Journal of Medical Systems (2022) 46: 25
https://doi.org/10.1007/s10916-022-01813-3

HEALTH POLICY

Lessons from Theranos – Restructuring Biomedical Innovation

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Received: 21 March 2022 / Accepted: 24 March 2022 / Published online: 4 April 2022

Abstract
After raising more than $700 million, Elizabeth Holmes, the founder and chief executive officer of a healthcare startup once valued at $10 billion, was found guilty on four charges of defrauding investors. Founded in 2003, Theranos Inc. was a privately held corporation that aimed to disrupt the diagnostics industry with rapid, direct-to-consumer laboratory testing using only "a drop of blood" and the company's patented Nanotainer technology. By exploiting gaps in regulatory policy, Theranos brought its panel of laboratory tests to patients without pre-market review or validation from peer-reviewed scientific research. Investigations into Theranos' dubious operations and inaccurate test results exposed the failed venture which had squandered millions of dollars. Theranos affected the lives and health of patients further disrupting an already tenuous relationship between healthcare and the public – the importance of which cannot be understated in the setting of the COVID-19 pandemic. As medical systems address a national public health crisis and pervasive structural inequities, we must align stakeholder incentives between industry and academic biomedical innovation to rebuild trust with our patients.

Keywords Theranos · Diagnostics · Biomedical innovation · Venture capital · Funding · Research

After raising more than $700 million, Elizabeth Holmes, the founder and chief executive officer of a healthcare startup once valued at $10 billion, was found guilty on four charges of defrauding investors [1]. Founded in 2003, Theranos Inc. was a privately held corporation that aimed to disrupt the diagnostics industry with rapid, direct-to-consumer laboratory testing using only "a drop of blood" and the company's patented Nanotainer technology. By exploiting gaps in regulatory policy, Theranos brought its panel of laboratory tests to patients without pre-market review or validation from peer-reviewed scientific research. Investigations into Theranos' dubious operations and inaccurate test results exposed the failed venture which had squandered millions of dollars. Theranos affected the lives and health of patients further disrupting an already tenuous relationship between healthcare and the public – the importance of which cannot be understated in the setting of the COVID-19 pandemic. As medical systems address a national public health crisis and pervasive structural inequities, we must align stakeholder incentives between industry and academic biomedical innovation to rebuild trust with our patients.

Juxtaposed with Holmes' verdict, the Biden administration commenced its plan to purchase and distribute 280 million at-home COVID-19 rapid tests. These two events highlight the discordance between private and academic biomedical innovation. Theranos leveraged its position outside of risk-averse academic and regulatory processes to efficiently bring routine, direct-to-consumer laboratory testing to the public. Meanwhile, administrative and bureaucratic burdens associated with ensuring reliability and transparency have resulted in substantial delays in the approval and distribution of at-home COVID-19 tests. Even now, cumbersome regulatory policy in the United States has created an oligopoly and inflated unit prices when compared to other nations. However, these same policies would have prevented Theranos from releasing their own COVID-19 tests if the company were still in operations.

Healthcare startups are powerful forces of disruption given their ability to easily pivot and act fluidly on new information. In 2021, $72.4 billion of venture capital funding was invested in healthcare companies – a 164% increase

This article is part of the Topical Collection on *Health Policy*

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from the year prior [2]. This capital is largely allocated with little or no clinician perspective. Without processes in place to evaluate the reliability, safety, and efficacy of new medical interventions and products, our patients and their trust in healthcare understandably suffer. The absence of convicted charges related to Theranos' longstanding negative consequences to patients sets a dangerous precedent for what healthcare entrepreneurs can be held accountable for.

Theranos' effects on patient behaviors and perceptions demonstrate how agents other than clinicians and scientists can influence public health. Through ill-advised marketing campaigns and press releases, Theranos weaponized the fear of medical diagnoses to promote their business model and product. In advertisements, patients were advised to take control of their health and seek out Theranos' panel of routine laboratory tests before "it was too late." The core of this message opposes evidence-based guidelines in diagnostic methodology, which seek to minimize unnecessary and redundant testing for improved post-predictive and negative predictive value [3]. Patients should be involved in their medical care, and direct-to-consumer diagnostics can enhance autonomy. However, shared decision-making with a trusted clinician must be at the core of our healthcare system.

Theranos' equipment provided inaccurate results for an estimated one out of ten tests, resulting in thousands of unnecessary and negative experiences for patients. Patient anecdotes of emotional trauma following false cancer diagnoses from Theranos tests were not uncommon among the 890,000 results each year. Furthermore, treatment decisions made using inaccurate diagnostics are dangerous and can even be life threatening.

Insights from the rise and fall of Theranos can help move us toward a system that balances reliability and efficiency to advance medicine for the benefit of our patients. Stakeholders in healthcare such as private healthcare corporations, investors, clinicians, payers, and policymakers are motivated by different incentives. Steps toward aligning these incentives may curb adverse events affecting patient trust in healthcare.

First, evidence and transparency should be the foundation of healthcare operations and medical innovation. The peer-review process offers leaders in science and medicine the opportunity to validate new information that could directly inform clinical care. Yet highly-valued healthcare start-ups rarely contribute to peer-reviewed research [4]. When they do, the contributions from their studies are marginal or unrelated to their product. Management teams scapegoat concerns for intellectual property in defense of their lack of research. However, companies are not required to disclose the specific mechanisms of products under development to contribute to the literature. Unfortunately, editors and reviewers may have conservative attitudes and biases toward innovation that occurs outside of the traditional academic framework. Accordingly, private corporations should communicate with editors about their studies to understand how methodology can be improved to meet publication criteria. Several companies offer research fellowships to graduate students that provide a mutually beneficial opportunity to conduct high quality research that contributes to the literature.

Second, collaboration between industry and academic centers should be encouraged. Increasing academic stakeholders in biomedical innovation allows for effective utilization of pooled resources and aligns incentives. For example, the unprecedented speed and scale of the development of the COVID-19 vaccine hinged on science-industry collaboration. In the case of Theranos, licensing its technology to researchers using analogous laboratory tests in their studies could have exposed the inaccuracy of the company's product. Such collaborations also increase efficiency and reduce administrative burdens as academic centers already have processes in place for institutional review and reporting.

Third, investor due diligence must be revitalized in the healthcare sector. A substantial amount of private capital is invested into the healthcare sector every year, creating the potential for meaningful benefit when resources are allocated toward promising, well-validated diagnostics and interventions. Unfortunately, clinicians are not routinely consulted to advise due diligence, and many of these transactions are made based on industry relationships rather than quality of evidence. This approach to asset management is contrary to an investor's fiduciary obligation to their limited partners (e.g., pension funds, university endowments) and detrimental to patients. As part of due diligence, executives from companies provide data to prospective investors regarding the efficacy and financial viability of their products under development. This information is usually procured internally, biased, and intentionally vague to encourage investment. Because they offer external validation and promote clinician involvement, peer-reviewed research and partnerships with academic medical centers must be considered key performance metrics in the evaluation of potential healthcare investments.

Fundamentally, stealth research and the conflict between industry and academic innovation affect patients and their trust in healthcare and medicine. While Holmes' trial focused on charges related to investor fraud, the effects of Theranos on the public are more insidious, especially in the setting of the COVID-19 pandemic and other recent high-profile events from healthcare companies including Purdue Pharmaceuticals and Johnson & Johnson. Skepticism about the vested interests of our medical systems is a natural defense mechanism against these heavily publicized failures. Efficiency and reliability are not mutually exclusive. To achieve a balance of both, resources must be allocated more

effectively. As funding in healthcare corporations continues to grow, policy and institutional governance must encourage stakeholders in our healthcare system to adopt a unified approach to biomedical innovation. Without such structures, we hamper progress toward rebuilding trust in healthcare and greater health equity.

Funding The authors have no financial interest to declare in relation to the content of this article.

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