assessment. First, needing minimal FDA oversight in the approval process being a “lab-developed test” was viewed as a positive investment element. In cross examination, there was admission to not understanding the types of scientific tests in review documents, not scrutinizing patent filings, and not consulting regulatory or legal experts. There was more emphasis on relying on and not “upsetting” Holmes than the deep diligence typical of such large investments.

Diligence is another fundamental of investing and governance that should never be compromised. One needs risk identification in order to evaluate risk mitigation. As highlighted by De Cleyn and Braet [17] risks should be discussed, not kept secret.

## 5 Personal relationships in the office

While romantic relationships in the workplace may or may not impact the deliverables expected of employees, and the right to demand privacy about workplace romance has been reported as an underlying belief about workplace romance [18], the judge in the Theranos trial ruled on the significance of transparency of personal relationships in investment decisions. Specifically, it was ruled the government (Plaintiff) can ask investors examined in the trial about the knowledge of such, noting such a relationship between the firm’s two highest executives could be considered relevant to investment decisions. One major investor testified that he was unaware of the relationship between Holmes and Balwani and had he known it could have raised flags [19].

In yet another element to the saga, Holmes accused Balwani, nearly 20 years her elder, of physical sexual abuse while she was CEO—charges Balwani denied [20]. As noted in Table 1, transparency of intercompany relationships is optimal, particularly when involving officers of the company. Investments in companies with sound human resource disclosure policies is best practice.

## 6 Conclusion and avoidance of pitfalls

There are fundamental business governance principles that any physician-scientist who considers working in the business of health should be aware of. When best practices are followed, business misadventures are minimized; when they are ignored misadventures are exacerbated and disaster may ensue.

The recent trial of Theranos executives serves to highlight several fundamental governance issues that provide the physician-scientist new to business with valuable lessons and a course to follow as they pursue the noble venture in the business of medical science and the development of technologies with tremendous benefits. We hope that the several basic steps outlined in this paper (summarized in Table 1) assists one in avoiding pitfalls in the future.

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## References

1. Carreyrou J. Hot Startup Theranos has struggled with its blood-test technology. *The Wall Street Journal*. <https://www.wsj.com/articles/theranos-has-struggled-with-blood-tests-1444881901>. Published October 16, 2015. Accessed 18 Jul 2022.
2. Diamandis EP. Theranos phenomenon: promises and fallacies. *Clin Chem Lab Med (CCLM)*. 2015;53(7):989–93.
3. Diamandis EP, Lackner KJ, Plebani M. Theranos revisited: the trial and lessons learned. *Clin Chem Lab Med (CCLM)*. 2022;60(1):4–6.
4. United States Attorneys. Northern District of California. Public Notifications. *U.S. v. Elizabeth Holmes, et al.* United States Department of Justice. <https://www.justice.gov/usao-ndca/us-v-elizabeth-holmes-et-al#:~:text=Elizabeth%20A.,hundreds%20of%20millions%20of%20dollars>. December 12, 2022. Updated July 14, 2022. Accessed 18 Jul 2022.
5. Clearfield C, Tilcsik A. How Board Diversity Might Have Prevented Theranos Fiasco. *The Globe and Mail*. <https://www.theglobeandmail.com/report-on-business/rob-commentary/how-board-diversity-might-have-prevented-the-theranos-fiasco/article38304767/>. Published March 19, 2018. Accessed 18 Jul 2022.
6. Atkins D. Mattis Doubted Theranos 'Transparency', Holmes Jury Hears. *Law360*. <https://www.law360.com/articles/1424133/mattis-doubted-theranos-transparency-holmes-jury-hears>. Published September 22, 2021. Accessed 25 Jun 2022.
7. Leblanc R. *The handbook of board governance: a comprehensive guide for public, private, and not-for-profit board members*. 2nd ed. USA: Wiley; 2020.
8. John Caldwell, Ken Smith. *Overseeing Strategy. A Framework For Board of Directors*. [Internet]. Chartered Professional Accountants; 2016 May. Available from: <https://www.google.com/search?q=Overseeing+Strategy+A+FRAMEWORK+FOR+BOARDS+OF+DIRECTORS&aq=chrome..69i57j0i22i30j0i390i650i4.661j0j7&sourceid=chrome&ie=UTF-8#:~:text=to%20maximize%20shareholder%C2%A0...-,Overseeing%20Strategy%3A%20A%20Framework%20for%20Boards%20of%20Directors,https%3A/www.cpacanada.ca%20%E2%80%BA%20media%20%E2%80%BA%20site%20%E2%80%BA%20docs,-PDF>.

9. Straker K, Peel S, Nusem E, Wrigley C. Designing a dangerous unicorn: lessons from the Theranos case. *Bus Horiz.* 2021;64(4):525–36.
10. Das RK, Drolet BC. Lessons from Theranos-restructuring biomedical innovation. *J Med Syst.* 2022;46(5):25. <https://doi.org/10.1007/s10916-022-01813-3>.
11. Paul K. Theranos verdict: five key moments from the trial that shook Silicon Valley. Yahoo News (Accessed from The Guardian). Published January 3, 2022. Available from: <https://news.yahoo.com/theranos-verdict-five-key-moments-004032969.html?guccounter=1>. Accessed 14 Sept 2023.
12. Atkins D. Ex-Theranos Lab Chief Doubted Holmes ‘Implausible Takes’. *Law360.* <https://www.law360.com/articles/1439134/ex-theranos-lab-chief-doubted-holmes-implausible-takes>. Published November 9, 2021. Accessed 25 Jun 2022.
13. American Medical Association. Physician financial transparency reports (Sunshine Act). Medicare & Medicaid. <https://www.ama-assn.org/practice-management/medicare-medicare/physician-financial-transparency-reports-sunshine-act>. Published 2022. Accessed 12 Aug 2022.
14. Mullins T, Thornton B, Adams M. The role of due diligence in the business valuation process. *J Bus Econ Res.* 2007;5(5).
15. Kerrin B, Slattery, Kristian A, Werling. Focus on Innovation Centers: Due Diligence For Collaborative Ventures [Internet]. 2019 Oct. Available from: <https://www.natlawreview.com/article/focus-innovation-centers-due-diligence-collaborative-ventures>.
16. Wetsman N. Theranos FOMO kept the devos family from doing its investment homework. The Verge. <https://www.theverge.com/2021/10/26/22747918/theranos-devos-due-diligence-fraud-trial>. Published October 26, 2021. Accessed 25 Jun 2022.
17. De Cleyn S, Braet J. The due diligence process—guiding principles for early stage innovative products and venture capital investments. *J Private Equity.* 2007;1:43–51.
18. La France BH. “Don’t get your meat where you get your bread”: beliefs and advice about workplace romance. *Behav Sci.* 2022;12(8):278.
19. Atkins D. Balwani Jurors can hear if investors knew he dated Holmes. *Law360.* <https://www.law360.com/insurance-authority/articles/1487520/balwani-jurors-can-hear-if-investors-knew-he-dated-holmes>. Published April 26, 2022. Accessed 25 Jun 2022.
20. Layne N, Chang R. Theranos Founder Claims Abuse by Ex-boyfriend In Fraud Trial—Court Filings. Reuters. <https://www.reuters.com/world/us/theranos-founder-claims-abuse-by-ex-boyfriend-fraud-trial-court-filings-2021-08-28/>. Published August 30, 2021. Accessed 18 Jul 2022.

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