

A Case Study: “Theranos - The White Elephant That Wanted to Be a Unicorn”

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Abstract The Theranos case exemplifies a highly publicized failure in public health leadership that jeopardized patient safety and undermined public trust in blood testing diagnostics. This case study examines the leadership failures that led to Theranos's downfall and eventual closure in 2018 from Elizabeth Holmes's perspective as she reflects on her journey while standing trial in 2021. By adopting Kotter's change management framework and incorporating deontological principles into her leadership style during her tenure as CEO of Theranos from 2003 until the scandal's exposure in the *Wall Street Journal* in 2015, Holmes could have transformed Theranos into a success story. The recommendations provided are presented as an “Ethical Disruptor Roadmap”, which seeks to bolster Kotter's structured framework with a foundation in deontological principles. This roadmap aims to guide emerging biotech companies that are developing similar blood testing technologies to avoid the “Theranos Effect,” which has left a lasting (blood) stain on the industry.

Keywords: Ethics, Change Management, Entrepreneurship, Behavioral Ethics

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1. Introduction

“I wish I had done it differently,” stated 37-year-old Elizabeth Holmes on her third day of testimony during the high-profile criminal trial in 2021, where she acknowledged her mistakes as CEO of Theranos, a company she founded in 2003 that aimed to develop innovative blood testing technology [1]. This case study offers a retrospective exploration of Elizabeth Holmes's leadership failures that surfaced during her 2021 trial, and that contributed to the collapse of the company in 2018. Holmes' leadership failures can be categorized as violations of ethical principles or as inadequate approaches to managing change. Specifically, Holmes' leadership failures encompass a lack of validation for the new technology, exploitation of regulatory loopholes, a company culture characterized by fear, and multiple ethical breaches regarding patient safety. The case study examines these failures through the lens of two frameworks: Deontological ethics and Kotter's change management model. These frameworks are ultimately integrated into a comprehensive Ethical Disruptor Roadmap. This roadmap utilizes Kotter's structured framework and incorporates deontological principles to provide a set of recommendations for enhancing leadership and change management practices for aspiring industry disruptors.

2. Background and Problem Identification

2.1. Background

Elizabeth Holmes' leadership failures, coupled with organizational governance issues, resulted in a toxic company culture at Theranos marked by secrecy, fear, and ethical breaches, all of which led to the endangerment of public safety. Between 2013 and 2016, Theranos sold approximately 1.5 million faulty blood tests to over 175,000 Arizona residents through a pilot project with Walgreens' Wellness Centers [2]. However, a lawsuit filed in 2017 by the Arizona Attorney General's office against Theranos revealed that the company grossly misrepresented the methods, accuracy, and reliability of its blood tests and failed to comply with federal regulations established in the CLIA [2]. As a result, Theranos invalidated two years' worth of blood tests and paid \$4.65 million to Arizona residents who purchased those tests [2]. Subsequent investigations into Theranos' blood testing technology uncovered an 87% failure rate during quality testing [3]. Considering approximately 14 billion blood tests are administered annually in the US, had the technology been distributed beyond the initial pilot, the public health implications resulting from

potential misdiagnoses or inappropriate treatments could have been catastrophic. The threat to patient safety became especially evident in January 2016, when the Centers for Medicare and Medicaid Services (CMS) released a 121-page report summarizing their investigation into Theranos, concluding that the technology “put patients in immediate jeopardy and is likely to cause serious injury, harm, or death. [4]” When examining the missteps and failures that ultimately led to the company’s demise, it becomes evident that these were not isolated incidents. Holmes’ leadership failures were recurring patterns that persisted over multiple years, ultimately resulting in profound and systemic dysfunction at the organizational level. A comprehensive list of leadership and organizational failures is summarized in the table presented in Appendix D, and the following sections provide an overview of key issues that led to Theranos’ failure and the significant threat to patient safety.

Lack of Validated and Reliable Technology and Exploitation of Regulatory Loopholes: By exploiting existing FDA regulatory requirement exemptions for medical device diagnostic testing classified as laboratory-developed tests, Elizabeth Holmes promoted her Edison technology without appropriate pre-market regulatory review. In an effort to disrupt a \$75 billion industry and provide revolutionary rapid diagnostic tests derived from small blood volumes, Holmes made overly ambitious claims that her technology could provide more than 30 diagnostic tests using a single droplet of blood despite having no scientific data demonstrating its product’s capability [5]. Rather than provide scientific evidence, Holmes focused on establishing partnerships with prominent public figures and nationwide retail stores to establish credibility while claiming its technology as proprietary to avoid scrutiny, regulatory oversight, and public disclosure.

Company Culture of Fear and Secrecy: Holmes cultivated a culture of secrecy, ensuring that employees were unaware of the technology’s development issues. This was achieved through a lack of transparency regarding internal processes, physically blocking access to rooms where technology was developed, and even censoring internal IT systems to prevent communication between employees [6]. Partners and investors were also deliberately misled. When Walgreens executives visited Theranos in 2010 after agreeing to a pilot program, Holmes refused to show them the labs; instead, she redirected them to COO Balwani’s office and did not allow unaccompanied visitors at the facility [7]. Holmes presided over a company culture of fear that did not tolerate dissenting views or doubt about the technology. In 2006, as the Edison device malfunctioned during a presentation to Novartis, Theranos’ CFO Henry Mosley criticized Holmes for misrepresenting the technology’s capabilities to investors, resulting in his immediate termination [8]. This marked the beginning of several instances where employees who voiced their concerns or whistleblowers, such as lead scientist Erika Cheung and engineer Tyler Schultz, faced immediate termination and threats of lawsuits for allegedly violating non-disclosure agreements. They were also verbally intimidated into silence and resignation [9].

Lack of Expertise and Inadequate Governance: A

critical factor in Theranos’ downfall was its lack of industry and regulatory expertise among its leadership and board, resulting in weak governance and lack of fiduciary and ethical oversight at all levels. Unlike other biotech firms that establish advisory boards with regulatory, scientific, and public health experts, Holmes prioritized recruiting high-profile individuals without relevant experience. In 2006, aside from Holmes, the company’s governing board consisted of only four members, none of whom had relevant experience, as summarized in Appendix B. By 2014, Holmes expanded Theranos’ board to include former politicians and military leaders such as Henry Kissinger and General James Mattis as summarized in Appendix C, yet still lacked individuals with backgrounds in biomedical science, regulatory compliance, or clinical diagnostics [9]. Further exacerbating operational missteps was Theranos’ COO, Sunny Balwani, who had no formal education or experience in healthcare yet played a central role in decision-making [10]. A separate scientific advisory board was formed in 2016 [11] only after the company was already embroiled in scandal. Looking at the evolution of the board not only highlighted that the board’s composition was flawed due to Holmes’ recruiting decisions, but the company culture also hindered its effective governance and duty completion. According to Jeffrey Sonnenfeld of Yale’s Executive Leadership Institute, board effectiveness depends not just on structural composition but on a culture of respect, trust, and candor among leadership [12]. Theranos’ corporate culture, however, was mired in secrecy, preventing transparency between employees and board members. The board was purposely kept in the dark about the company’s technical operations, enabling Holmes to maintain unchecked control and evade accountability. While secrecy is common in government defense contracts, such an approach is not well suited for a biotech startup [13]. Theranos’ board, lacking technical expertise, was unable to question the reliability of its technology, failed to demand data as proof of concept, and, consequently, could not provide any meaningful oversight.

Lack of Ethics and Disregard for Patient Safety: A personal desire to become a disruptor and to be recognized as the female equivalent of Steve Jobs, combined with Holmes’ unwavering urge for quick results [9], led her to engage in actions that violated public health ethics to achieve her personal vision. Rushing unvalidated technology to the market resulted in patients receiving inaccurate test results about their health conditions, as shown in Exhibit D, and violated their rights to informed decision-making due to the erroneous information that was provided to them regarding the reliability of these blood tests [14]. In addition to damaging the credibility of the medical diagnostics industry, these events also stained the emerging movement to improve patient autonomy by championing secondary prevention measures (i.e. preventative screenings) in public health [15]. Throughout her tenure, Holmes clearly violated her ethical duty to ensure patient safety and provide truthful information to all stakeholders and the public. Furthermore, she demonstrated a profound lack of virtues such as honesty, integrity, and moral responsibility, likely because her actions were driven by ambition, self-preservation, and financial gain [9], rather than a commitment to ensuring patient safety.

2.2. Problem Statement

Holmes' ambition to disrupt the medical diagnostic industry outpaced her leadership abilities to ethically manage change, leading her to exploit regulatory loopholes, prioritize premature strategic partnerships, and foster a culture of fear. Ultimately, her leadership failures cascaded into undermining the organization's ethical governance, promoting flawed technologies, eroding public trust, and endangering patient safety through clinical misdiagnoses.

3. Company and Protagonist Profile

3.1. Company Profile

Theranos, whose name is derived from "therapy" and "diagnosis," [16] was a Silicon Valley healthcare startup founded by Elizabeth Holmes in 2003. The company developed the Edison (later renamed miniLab) device, introduced the nanotainer vial to collect blood samples (see Exhibit A), and claimed that these proprietary technologies were capable of conducting more than 200 blood tests using just a drop of blood [17]. At its peak in 2014, Theranos attracted high-profile investors, secured partnerships with major organizations such as Walgreens, Safeway, and the U.S. Department of Defense (DOD), and the company was valued at over \$9 billion [18]. However, an investigative journalism piece by John Carreyrou published in the *Wall Street Journal* in 2015 [19] led to regulatory investigations and lawsuits that later revealed that Theranos' technology was neither reliable nor validated. Theranos officially dissolved in September 2018 [20]. For further detail, a timeline of events related to Theranos' operations and financing is provided in Exhibit B.

3.2. The Protagonist

The protagonist, Elizabeth Holmes, is an American entrepreneur who founded Theranos at the age of 19 after dropping out of Stanford University [21]. Due to her 50% ownership stake in the company, she became the youngest female self-made billionaire in 2014 following Theranos' \$9 billion valuation [21]. As CEO, she positioned herself as a visionary leader, comparing herself to tech icon Steve Jobs [22]. Holmes displayed a charismatic yet deeply flawed authoritarian leadership style, fostering a culture of fear and secrecy while prioritizing rapid expansion and investor relations over patient safety. After the scandal over Theranos' technology broke in 2015, Holmes and other key executives faced trial, and she was ultimately charged with defrauding investors and patients [21]. Holmes is currently serving an 11-year prison sentence in Bryan, Texas [23].

4. The Frameworks

When examining the leadership failures at Theranos, a common root emerges: a profound lack of ethical leadership and violations of ethical principles.

Furthermore, leadership decisions that Holmes likely believed would accelerate innovation, such as silencing feedback and bypassing regulations, ultimately hindered her ability to lead meaningful change. This duality informed the selection of two key conceptual and theoretical frameworks: the ethical framework of Deontology and Kotter's Change Management Model. The core principles of these frameworks will be analyzed through inspiring success stories where leaders have ethically and responsibly disrupted their industries. These stories provide evidence for how these principles could have prevented and corrected the shortcomings in Elizabeth Holmes' leadership and decision-making at Theranos.

4.1. Ethical Framework: Deontology

4.1.1. Overview

Public health ethics frameworks guide professionals in making decisions that prioritize patient and community well-being, support informed decision-making, and promote equity [24]. Deontology is a fundamental ethical framework in public health that emphasizes duties, rules, and obligations over outcomes. Unlike utilitarianism, which aims to maximize the collective good, or virtue ethics, which focuses on individual moral character, deontology requires adherence to ethical and legal standards regardless of the consequences [25]. It acts as a "fence," delineating ethical conduct boundaries and helping to determine whether actions violate professional standards or public health regulations [25]. A central tenet of deontology is the moral imperative to "do no harm," echoing the Hippocratic Oath [25]. These imperatives can be negative (prohibiting actions such as misrepresentation or breach of confidentiality) or positive (promoting honesty, health equity, and beneficence). For purposes of this case study, the ten core deontological principles were identified and categorized into three main duties as further outlined in Exhibit C: (1) Duty to adhere to legal and regulatory rules; (2) Duty to truthfulness and doing no harm; and (3) Duty to respect all stakeholders. These duties ensure that public health professionals and leaders like Elizabeth Holmes operate with integrity, safeguard patient welfare, and build public trust.

4.1.2. Evidence and Application

Theranos' collapse and Elizabeth Holmes' leadership failure originated from significant ethical breaches. Her pursuit of rapid success, coupled with the company's unvalidated technology and premature nationwide partnerships, violated multiple public health ethics. Prioritizing her personal ambition over patient safety resulted in false marketing claims and endangered the public. Adhering to ethical decision-making grounded in duty, honesty, and accountability could have helped avoid these lapses. Deontology was the most appropriate ethical framework to apply because it primarily focuses on the duty to "do no harm" and mandates adherence to ethical and legal standards, regardless of the outcomes. Furthermore, it provides a comprehensive list of ethical duties and principles that should be operationalized within leadership decisions and organizational processes to prevent ethical lapses.

Duty to Adhere to Legal and Regulatory Rules

When applying the concept of deontology to public health actions, it is imperative that health leaders act with integrity, uphold accountability, and maintain respect for established oversight. Holmes repeatedly violated compliance with laws and regulations by purposely misclassifying the Edison device as a Laboratory Developed Test (LDT), thereby enabling her to bypass FDA regulatory oversight and requirements governing medical devices [9]. Holmes' deliberate attempts to evade regulatory bodies and allow patients to use an unvalidated technology compromised public safety and undermined public trust. Moreover, Holmes displayed a complete disregard for the principles of accountability, honesty, and transparency; she presented false information to company investors and business partners and terminated the employment of staff who voiced concerns – most notably CFO Henry Mosely, when questioned about the viability of the company's technology and deceptive marketing practices about the technology's diagnostic capabilities and test results [9]. Moreover, Holmes deliberately concealed information from stakeholders such as Walgreens through practices such as denying access to her labs and claiming the technology's capabilities as proprietary to evade product demonstration and validation requests [9]. Finally, Holmes refused to acknowledge her lack of professional competence and expertise by failing to recruit scientific, regulatory, and technical advisors, and dismissed feedback and criticism from experts in the field. This was evident, for example, through her decision to create a governing board composed of prominent political and military leaders with no biomedical expertise. When called to account for her flawed technology and lack of reliable test results during her trial, she refused to admit that she acted unethically and that her decision-making lacked evidence-based recommendations. Holmes repeatedly violated her duty to adhere to legal and regulatory standards, as well as the deontological principles of compliance with laws, accountability, responsibility, transparency, honesty, and professional competence.

Duty to Truthfulness and Doing No Harm

In the practice of deontology, it is critical for leaders to exhibit a duty to be truthful and to do no harm in public health. Leaders are obligated not only to avoid causing harm (non-maleficence) but also to actively promote the well-being of communities and individuals (beneficence). Elizabeth Holmes violated the principle of non-maleficence by allowing public companies such as Walgreens and Safeway to administer her inaccurate blood tests to thousands of patients. Numerous inaccurate blood tests were given to patients, causing irreparable harm due to misdiagnosed conditions, unnecessary treatments, and delayed care. Specifically, in Arizona, approximately 1.5 million faulty blood tests were sold, later invalidated, resulting in a \$4.65 million settlement with patients [26]. Additionally, these actions did not promote the general well-being of the communities that relied upon these tests, nor did they contribute to any meaningful healthcare innovation as she had hoped, thereby violating the principles of beneficence. Throughout her tenure, she repeatedly prioritized securing

investor capital and partnerships and violated the principles of accountability and responsibility by refusing to address technological issues with her product. In contrast, responsible adherence to accountability was evident in the 1982 Johnson & Johnson Tylenol poisoning case, where leadership demonstrated immediate responsibility by recalling 31 million bottles, collaborating with regulators, and redesigning packaging to protect consumers despite financial losses exceeding \$100 million [27]. Johnson & Johnson exemplified that ethical leadership should always prioritize public safety and trust over profit and organizational ambition. Had Holmes embraced these deontological values, corrective measures would have been taken, and her unvalidated technology would not have been released, thus averting such catastrophic damage. Her insistence on dishonesty and her failure to prevent harm contributed not only to Theranos' collapse but also to widespread public distrust in emerging health technologies.

Duty to Respect All Stakeholders

Holmes violated her duty of respect for all stakeholders, including patients, employees, investors, board members, and regulatory bodies. Respect is the guiding principle for fairness, competence, and autonomy, and public leaders must engage in inclusive dialogue, welcome dissenting opinions, and uphold inclusivity in decision-making. Elizabeth Holmes' personal ambitions and inflated ego led her to disregard respect for everyone involved with Theranos. Her vision of grandeur replaced her commitment to professional competency. Neither she nor her COO, Sunny Balwani, possessed scientific or regulatory expertise. Consequently, she deliberately delayed the establishment of a Scientific Advisory Board until after she was publicly criticized for the company's misleading reporting regarding the Edison's unreliable testing capabilities. Instead, she isolated herself from scrutiny with a board of celebrities and loyalists, further diminishing appropriate oversight due to a lack of professional competence. The principles of justice and fairness were also overlooked, as she prioritized secrecy and fear. Employees like Tyler Shultz and Erika Cheung, who voiced legitimate concerns or asked probing questions, were silenced, terminated, and threatened with legal action [28]. Organizations thrive when everyone, regardless of rank or position, is allowed to contribute and provide meaningful input on important decisions [29], which Holmes repeatedly denied to all other stakeholders involved. Lastly, Holmes disrespected patients' autonomy to make informed decisions about their health, as she chose to continuously manipulate the accuracy and reliability of Theranos' blood tests and knowingly endangered patient safety. Contrary to the blatant disrespect that Holmes exhibited towards her stakeholders, strong ethical leadership is exemplified by companies like The Muse, where CEO Kathryn Minshew demonstrated fairness and respect for employees by terminating a contract with a disrespectful client, prioritizing team well-being over profit [30]. Had Holmes embraced this same commitment to respect, justice, fairness, and accountability, she could have cultivated a culture of trust, protected stakeholder interests, and built sustainable innovation rather than fostering secrecy and deception [30].

4.2. Kotter's Change Management Framework

4.2.1. Overview

Leading successful transformations and effectively managing change is crucial for companies trying to disrupt entire industries, as Holmes was aiming to do with her blood-testing technologies. John P. Kotter introduced an eight-step model for change management in *Leading Change*, emphasizing that transformation is a structured process rather than a singular event. Kotter's model highlights critical stages for navigating change effectively as follows: creating a sense of urgency, building a guiding coalition, developing and communicating a vision, empowering stakeholders to action, generating short-term wins, consolidating gains, and anchoring changes within an organization's culture [31]. Kotter's framework has been widely used in industries facing rapid innovation, and existing research suggests that organizations leveraging this model achieve higher success rates in implementing change, particularly in high-stakes industries such as healthcare and technology [32].

4.2.2. Evidence and Application

Theranos' failure highlights Holmes' neglect of structured change management. The Kotter framework, with its comprehensive approach to leading change, offers solutions to Holmes' missteps. It emphasizes establishing strong governance through a guiding coalition, fostering incremental change through smaller wins, and anchoring change and transparency into company culture. Adhering to Kotter's eight-step approach could have established a patient-centric vision, fostered transparent communication, and built upon incremental successes. This phased approach maintains scientific integrity and ensures regulatory compliance. In the following analysis, the framework's eight steps are supported by biotech success stories and innovative organizations that effectively adopted its principles. Implementing these strategies could have prevented Elizabeth's leadership failures and helped Theranos foster a culture capable of managing change.

1. *Establish Urgency*: Effective change initiatives start with a compelling reason for transformation and by leveraging this reason to create a sense of urgency to build momentum. IBM under Lou Gerstner and GE Healthcare under Jeff Immelt successfully created urgency by identifying existential threats in their industries. As Gerstner stated, "Transformation begins with a sense of crisis or urgency. [33]" In the early 1990s, IBM faced declining relevance due to technological changes. Aware of this, Gerstner led IBM's shift from hardware to services [33]. GE Healthcare similarly fostered urgency for digital transformation in medical imaging by aligning stakeholders with an innovative vision. Immelt remarked, "Real urgency comes from a determination to win, not anxiety about losing. Leaders who inspire urgency encourage teams to embrace change. [34]" For Theranos, Holmes could have emphasized urgency in meeting regulatory and scientific standards to eliminate any threats to patient safety instead of fostering a false urgency around achieving celebrity status as the first female disruptor of an industry [35]. This approach would have

positioned the company as a leader in responsible diagnostic innovation by highlighting risks related to inaccurate test results and by fostering a collective urgency among employees, regulators, and investors to minimize potential threats to patients through misdiagnoses.

2. *Building a Guiding Coalition*: To achieve transformational and sustainable change, it is essential for leaders to be supported by a team of experts and advocates who have the necessary skills to fill knowledge gaps and help bring the vision to life. During the COVID-19 pandemic, Moderna succeeded in accelerating the development of mRNA vaccines by assembling a guiding coalition of committed and knowledgeable public health professionals, scientists, and regulatory officials [36]. As Stéphane Bancel, CEO of Moderna, noted: "The best way to drive change is to surround yourself with experts who challenge conventional thinking and foster innovation.[36]" Instead of recruiting high-profile board members without scientific backgrounds and relying on COO Sunny Balwani's authoritarian approach, Holmes should have established an advisory board of biomedical scientists, regulatory professionals, and public health experts from the outset. By insulating herself with loyalists, celebrities, and non-experts, Holmes missed the opportunity to apply core ideas from Collins' book *Built to Last*. She would have been better served by surrounding herself with industry experts capable of ensuring scientific validation, fostering balanced and ethical decision-making, enabling early identification of technological issues, and implementing risk mitigation strategies, while also offering diverse perspectives and decision-making skills [37].

3. *Develop a Patient-Centered Vision and Strategy*: A clear vision is crucial for ensuring stakeholder alignment and garnering support and can provide necessary guidance during crises and volatile times. Johnson & Johnson takes pride in its patient-centric vision, and its credo emphasizes responsibility to patients, doctors, and all users of their products [38]. Additionally, the leadership team at Johnson & Johnson effectively communicates this patient-centric vision through press releases and, most importantly, through actions consistent with that vision [39]. During the Tylenol crisis in 1982, this vision led to proactive measures that prioritized the well-being of their customers, including the voluntary recall of millions of Tylenol bottles, collaboration with regulators on product safety, and investments in tamper-proof packaging. [39]. Although these actions negatively impacted Johnson & Johnson's bottom line, they ultimately helped restore public trust in the company's products and even accelerated the establishment of new industry safety standards. This demonstrates how a patient-centered vision can foster not only ethical decision-making within a company but also inspire advancements within the broader industry. Instead of pursuing her overly ambitious goal of becoming the next Steve Jobs, Holmes should have learned from Johnson & Johnson and committed herself and her company to a patient-centered vision that prioritized validated and reliable technologies. She should have established a long-term vision and an accompanying strategic plan in collaboration with her guiding coalition that focused on patient safety and accuracy over rapid market expansion and premature partnerships.

4. *Communicate the Patient-Centered Vision*:

Transparent communication of a company's vision, goals, and strategies is vital for gaining employee, investor, and regulatory understanding and support. Moderna's CEO, Stéphane Bancel, emphasized that "transparency builds trust, which is the foundation of scientific progress.[40]" Rooted in this belief, Moderna implemented a clear communication strategy that helped all stakeholders grasp its vision to revolutionize healthcare through mRNA technology and develop life-saving vaccines while upholding patient safety and scientific standards. By publicly sharing clinical trial results, Moderna provided stakeholders with clear evidence of its vaccine's safety and efficacy, thereby fostering trust and alignment with its vision [41]. Furthermore, Moderna's president, Stephen Hoge, ensured open communication with regulators and fostered ongoing dialogue with public health experts, thereby reinforcing the commitment to ethical innovation and aligning all stakeholders in advancing Moderna's vision of bringing validated medical breakthroughs to market [42]. Holmes and her leadership team could have prioritized communicating the patient-centric vision by sharing validation study results, engaging in independent peer reviews, and fostering honest investor relations to build trust and credibility. Instead of exaggerated claims, Holmes should have emphasized transparent communication to align with the vision. This would have ensured that stakeholders, especially patients, understood the technology's potential and limitations, allowing them to make informed decisions. Open dialogue with regulatory bodies would have ensured compliance and patient safety, while transparent internal communication would have fostered technologies that improve patients' lives.

5. Empower Stakeholders to Take Action: Empowering employees to actively participate in change can decrease feelings of helplessness during uncertain times and foster innovation and accountability [31]. Under Satya Nadella's leadership, Microsoft transformed its company culture to encourage openness and collaboration while promoting psychological safety [43]. Nadella effectively encouraged dissenting voices and embodied the principles of a growth mindset by advocating collaboration over internal competition [43]. He firmly believed in embracing uncertainty, taking risks, and learning from mistakes, which led to the establishment of tools such as forums and open-door policies that actively encourage employees to voice dissent without fear [43]. These initiatives empowered stakeholders and ultimately helped propel the company forward by integrating diverse perspectives in decision-making. Instead of silencing whistleblowers like Erika Cheung and Tyler Shultz, who raised concerns about the accuracy of the Edison device [9], Holmes should have promoted open dialogue and welcomed employee feedback. By avoiding strict NDAs and retaliatory practices, she could have created a safe environment for discussing product reliability. Additionally, Holmes should have embraced the concept of psychological safety [44], inspired by Nadella, to encourage employees to discuss challenges openly to facilitate early identification of flaws. Viewing internal dissent as a tool for improvement could have cultivated a culture of learning and transparency at Theranos instead of one of secrecy and fear.

6. Generate Short-Term Wins: Short-term wins help

maintain momentum and demonstrate progress, thereby ensuring that employees and stakeholders remain committed to the vision. Google's DeepMind in healthcare AI exemplifies this approach by iterating gradually and focusing on small-scale successes. Their strategy involved building on incremental breakthroughs in protein folding predictions for a limited number of proteins with their AlphaFold tool before expanding to broader applications in drug discovery [45]. Additionally, DeepMind successfully applied AI to improve medical diagnostics in specific disease areas, such as detecting eye diseases in collaboration with Moorfields Eye Hospital, before scaling up to broader innovations in healthcare AI [46]. Furthermore, to ensure regulatory compliance and patient safety, DeepMind worked closely with the UK's National Health Service (NHS) to conduct rigorous clinical evaluations and sought approvals from health regulators before deploying its AI solutions in broader real-world healthcare settings [47]. Holmes could have learned from this incremental approach instead of rushing an incomplete product to market and overpromising sweeping blood testing advancements. By setting realistic benchmarks, like demonstrating a single test's reliability before claiming to run hundreds of tests, Holmes could have built scientific and regulatory credibility. Narrowing test scope and incrementally validating through smaller pilot studies could have generated short-term wins.

7. Consolidate Gains and Expand Improvements: Building on initial wins creates momentum and ensures that transformation continues after achieving early successes. Only after successfully launching its COVID-19 vaccine did Moderna expand its mRNA technology to explore treatments for other diseases [48]. The company leveraged its initial mRNA platform to expand into other diseases to develop vaccines for respiratory syncytial virus (RSV) and cytomegalovirus (CMV), while also exploring therapeutic applications for cancer and rare genetic disorders [49]. By continuously investing in research, strategic partnerships, and scalable production capabilities, Moderna ensured that its early success translated into sustained industry leadership. Instead of prematurely establishing large-scale partnerships with Walgreens and Safeway, Holmes should have conducted smaller pilot rollouts and utilized the insights from these experiences to guide larger expansions with nationwide partners. From a technological standpoint, Holmes could have begun by refining and testing her technology on a single, high-impact disease, such as diabetes or cancer detection, rather than attempting to revolutionize all diagnostic testing simultaneously. This approach, similar to Moderna's strategic focus on mRNA vaccines for COVID-19 before expanding into other applications, would have enabled her to refine the technology and use the gained insights to inform expansion into other disease areas.

8. Anchor Changes in Organizational Culture: For lasting transformation, a company must embed its vision and values into everyday operations. In the case of Johnson & Johnson, their commitment to ethical leadership and patient safety has guided decision-making for decades, fostering public trust and long-term stability [50]. Johnson & Johnson has operationalized its credo by embedding its values of changing patient lives for the better into its culture through continuous employee

training, an independent ethics board, and a Credo Hotline, which includes a whistleblower protection system to reinforce accountability [51]. Holmes could have prioritized ethical innovation, transparency, and scientific integrity in its core culture, ensuring regulatory compliance and internal accountability were non-negotiable. By incorporating independent audits into its operations, setting up an ethical review board, instituting whistleblower protection programs, fostering transparent reporting, and engaging in open scientific collaboration [52], Holmes could have integrated sustainable innovation into Theranos' organizational structure, ensuring long-term credibility.

Companies like GE Healthcare, Moderna, and Johnson & Johnson have demonstrated that creating urgency, building coalitions, promoting strategic communication, and integrating change into organizational culture are effective strategies for leaders navigating change and fostering sustainable innovation. If Elizabeth Holmes had applied Kotter's eight-step approach to change management, she might have achieved success as a disruptor in the blood testing industry. These industry examples underscore the importance of a structured approach in healthcare and technology disruption, emphasizing collaboration, trust, and a commitment to long-term impact.

5. Recommendations: The Ethical Disruptor Roadmap

Elizabeth Holmes' approach to disruption was marked by failures in ethical leadership and an inability to effectively manage change. Appendix D summarizes her leadership failures and how they violated deontological principles, change management approaches, or both. While the previous sections explored problems through the lens of each framework, this recommendation section focuses on integrating both frameworks into an "Ethical Disruptor Roadmap". The recommendations that follow integrate both frameworks by following Kotter's eight-step approach to disrupting an industry while overlaying deontological principles on each step to support ethical leadership. This roadmap provides a comprehensive guide for operationalizing ethical principles within a structured change management approach, complementing initial recommendations highlighted in the previous sections on how Holmes could have prevented and addressed leadership failures. Each step in the Kotter framework is expanded upon with concrete, actionable recommendations for fostering ethical behavior. With this expanded roadmap, Holmes could have directed Theranos toward long-term success through transparency, ethical leadership, data-driven decision-making, and sustainable change management.

1. Establishing an Ethical Sense of Urgency Rooted in Patient Welfare

Actionable Recommendation: Redirect urgency from market pressures to an urgency around ensuring patient safety by implementing internal checkpoints focused on harm prevention.

Rationale: The protagonist failed to foster a genuine sense of ethical urgency rooted in her fundamental duty as

a health innovator: to protect patients. From a deontological standpoint, the imperative to act should not be driven by financial pressures or the pursuit of personal recognition, but rather by a moral obligation to "do no harm" and prioritize truth, transparency, and compliance, irrespective of the consequences [53]. Holmes had an ethical duty to recognize the risks associated with deploying unvalidated technology that had the potential to be life-threatening for patients, rather than considering those risks as secondary to market disruption or investor enthusiasm. An ethical sense of urgency would have involved sounding early and frequent internal alarms about the product's lack of validation. Like Johnson & Johnson, Holmes should have prioritized patient safety as Theranos's mission, emphasizing that meeting regulatory and scientific standards was a moral duty for all stakeholders. Instead of misleading investors and fast-tracking partnerships to build false urgency and be first to market [9], she should have redirected that sense of urgency toward launching safe technology and overcoming challenges by openly acknowledging limitations and risks. This approach would have enabled her to fulfill her duty of nonmaleficence and beneficence while achieving a more balanced relationship between urgency and patient safety, ensuring that neither was compromised.

2. Building a Guiding Coalition with Ethical Expertise

Actionable Recommendation: In addition to assembling an appropriately skilled governing board, establish an Ethical Advisory Board and conduct quarterly ethics audits to strengthen leadership accountability.

Rationale: Holmes's board members lacked sufficient scientific knowledge, and Theranos's ethical standards faltered as she relied on COO Balwani's authoritarian leadership style. A deontological viewpoint emphasizes the need for leaders to possess the appropriate expertise to make both ethical and technically sound decisions. To address her poor recruitment choices and ensure her governing board has the necessary skills, Holmes should have established an independent Ethical Advisory Board with biomedical scientists, ethics and regulatory experts, and public health professionals. As Beauchamp et al. suggest, the main responsibility of an Ethical Advisory Board would be to promote transparency and integrity, provide scientific validation, and encourage ethical decision-making to support the operationalization of deontological principles of beneficence and professional competence throughout the company [53]. Additionally, Holmes should have implemented mandatory quarterly ethics audits, where independent advisors would evaluate compliance with scientific, regulatory, and ethical standards [53]. To enhance internal accountability, a whistleblower protection program should have been established. This step would have enabled relevant stakeholders to express their concerns confidentially, ensuring that the principles of professional competence, transparency, and honesty are upheld. Lastly, the Ethical Advisory Board could also have served as a direct link and liaison to foster collaboration and receive feedback from external regulatory agencies, including the FDA and CMS.

3. Developing a Patient-Centered, Ethically Sound Vision and Operationalizing the Vision

Actionable Recommendation: Create a Vision

Alignment Taskforce to ensure the company's vision and mission reflect a commitment to scientific integrity and patient-first innovation.

Rationale: A deontological perspective requires that an organization's vision and mission focus on beneficence and nonmaleficence by emphasizing patient safety, transparency, and ethical medical advancements over profit. Similar to Johnson & Johnson, Holmes should have revised Theranos' vision and mission statements to clearly convey its commitment to scientific integrity, regulatory adherence, and patient welfare. This could have been achieved by relying on the Ethics Advisory Board mentioned in Step 2, composed of medical ethicists, public health experts, and scientific advisors, to form a new Vision Alignment Taskforce. This group would be tasked with drafting an updated vision and mission statement and meeting on a quarterly basis to review the alignment between business practices and the vision. Based on research conducted by Singer, this would ensure that all business strategies and technological advancements prioritize a patient-first approach and align the vision, mission, and operations of the company [54].

4. Communicating the Vision and Marketing Products with Honesty and Accountability

Actionable Recommendation: Launch a transparent data-sharing platform and adopt a truth-in-marketing policy to ensure accurate, patient-accessible communication in support of the patient-centric vision.

Rationale: A patient-centered vision must be conveyed with unwavering honesty and through actions that are in alignment with the vision, as dictated by deontological ethics. Furthermore, all communication and marketing regarding the vision must be clear and truthful. Similar to Moderna, Holmes should have implemented a transparent data-sharing initiative by publishing peer-reviewed studies confirming test accuracy, providing clinical trial results, and making regulatory reports readily accessible on its website [55]. Patients and physicians should have been able to access a dedicated online portal offering clear, jargon-free explanations of test reliability and clinical significance. This approach would have demonstrated scientific integrity, upholding honesty, professional competence, patient welfare, and beneficence by providing accurate, up-to-date information about Theranos's capabilities. Patient autonomy would be illustrated by supporting informed health decisions. Involving independent peer reviewers to examine published claims would have provided external validation, ensuring accurate messaging reflecting diagnostic tool performance. Moreover, research by Guttman et al. suggests that a truth-in-marketing policy should have been established [56], mandating that all promotional materials accurately represent both the strengths and weaknesses of Theranos's technology and align with Theranos' vision of preserving patient safety.

5. Empowering Employees and Leadership to Uphold Ethical Standards

Actionable Recommendation: Create an Ethics and Compliance Office to oversee anonymous reporting, town halls for employees, and mandatory ethics training for executives.

Rationale: A deontological perspective emphasizes the duties of justice and fairness, requiring organizations to

create a work environment where employees can voice concerns freely. Instead of enforcing rigid NDAs and retaliating against whistleblowers [9], Holmes should have established an independent Ethics and Compliance Office (ECO), as suggested by Capron's research on leading practices in healthcare organizations [57]. The ECO would be overseen by the Ethics Advisory Board mentioned in Step 2, and it would be granted the authority to investigate employee concerns confidentially. Additionally, the ECO would be tasked with implementing an anonymous reporting system that enables employees to flag ethical issues without fear of retaliation [57]. To promote respect for professional competence, the ECO should conduct quarterly town hall meetings, allowing employees to openly discuss challenges and technological concerns. Furthermore, a leadership accountability program similar to the one proposed by the Department of Health and Human Services (HHS) would mandate executives to participate in ethics training [58] and regulatory compliance workshops and would help to ensure that management understands and upholds deontological principles in their decision-making.

6. Generating Short-Term Wins Through Validated Scientific Progress

Actionable Recommendation: Promote gradual short-term achievements coupled with a milestone-based, evidence-driven development model with third-party validation and public reporting of results.

Rationale: Instead of making sweeping and unverified assertions about its technology to quickly disrupt the industry, Holmes should have emphasized gradual technological achievements similar to DeepMind's approach [45]. A deontological perspective highlights the necessity of professional competence and the duty to protect health. Therefore, the governing board, alongside Holmes, should have mandated that each technological advancement be thoroughly validated prior to any progression. Instead of making grandiose, unprovable claims, Holmes should have adopted an incremental validation strategy akin to Moderna and DeepMind. This approach would involve validating one test at a time and ensuring that each test passes through rigorous clinical trials to minimize the risk of misdiagnosis and safeguard patient well-being. Resnik et al. recommend that routine third-party evaluations of test outcomes by independent laboratories and conducting peer-reviewed studies would have reinforced continuous wins and built credibility while preserving public trust [59]. As recommended by the FDA, Holmes could have adopted a milestone-based regulatory approval process [60], which would have guaranteed that all innovations complied with industry safety standards before their release, thereby allowing her to uphold her duty to be accountable and responsible.

7. Consolidating Gains and Embedding Ethics into Operations for Long-Term Success

Actionable Recommendation: Create a Scientific Integrity Division to guide thoughtful expansion based on lessons learned and implement ethics scorecards to institutionalize accountability.

Rationale: Achieving long-term ethical sustainability requires building upon small successes, integrating lessons learned into long-term expansion plans, and applying

deontological principles of transparency and honesty in everyday operations. To uphold the duty of preserving professional competence in the long run, Holmes should have created a Scientific Integrity Division, as suggested by HHS, tasked with overseeing test accuracy and conducting annual external audits [61]. This division could have advised to focus on small, validated achievements rather than immediate market growth and operated under the guiding principles of ensuring research quality, professional competence, and protection from political or commercial influence [61]. It could also manage transparent communication of validated results to stakeholders and compile insights from pilot studies, integrating these lessons into a broader vision for expanding the technology to various disease areas. With the Scientific Integrity Division's guidance, Holmes could have led her team to initially target a high-impact disease like diabetes or cancer instead of revolutionizing the entire diagnostic testing landscape at once. Similar to Moderna's strategy regarding the mRNA vaccines [48], this approach would build on initial gains, foster regulatory trust, minimize risks, and demonstrate clear clinical effectiveness before widening its scope. Lastly, Kaptein's research suggests that establishing a systematic ethics scorecard that evaluates leadership on regulatory adherence and ethical business practices would have held executives accountable for their actions [49], embedded ethics and accountability into operations, and laid the groundwork for creating a lasting company culture that values and transparently assesses ethical practices regularly.

8. Anchoring Ethical Innovation in Organizational Culture

Actionable Recommendation: Mandate annual ethics training, encourage executive ethics pledges, and implement strict patient data protection measures, with support and oversight from the Ethical Advisory Board.

Rationale: To establish ethics as a core value, organizations must promote transparency and honesty within their company culture. This is crucial to ensure accountability and regulatory compliance at every level. To operationalize these deontological principles necessary for ethical decision-making, Holmes should have implemented annual ethics training for all staff as outlined by HHS [58]. As suggested by Epley and Amit, a company-wide ethics policy requiring all executives to sign a personal pledge could further promote accountability and responsibility among the board members and leadership team [62]. To emphasize the organization's commitment to safeguarding the confidentiality and privacy of patients in the long run, Holmes should have enforced strict data protection protocols in line with guidance published by HHS to ensure the security of patient data [63]. As previously discussed, creating an independent Ethical Advisory Board with the power to evaluate all company practices on a quarterly basis would ensure adherence to laws and regulations while fostering a culture of trust and integrity. By embedding these ethical principles into its organizational framework, Holmes could have nurtured a lasting culture of ethical innovation and scientific integrity.

6. Conclusion

Elizabeth Holmes' downfall serves as a cautionary tale about balancing ethical leadership with effective change management for medical innovation. Her vision to disrupt the diagnostics industry overshadowed her decision-making and change management capabilities, exposing patients to unvalidated technology with faulty results. Holmes' leadership failures were consistent ethical breaches that created systemic issues and ultimately led to the company's collapse. Three key learnings about leadership emerge from this cautionary tale: (1) Leaders must prioritize ethics in innovation, ensuring truthfulness and patient safety over speed or profit; (2) Leading change requires urgency rooted in facts, inclusive coalitions, realistic visions, and trust-building communication; and (3) Leading by example and fostering an inspiring company culture is crucial, including creating a psychologically safe environment for feedback, essential for sustained innovation. For future disruptors, the lessons from Theranos emphasize the need to uphold validated scientific truth, patient safety, and transparent communication over rapid expansion and unchecked ambition. Implementing ethical frameworks and adhering to structured change management models can lead to sustainable and responsible innovation. Ultimately, the success of any innovative venture lies in embedding ethics, integrity, and accountability into its core operations.

7. Discussion Questions and Suggested Answers

Elizabeth Holmes took advantage of external factors, such as regulatory loopholes, to bypass oversight. What reforms could prevent similar issues in the future, and what other stakeholders should be involved to target this problem?

Medical devices are subject to regulatory requirements imposed by the FDA under the Food, Drug, and Cosmetic Act [64]. Despite federal regulation, LTDs are waived from these requirements (Refer to Appendix E). This is concerning given that nearly 3.3 billion IVDs are conducted annually in the US with LTDs accounting for an unknown number of these tests due to their exemption from reporting requirements [65]. Intended to provide diagnostic capabilities for rare diseases for which existing testing is limited or otherwise unavailable, LTDs have since expanded beyond their intended purpose and are used for diagnosis of infectious diseases and to provide broad-based genetic testing. The company, 23andMe, for example, was warned by the FDA in 2013 for offering direct-to-consumer broad-based genetic testing for approximately 254 diseases and conditions without necessary clinical validation [5]. Theranos classified its diagnostic test as an LDT despite being developed and used in more than one laboratory, a violation of LDTs requirements. Accordingly, LDTs must be subject to the same federal regulatory requirements as other IVD to

ensure that diagnostic technologies are subject to clinical and analytical validation standards. Legislative reform, such as the Verifying Accurate Leading-edge IVCT Development (VALID Act) of 2022, which failed to pass Congress, is needed to ensure that LDTs are subject to FDA oversight and to hold device manufacturers accountable. Moreover, the VALID Act would have encouraged buy-in from device manufacturers, commercial laboratories, patient advocacy groups, and the public to enable comprehensive reform through stakeholder collaboration. In addition, the VALID Act would have focused on the adoption of a risk-based regulatory framework for LTDs and ensured that these devices were subject to mandatory evaluation prior to clinical use [65]. Additionally, enhanced whistleblower protections could encourage employees to report scientific misconduct.

How did Holmes' decision-making reflect cognitive biases, and what strategies could have prevented these biases from leading to failure?

Holmes' decision-making appears to have been influenced by two types of cognitive biases: overconfidence bias and confirmation bias. The most prominent of these is likely her overconfidence bias [66], where she blindly trusted in the success of her blood-testing technology, despite clear evidence of its ineffectiveness. She disregarded medical and scientific experts' concerns about her claims and remained committed to her belief in the technology. Unfortunately, this blind belief led her to mislead investors, regulators, and the public. One approach to address this bias would have been to establish an independent technical advisory committee at Theranos with the authority to prevent unvalidated technology from being presented to partners and stakeholders. This board should have comprised medical and scientific professionals capable of evaluating the technology objectively and guiding decision-making based on evidence rather than on Holmes' personal belief and wishful thinking [66]. Compounding the issue, Holmes also demonstrated confirmation bias [66] by only accepting data that supported her belief in the technology while actively ignoring or suppressing reports of failures within the company. Employees who voiced concerns about faults in the technology faced termination or threats to remain silent. To address this bias, Holmes and the governing board should have implemented whistleblower protection policies. Additionally, they should have scheduled regular third-party audits and peer reviews to ensure a neutral evaluation of the data. Establishing structured decision-making processes and ensuring that alternative data and information are evaluated as part of the review process, as suggested by Kahneman et al. [66], could have effectively countered this bias.

In what ways does emotional intelligence enhance ethical leadership, and how might the situation at Theranos have been different had Elizabeth Holmes exhibited greater emotional intelligence?

Emotional intelligence refers to the ability to recognize, understand, and manage one's own emotions as well as those of others, and it is considered a core aspect of ethical and transformational leadership [67,68]. Research suggests that leaders with strong emotional intelligence are typically better at building trust, encouraging open

dialogue, and handling conflicts with empathy instead of defensiveness [68]. Holmes displayed little to no emotional intelligence by consistently ignoring employee concerns, punishing dissenters, and failing to create psychological safety, all of which contributed to a company culture of fear and secrecy [9]. If Holmes had demonstrated greater self-awareness, emotional regulation, and social awareness, which are all crucial components of emotional intelligence, she might have been more receptive to internal feedback and demonstrated empathy by acknowledging and addressing the emotional distress her punitive actions caused her teams. As Mayer et al. suggest, emotional intelligence supports moral reasoning and ethical decision-making by helping leaders grasp the repercussions of their choices on others [68].

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The authors have no competing interests. No funding is declared for this article.

Appendices and Exhibits

Appendix A: Full List of Definitions of Terms

- **CLIA (Clinical Laboratory Improvement Amendments):** A set of U.S. federal regulations with the purpose of safeguarding patient safety by ensuring quality and reliability in all clinical laboratory testing on human samples.
- **CMS (Centers for Medicare and Medicaid Services):** The federal agency overseeing laboratory testing under CLIA and ensuring compliance with regulations.
- **Nanotainer and Edison/miniLab Devices:** Proprietary blood-testing devices developed by Theranos. The blood testing device was conceptualized as the Edison in 2006 and later built out and renamed the miniLab in 2010. Theranos also developed the nanotainers, which are small vials used to collect a drop of blood from the fingertip. The devices claimed to perform hundreds of tests with minimal blood.
- **FDA (Food and Drug Administration):** A U.S. agency responsible for protecting public health by ensuring the safety, efficacy, and security of medical devices and diagnostics.
- **Laboratory-Developed Tests (LDTs):** Diagnostic tests designed, manufactured, and used within a single laboratory.
- **Unicorn:** In finance, a unicorn is a privately owned startup company valued at over US\$1 billion that is not listed on a share market.

- **Validation Studies:** Research conducted to ensure a medical device or diagnostic test meets safety, efficacy, and reliability standards.
- **In Vitro Diagnostic (IVD) Testing:** Clinical laboratory tests, including lab-developed tests (LTDs), used to analyze samples taken from the human body.
- **White Elephant:** In finance, a white elephant is an investment whose upkeep costs are not in line with its usefulness or value.
- **Whistleblower:** An individual who exposes unethical or illegal activities within an organization.

Appendix B: Theranos Board of Directors 2006

Table 1. Theranos Board of Directors 2006

Member	Background
Elizabeth Holmes (CEO)	Theranos founder and CEO
Donald L. Lucas (Chairman)	Private venture capitalist and early investor in Oracle Corporation. He was Chairman of Oracle (1980-1990) and served as a director in several Silicon Valley tech firms, such as DexCom, PDF Solutions, Spansion, Vimicro International.
Pete Thomas (Director)	Co-founder and Managing Director of ATA Ventures (early investor in Theranos). Over 15 years of experience in venture capital, 10+ years of experience in industry companies such as Intel Corporation. Previously served as director of 6 different companies. Thomas has a BSEE degree from Utah State University and an MS degree in Computer Science from the University of Santa Clara.
Avie Tevanian (Director)	Chief Software Technology Officer at Apple (2003-2006), Vice President of Software Engineering at Apple (1997-2003). Tevanian has a BA in mathematics from the University of Rochester and holds both MS and PhD degrees in computer science from Carnegie Mellon University.
Channing Robertson (Director & Technical Consultant)	Senior Associate Dean and professor of Chemical Engineering at Stanford University. Founding fellow of the American Institute of Medical and Biological Engineering. Robertson holds a BS in Chemical Engineering from the University of California at Berkeley and both an MS & PhD in Chemical Engineering from Stanford University.

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Appendix C: Theranos Board of Directors 2014

Table 2. Theranos Board of Directors 2014

Member	Background
Elizabeth Holmes (Chairman & CEO)	Theranos founder, Chairman and CEO
Sunny Balwani (President, COO & Director)	Former founder, President and CTO at CommerceBid.com (1999-2001). Previously, Sunny worked as a software engineer for Lotus Development Corporation (IBM) and Microsoft. He holds a BA in Information Systems from the University of Texas at Austin and an MBA from the University of California at Berkeley.
George P. Schultz (Director)	Former U.S. Secretary of State (1982-1989), U.S. Secretary of Treasury (1972-1974), first director of the Office of Management and Budget (1970-1972) and U.S. Secretary of Labor (1969-1970). Schultz was also President and director of the Bechtel Group and a former professor of international economics at Stanford University. He is a fellow at the Hoover Institution and a recipient of the Presidential Medal of Freedom. Schultz holds a BA in economics from Princeton University and a PhD in Industrial Economics from MIT.
Gary Roughead (Director)	Former U.S. Navy Admiral who served as the 29th Chief of Naval Operations. Roughead graduated from the U.S. Naval Academy in 1973 and has since held six operational commands. He is a fellow at the Hoover Institution and the recipient of several awards, including the Defense Distinguished Service Medal, Navy Distinguished Service Medal, and Legion of Merit.
William J. Perry (Director)	Former U.S. Secretary of Defense (1994-1997), Deputy Secretary of Defense (1993-1994), and Undersecretary of Defense for Research and Engineering (1977-1981). Perry is a senior fellow at the Hoover Institution, a professor at Stanford University, and a recipient of the Presidential Medal of Freedom. He received a BS and MS from Stanford University and a PhD from Pennsylvania State University, all in mathematics.
Samuel Nunn (Director)	Former U.S. Senator from Georgia (1972-1996) and chairman of the Senate Armed Services Committee (1987-1995). Nunn was also on the Intelligence and Small Business Committees. He served as a board member of the Coca-Cola Company and General Electric Company and is a fellow at the Hoover Institution. He graduated with honors from Emory Law School.

Member	Background
James Mattis (Director)	Former U.S. Marine Corps General who served as Commander of the U.S. Central Command (2010-2013), Commander of U.S. Joint Forces Command (2007-2010), and NATO's Supreme Allied Commander for Transformation (2007-2009). Later on, he would also serve as the 26th U.S. Secretary of Defense (2017-2019) in the Trump Administration. Mattis is a fellow at the Hoover Institution.
Henry A. Kissinger (Director)	Former U.S. Secretary of State (1973-1977), U.S. National Security Advisor (1969-1975), and member of the Defense Policy Board (2001-2016). Kissinger is a fellow at the Hoover Institution, Honor Member of the International Olympic Committee, and served on the board of ContiGroup Companies (1988-2014). He is the recipient of the Nobel Peace Prize (1973), the Presidential Medal of Freedom, and a Bronze Star from the U.S. Army. Kissinger holds a BA in Political Science from Harvard College and received MA and PhD degrees from Harvard University.
William H. Frist, MD (Director)	Former U.S. Senator from Tennessee (1994-2006) and Senate Majority Leader (2003-2006). Frist was a renowned heart and lung transplant surgeon and a professor of surgery at Vanderbilt University. He served as chairman of private equity firm Cressey & Company and held board positions in three public companies as well as numerous institutions, including Harvard Medical School Board of Fellows. Frist graduated from Princeton University and Harvard Medical School.
William H. Foege, MD (Director)	Physician and epidemiologist. Foege served as the Director of the Centers for Disease Control and Prevention (1977-1983) as well as Executive Director of The Carter Center (1986-1992). He is also a former professor of International Health at Emory University. Foege received his medical degree from the University of Washington and his Master of Public Health from Harvard University.
Riley P. Bechtel (Director)	Chairman (1990-2017) and former CEO (1990-1996) of Bechtel Group. He is a director of Fremont Investors and a member of Fremont Group's Board of Advisors. He received a combined JD and MBA degree from Stanford University's School of Law and Graduate School of Business. Bechtel also has a bachelor's degree in political science and psychology from the University of California at Davis.
Richard Kovacevich (Director)	Former Chairman (2001-2009), President (1998-2005), and CEO (1998-2007) of Wells Fargo. Kovacevich previously served on the boards of directors of Cisco Systems, Target, PetSmart, Northern States Power Company, and ReliaStar Financial Corporation. He holds a BS and MS in Industrial Engineering as well as an MBA from Stanford University.

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Appendix D: Summary of Problems and Violations of Deontological Principles and Kotter's Eight Steps

Table 3. Summary and Categorization of Failures

Problem	Detailed Description	When it Occurred	Ethical Problem	Change Management Problem	Violated Deontological Principle	Violated Kotter's Steps
Lack of validated and reliable technology	Holmes failed to conduct proper validation studies for its blood-testing technology, leading to unreliable and inaccurate results.	2003-2015	Yes	Yes	Respect for Autonomy, Nonmaleficence, Beneficence, Honesty, Duty to Protect Health: Failure to ensure reliable and validated technology endangered patient safety.	Establishing a Sense of Urgency: Failed to acknowledge the need for proper validation before market entry.
Exploitation of regulatory loopholes	Holmes leveraged FDA loopholes for Laboratory-Developed Tests (LDTs) to avoid regulatory scrutiny, allowing unproven tests to be used on patients.	2003-2015	Yes	Yes	Compliance with Laws and Regulations: Holmes bypassed FDA regulations, undermining regulatory oversight.	Building a Guiding Coalition: Did not collaborate with regulatory bodies or experts for oversight.
Company culture of fear and secrecy	Holmes fostered a toxic work culture that discouraged dissent, silenced whistleblowers, and punished employees who raised concerns about the technology.	2006-2015	Yes	Yes	Transparency and Honesty, Professional Competency: The culture of secrecy prevented accountability and ethical decision-making.	Creating a Vision for Change: Lack of transparency and trust hindered employee engagement and ethical leadership.
Misrepresentation of technology to investors	Holmes falsely claimed its devices could perform hundreds of tests with just a few drops of blood, misleading investors and partners.	2005-2015	Yes	Yes	Respect for Autonomy, Transparency and Honesty: Misleading investors violated ethical obligations of truthfulness.	Communicating the Vision: Provided misleading information instead of clear, truthful communication.
Firing employees who raised concerns	Employees who voiced concerns about technological failures were fired, including CFO Henry Mosley, who questioned	2006-2015	Yes	Yes	Respect for Autonomy: Employees were denied a safe environment to voice concerns	Empowering Stakeholder and Employees for Broad-Based Action: Suppressed dissent and punished employees

Problem	Detailed Description	When it Occurred	Ethical Problem	Change Management Problem	Violated Deontological Principle	Violated Kotter's Steps
	misleading statements to investors.				about unethical practices.	who raised concerns.
Lack of scientific and regulatory expertise on the board	Instead of recruiting biomedical and regulatory experts, the board was composed of high-profile individuals without relevant healthcare or scientific experience.	2003-2015	Yes	Yes	Professional Competence: Lack of relevant expertise among board members led to poor governance and oversight.	Building a Guiding Coalition: Board lacked necessary expertise to challenge decisions effectively.
Failure to conduct proper validation studies	Holmes rushed to market without conducting proper clinical trials or validation studies, leading to major failures in test accuracy and reliability.	2003-2015	Yes	Yes	Duty to Protect Health, Beneficence, Nonmaleficence: Lack of proper validation risked inaccurate diagnoses and patient harm.	Generating Short-Term Wins: Rushed product development without demonstrating incremental, validated progress.
Providing inaccurate test results to patients	Holmes provided patients with inaccurate test results, leading to misdiagnoses and unnecessary treatments, posing serious public health risks.	2013-2016	Yes	No	Respect for Autonomy, Nonmaleficence: Providing faulty test results caused direct harm to patients.	
Deceptive marketing and misleading investors	Holmes engaged in deceptive marketing strategies, overstating its capabilities and withholding critical information from investors and regulators.	2003-2015	Yes	No	Transparency and Honesty: Deceptive marketing misled stakeholders and violated ethical standards.	
Lawsuits from investors and regulators	Following exposure of the scandal, Holmes faced lawsuits from investors, patients, and business partners, leading to	2016-2018	Yes	No	Accountability and Responsibility: Holmes evaded responsibility for its unethical actions.	

Problem	Detailed Description	When It Occurred	Ethical Problem	Change Management Problem	Violated Deontological Principle	Violated Kotter's Steps
	financial and legal repercussions.					
Walgreens and Safeway partnerships terminated	Walgreens and Safeway terminated their partnerships after discovering that the technology was flawed and did not work as advertised.	2015-2016	Yes	Yes	Transparency, Honesty, Justice and Fairness: Misrepresentation of technology led business partners to make uninformed decisions.	Generating Short-Term Wins: Did not establish credibility with validated results before scaling partnerships.
CMS revoking Theranos' CLIA lab license	The Centers for Medicare & Medicaid Services (CMS) revoked Theranos' CLIA license due to regulatory noncompliance and patient safety violations.	2016	Yes	No	Compliance with Laws and Regulations: Regulatory violations led to loss of certification and increased risks to patients.	
Company dissolution	After multiple investigations and legal battles, Theranos shut down in 2018, ceasing all operations permanently.	2018	Yes	Yes	Accountability and Responsibility: Lack of ethical leadership resulted in the company's failure.	Anchoring New Approaches in Culture: Lack of ethical leadership led to company collapse.
Elizabeth Holmes' trial and conviction	Holmes was convicted of fraud and sentenced to 11 years in prison for misleading investors and endangering patient safety.	2021-2022	Yes	No	Duty to Truthfulness and Do No Harm: Holmes' fraudulent actions compromised public trust in medical technology.	

Appendix E: Regulatory Oversight Disparities Between LTDs and FDA-Reviewed IVDs

Table 4. Regulatory Oversight Disparities

Public Health Protections	FDA-Reviewed IVD	LDT IVD
Moderate- and high-risk tests are reviewed before use on patients	Yes	No
Tests are registered in a public database	Yes	No
Mandatory reporting of adverse events related to an incorrect test result	Yes	No
Product labeling is reviewed and approved to ensure accuracy	Yes	No
Marketing claims must be supported by evidence and approved prior to use in a clinical setting	Yes	No
Oversight body is able to recall faulty tests	Yes	No

Source: The Pew Charitable Trusts. "Diagnostic Tests Not Reviewed by FDA Present Growing Risks to Patients." *The Pew Charitable Trusts*, Oct. 2021, www.pewtrusts.org/en/research-and-analysis/fact-sheets/2021/10/diagnostic-tests-not-reviewed-by-fda-present-growing-risks-to-patients. Accessed Mar 18 2025.

Exhibit A: Technology Specs

The miniLab Spec

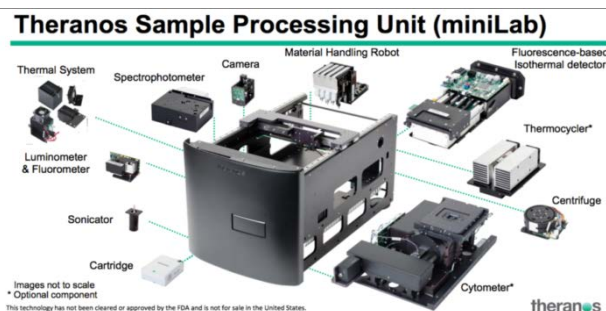


Figure 1. The minilab Spec

Source: "The Rise and Fall of Theranos - a Miniserial in 4 Parts." *Lubio.ch*, 2021, www.lubio.ch/blog/the-theranos-story-part-i. Accessed 25 Jan. 2025.

The Nanotainer



Figure 2. The Nanotainer

Source: Ramsey, Lydia. "Theranos Is Only Using Its Revolutionary Blood-Testing Technology on One of Its 200+ Tests." *Yahoo Finance*, 16 Oct. 2015, finance.yahoo.com/news/theranos-only-using-revolutionary-blood-191600927.html. Accessed 26 Jan. 2025.

Exhibit B: Timeline of Key Events

Table 5. Timeline of Key Events

Timeline	Event
February 11, 2005	Series A funding of \$5.8 million received
February 21, 2006	Series B funding of \$9.9 million received
July 2006	Edison technology is started
November 2006	First demo of technology with pharma company Novartis
November 7, 2006	Series C funding of \$28.5 million received
July 8, 2010	Series D funding of \$45 million received. Theranos valuation hits \$1 billion.
August 2010	Walgreens deal is made to place Edison devices in store and pilot study to begin in mid-2011
September 2010	Safeway partnership contract signed to offer blood testing in Safeway's wellness centers nationwide
First quarter 2011	MiniLab is conceptualized to replace Edison technology
First quarter 2012	Prototype of miniLab is completed
September 2013	Lucas Venture Group invests \$15 million driving valuation to \$6 billion
February 4, 2014	Partner Fund invest \$96 million driving valuation to \$9 billion
July 2, 2015	First FDA approval for HSV-1 herpes virus test received
October 15, 2015	Carreyrou publishes story in Wall Street Journal
November 10, 2015	Safeway terminates partnership
June 1, 2016	Forbes revises Holmes's net worth to zero, down from \$4.5 billion
June 12, 2016	Walgreens ends partnership
July 7, 2016	After investigation, CMS suspends Theranos' CLIA lab license
Fourth quarter 2016 - 2018	Lawsuits from investors, partners, and private citizens ensue
September 2018	Theranos closes its doors
August 31, 2021 - January 3, 2022	Trial of United States vs. Elizabeth Holmes occurs, concluding in a guilty verdict and an 11-year prison sentence
May 30, 2023	Holmes reports to Federal Prison Camp in Bryan, Texas to serve her sentence.

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Exhibit C: Table of Deontological Principles and Groupings into Duties

Table 6. Deontological Principles

Ethical Principle	Description
Duty to Protect Health	Public health professionals must safeguard and promote the population's well-being by preventing disease spread, promoting healthy behaviors, and ensuring equitable healthcare access.
Respect for Autonomy	Emphasizes the significance of respecting individuals' autonomy and their right to make informed decisions about their own health, involving informed consent and respecting privacy.
Justice and Fairness	Ensures that public health policies and interventions are fair and just, prioritizing the equitable distribution of resources and giving special attention to vulnerable and marginalized populations.
Transparency and Honesty	Public health professionals must be transparent and honest in their communications, providing accurate information and refraining from misleading practices.
Nonmaleficence	The principle of "do no harm," which ensures that interventions minimize harm and avoid unnecessary suffering.
Beneficence	Acting in the best interests of the population by promoting actions that benefit individuals and communities.
Compliance with Laws and Regulations	Adherence to laws, regulations, and policies governing public health practice.
Confidentiality and Privacy	Protecting the confidentiality and privacy of individuals' health information.
Accountability and Responsibility	Being accountable for one's actions and decisions, accepting responsibility for the results, and addressing any mistakes or shortcomings.
Professional Competence	Staying informed about the latest research, best practices, and advancements in the field is essential for maintaining professional competence.

The authors of this paper summarized Table 6 from the following sources:

Source: The Editor(s) and The Author(s). *Narrative Ethics in Public Health: The Value of Stories*. Springer International Publishing, 2022.

Source: The Editor(s) and The Author(s). *Navigating Ethical Frontiers: Contemporary Issues in Healthcare Practice*. Addition Publishing House, 2022.

The authors grouped the principles into the three duties as follows:

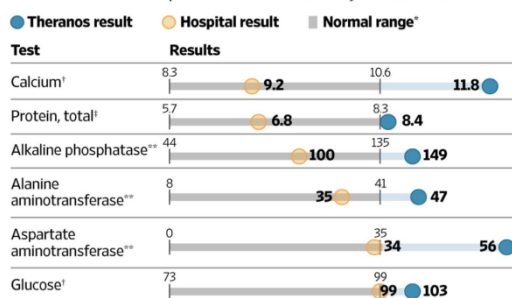
Table 7. Groupings of Principles

Duty	Groupings of Principles
Duty to Comply with Laws and Regulations	The duty to comply with laws and regulations highlights the importance of following legal standards, being accountable and responsible, demonstrating professional competence, as well as maintaining transparency and honesty. These principles help ensure that ethical and legal practices guide decision-making, uphold scientific integrity, and deter misconduct or noncompliance.
Duty to Truthfulness and Doing No Harm	The duty to truthfulness and doing no harm emphasizes the ethical duty to prioritize the best interests of patients and communities through beneficence, nonmaleficence, honesty, transparency, and accountability. This encompasses putting patient safety ahead of financial considerations, accurately communicating information to stakeholders, and ensuring ethical leadership in public health practices.
Duty to Respect All Stakeholders	The duty to respect all stakeholders highlights the ethical obligation to treat every individual, including patients, employees, and investors, with fairness, dignity, and inclusivity. Fundamental principles within this duty include respect for autonomy, justice and fairness, confidentiality and privacy, transparency, honesty, accountability, and professional competence.

Exhibit D: Faulty Test Results

Same Patient, Different Results

For one Arizona woman, Theranos found abnormally high levels for six tests. Hospital tests two days later were normal. Theranos says variation across labs is commonplace and can be caused by medicines and diet.



*As stated by Theranos [†]in milligrams per deciliter [‡]in grams per deciliter

**liver enzyme test, in units per liter

Sources: Theranos and HonorHealth Scottsdale Shea Medical Center via Nicole Sundene and Maureen Glunz

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Figure 3. Test Result Comparison

Source: "Hot startup Theranos has struggled with its blood-test technology." *The Wall Street Journal*. October 16. <https://www.wsj.com/articles/theranos-has-struggled-with-blood-tests-1444881901>. Accessed 10 Mar. 2025.

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