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Theranos: the Ethics of Innovation and Deception in Healthcare Technology

Theranos: a Ética da Inovação e Fraude na Tecnologia dos Cuidados de Saúde

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Abstract. The case of Theranos, a health technology company founded by Elizabeth Holmes, presents a profound ethical dilemma that exemplifies the consequences of misrepresentation in healthcare innovation. This analysis examines the company's fraudulent claims regarding its blood-testing technology, which promised groundbreaking results using minimal blood samples. Initially lauded for its potential, Theranos attracted significant investment and partnerships before facing growing scrutiny due to internal whistleblower accounts and investigative journalism. The ethical issues at the core of this case involve the deliberate falsification of leadership's technological capabilities, which leads to harm to patients and significant financial losses for investors. The methodology of this study involved a comprehensive review of academic literature identified through Google Scholar, applying inclusion criteria that focused on ethical analysis, corporate leadership, and regulatory oversight. The selected documents were analyzed using Atlas.ti to code critical themes such as corporate misrepresentation, stakeholder rights, and regulatory failures. Utilizing a multi-faceted ethical analysis—incorporating utilitarian, deontological, virtue ethics, and rights-based perspectives—this study explores the failures of corporate leadership in adhering to professional and ethical obligations. It critically evaluates the responses by stakeholders, including actions taken by regulatory bodies and law enforcement, and discusses the lessons learned for the broader health technology sector. The study concludes by recommending more robust internal governance, transparent leadership, and proactive regulatory oversight as essential measures to prevent future ethical lapses in the industry. The analysis contributes to understanding ethics' critical role in maintaining trust and accountability within healthcare innovation.
Keywords: Theranos. Corporate ethics. Healthcare innovation. Regulatory oversight. Ethical leadership.

Resumo. O caso da Theranos, uma empresa de tecnologia da saúde fundada por Elizabeth Holmes, apresenta um profundo dilema ético que exemplifica as consequências da deturpação na inovação em saúde. Esta análise examina as

alegações fraudulentas da empresa sobre sua tecnologia de testes de sangue, que prometia resultados revolucionários utilizando amostras mínimas de sangue. Inicialmente aclamada pelo seu potencial, a Theranos atraiu investimentos significativos e parcerias, antes de enfrentar crescente escrutínio devido a relatos de denunciantes internos e ao jornalismo investigativo. As questões éticas no cerne deste caso envolvem a falsificação deliberada das capacidades tecnológicas pela liderança, resultando em danos para os pacientes e perdas financeiras significativas para os investidores. A metodologia deste estudo envolveu uma revisão abrangente da literatura acadêmica identificada através do Google Scholar, aplicando critérios de inclusão focados na análise ética, liderança corporativa e supervisão regulatória. Os documentos selecionados foram analisados com o uso do *software* Atlas.ti, utilizando códigos para palavras-chave como má representação corporativa, direitos das partes interessadas e falhas regulatórias. Utilizando uma análise ética multifacetada—incorporando perspectivas utilitaristas, deontológicas, éticas das virtudes e baseadas em direitos—este estudo explora as falhas da liderança corporativa em cumprir suas obrigações profissionais e éticas. Avalia criticamente as respostas dos envolvidos, incluindo ações tomadas por órgãos reguladores e pela justiça, e discute as lições aprendidas para o setor de tecnologia da saúde em geral. O estudo conclui recomendando uma governança interna mais forte, uma liderança transparente e uma supervisão regulatória proativa como medidas essenciais para prevenir lapsos éticos futuros na indústria. A análise contribui para a compreensão do papel crítico da ética na manutenção da confiança e da responsabilidade na inovação em saúde.
Palavras-chave: Theranos. Ética corporativa. Inovação em saúde. Supervisão regulatória. Liderança ética.

1. Introduction

Theranos, once hailed as a revolutionary health technology company, was founded in 2003 by Elizabeth Holmes, a Stanford University dropout with a vision to transform diagnostic medicine. At its core, the company claimed to have developed groundbreaking technology capable of running hundreds of tests using just a few drops of blood, an innovation that could have drastically reduced the cost and invasiveness of traditional blood tests (Griffin, 2020). With her charismatic leadership, Holmes quickly attracted significant investments from influential individuals and organizations, including media mogul Rupert Murdoch and former U.S. Secretary of State Henry Kissinger. Ramesh "Sunny" Balwani, who joined the company as Chief Operating Officer in 2009, became Holmes' trusted assistant, overseeing the company's day-to-day operations. The allure of transforming healthcare attracted widespread attention, and by 2014, Theranos was valued at over $9 billion (Carreyrou, 2020; Grybos, 2023).

The company's core promise revolved around its proprietary Edison machine device, which allowed for comprehensive blood testing with minimal samples. This promise was particularly compelling because it positioned Theranos as a leader in making diagnostic testing more accessible, affordable, and less painful for patients (Fiala and Diamandis, 2018). The technology was also marketed as a tool that could democratize healthcare by placing diagnostic power directly into patients' hands, potentially revolutionizing preventive care. However, despite these grand claims, internal and external investigations later revealed that the technology was profoundly flawed and incapable of performing the tests it promised with the accuracy and reliability required in healthcare settings (Williams, 2022). This discrepancy between

promise and reality laid the foundation for a widespread ethical dilemma that affected patients, investors, employees, and regulatory bodies.

This case analysis explores the ethical issues at the heart of Theranos' fraudulent activities. At the core of the controversy is whether the leadership at Theranos, particularly Holmes and Balwani, acted negligently or with full knowledge of the company's technological limitations while continuing to mislead stakeholders. The analysis will investigate the violated ethical principles, including honesty, transparency, and accountability in healthcare innovation (Morris, 2024). Additionally, the case focuses on broader ethical questions about healthcare innovators' responsibilities in ensuring patient safety and the integrity of medical advancements (Hogarth *et al.*, 2022).

In the end, this analysis aims to discuss the broader impact of unethical behavior on various stakeholders, including patients who received inaccurate test results, employees who were pressured to remain silent about the company's flaws, and investors who were misled by false assurances of the technology's potential (Mcginn, 2022). Understanding the ethical breaches within Theranos provides valuable lessons for the healthcare sector, where the stakes are high, and patient lives may depend on the integrity of technology and corporate decision-making. This case is a cautionary tale for medical innovation and a reminder of the importance of ethical leadership in safeguarding public trust (Etse *et al.*, 2021).

2. Methodology

The analysis of the ethical dilemmas in the Theranos case was conducted through a comprehensive search and review of relevant academic literature. The primary tool used to identify these sources was Google Scholar. Key search terms included "Theranos," "Health technology," "Ethical analysis," "Corporate leadership," and "Regulatory oversight." These terms were carefully chosen to focus the search on materials that directly addressed the ethical and regulatory dimensions of the Theranos scandal. The search yielded various scholarly articles, case studies, and legal analyses, providing a deep understanding of the ethical violations and corporate misconduct involved.

Specific inclusion criteria were applied to the selection of documents. Only articles that directly engaged with the ethical aspects of the case, such as corporate leadership decisions, the rights of stakeholders, and the role of regulatory bodies, were included. Additionally, documents were required to focus on the intersection of health technology and corporate ethics, ensuring relevance to the Theranos case. Preference was given to publications from 2020 to 2024, as they offered the most current perspectives on the scandal and its broader implications. Peer-reviewed articles and investigative reports of high academic and professional quality were prioritized to maintain a rigorous analytical framework. Excluded from the selection process were non-academic sources such as blogs and opinion pieces unless they contributed verified information to the case. Articles that focused solely on technical aspects of Theranos technology without addressing the ethical concerns were also excluded, as were those that repeated content found in other selected sources.

After identifying the relevant documents, the qualitative data analysis software Atlas.ti 8 (ATLAS.ti Scientific Software Development GmbH, Berlin, Germany, 2019) was used to analyze the content systematically. This software enabled the coding and categorizing of critical themes related to the ethical violations in the Theranos case. The analysis followed a thematic approach, identifying patterns in ethical issues,

stakeholder responses, and regulatory failures. This coding process was essential for organizing the detailed case analysis material.

Several key codes emerged during the content analysis. Corporate misrepresentation was a significant theme, reflecting the false claims made by Theranos leadership about the capabilities of its blood-testing technology. Another vital code was stakeholder rights, highlighting the violations of patients' rights to accurate medical information and investors' rights to truthful financial disclosures. Regulatory failures were also a central theme, focusing on the inability of oversight bodies such as the FDA and CMS to detect early signs of malpractice within the company. The role of leadership ethics was explored through the actions of Elizabeth Holmes and Sunny Balwani, particularly their decisions that perpetuated unethical practices within the company. Whistleblower accounts were also examined, shedding light on how internal stakeholders raised concerns about the company's unethical actions.

The ethical framework guiding the analysis was multi-faceted, drawing on four main ethical theories. Utilitarianism was applied to assess the balance between the potential societal benefits of Theranos technology and the actual harm it caused to patients and the broader healthcare industry. Deontological ethics focuses on the duties and obligations of corporate leaders, especially in healthcare, where the safety and well-being of patients must be prioritized. Virtue ethics explored the integrity and character of Theranos' leadership, analyzing how the company's decision-making reflected—or failed to reflect—values like honesty and accountability. A rights-based approach was used to examine how the company's fraudulent practices violated the rights of various stakeholders, including patients and investors.

Each document selected for review was analyzed through this ethical lens, and codes were applied to capture recurring themes and patterns. Atlas.ti facilitated the comparison and synthesis of findings across the documents. For instance, the code on corporate misrepresentation consistently highlighted how Theranos exaggerated its technological capabilities to secure funding and partnerships. Similarly, under the stakeholder rights code, the analysis revealed extensive patient and investor trust violations. This thematic analysis provided a structured way to understand the ethical and regulatory failures that contributed to the company's downfall.

While the analysis provided a comprehensive understanding of the Theranos case, certain limitations were recognized. As the study relied on secondary sources, the data already available in the published literature constrained the findings, limiting the opportunity for new primary insights. Additionally, although the search strategy was designed to be comprehensive, there is a possibility that relevant sources outside of Google Scholar's database or those that did not meet the inclusion criteria were inadvertently excluded. Despite these limitations, the methodology enabled a robust analysis of the ethical challenges presented by Theranos and offered insights into how future health technology companies can avoid similar pitfalls.

3. Relevant Facts

Theranos was founded by Elizabeth Holmes in 2003 with the ambitious goal of revolutionizing the medical diagnostics industry. The company claimed to have developed a proprietary device that could run hundreds of diagnostic tests using only a few drops of blood, dramatically reducing the need for traditional, invasive blood draws (Diamandis *et al.*, 2021). Holmes, inspired by her vision of making healthcare more accessible and affordable, pitched the technology to investors, medical professionals, and the public as a significant change that would enable faster, cheaper,

and less painful testing. The innovation was seen as a breakthrough in diagnostics and a tool that could transform preventive care by giving individuals control over their health (Straker *et al.*, 2021).

Theranos' technology, centered around its proprietary Edison machine, promised to perform a broad range of tests—from cholesterol levels to cancer detection—using just a finger prick of blood. This claim was particularly compelling because it suggested that the company could democratize healthcare by providing rapid, cost-effective diagnostics at the point of care (Tourish and Willmott, 2023). Holmes and her team continuously assured investors and the public that the technology was effective, dependable, and poised to disrupt the traditional lab testing industry. However, from the beginning, the promises made by Theranos far exceeded the actual capabilities of its technology, laying the groundwork for future scrutiny and ethical challenges (Das and Drolet, 2022).

In the early years, Theranos gained substantial attention and financial backing. High-profile investors, including Rupert Murdoch and the Walton family, were drawn in by the company's potential to disrupt healthcare and its charismatic founder, Elizabeth Holmes, who was often compared to Steve Jobs for her visionary leadership (Williams, 2022). Theranos was valued at over $9 billion at its peak, making Holmes the youngest self-made female billionaire (Jeske, 2020). The company's rapid rise was fueled by its ability to secure partnerships with major corporations, including Walgreens, which agreed to roll out Theranos blood-testing centers in its retail locations across the United States (Diamandis *et al.*, 2021).

Theranos also attracted influential board members, including former U.S. Secretaries of State George Shultz and Henry Kissinger, which gave the company significant credibility despite its secrecy about the technology's workings (Guo *et al.*, 2024). The promise of Theranos' innovation led to a surge in investor confidence, with little technical transparency required, as many trusted the company's claims without demanding rigorous verification. This lack of accountability would eventually lead to its downfall, as the technology was far from functional (Straker *et al.*, 2021).

Despite its meteoric rise, internal concerns about Theranos' technology began to surface. Whistleblowers within the company, including Tyler Shultz, raised the alarm over the accuracy and reliability of the Edison device, which often produced inconsistent and erroneous test results (Rogal, 2020). These internal concerns were ignored, and employees were pressured to keep quiet about the flaws in the technology. The internal culture at Theranos, led by Holmes and COO Sunny Balwani, was described as secretive and hostile toward those who questioned the company's claims (Tourish and Willmott, 2023).

The public facade of Theranos started to crack in 2015 when The Wall Street Journal published an investigative report by John Carreyrou, revealing that the company's technology was unreliable and that many of the tests were not being conducted on its proprietary devices but on traditional machines (Mazer, 2022). This report prompted increased media scrutiny and regulatory investigations by the Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services (CMS), both of which uncovered severe deficiencies in Theranos' laboratory practices that posed immediate risks to patient health (Richards, 2022). The combination of whistleblower accounts, media investigations, and regulatory scrutiny led to the unraveling of Theranos, exposing the ethical and legal failures at the core of the company.

The Theranos scandal offers significant lessons for the medical technology industry, highlighting the dangers of prioritizing rapid innovation and financial success over transparency, safety, and ethical responsibility (Das and Drolet, 2022). As this

case demonstrates, the promise of innovation can become dangerous when sound scientific practices and accountability do not back it.

4. Ethical Dilemma

Elizabeth Holmes and Sunny Balwani bear the most significant ethical responsibility for the company's actions as the primary decision-makers at Theranos. As the founder and CEO, Holmes was the public face of Theranos and consistently made bold claims about the company's ability to revolutionize healthcare. Despite being informed of the technology's failures, Holmes presented it as operational and dependable. Ramesh Balwani, as the COO, was responsible for managing day-to-day operations and played a crucial role in enforcing a culture of secrecy and fear within the company, silencing employees who raised concerns (Jaffe, 2021). Together, they manipulated stakeholders and created a façade of success, knowing their product was flawed. Their actions demonstrate a clear breach of ethical standards in leadership. Instead of prioritizing patient safety and transparency, Holmes and Balwani placed their ambitions and the company's financial success primarily. This failure of leadership is a cautionary tale of what can happen when leaders in the healthcare sector prioritize profit over ethical responsibility (Mammadli, 2023).

Theranos managed to secure millions of dollars from prominent investors, including Rupert Murdoch and the Walton family. Many of these investors were drawn in by Holmes's charisma and the potential of the company to disrupt the traditional medical testing industry. However, they were systematically misled about the state of the technology and the company's progress (Mallaby, 2022). The company's board, including former U.S. Secretaries of State Henry Kissinger and George Shultz, also failed in its oversight role, trusting Holmes's vision without demanding sufficient technical transparency (Witek and Klein, 2023).

The investors and board members suffered financial losses, but their lack of due diligence also contributed to the problem. While Holmes and Balwani are primarily responsible for the ethical failings, the investors and board were responsible for questioning the company's claims and ensuring their investments supported legitimate technological advances. The passive role of the board in the face of such high-stakes innovation raises questions about the ethical responsibilities of investors in healthcare ventures.

The most severely impacted stakeholders in the Theranos case were the patients who relied on the company's tests for critical health information. Theranos operated testing centers in Walgreens stores across the United States, providing blood tests for conditions ranging from diabetes to cancer. Many of these patients received inaccurate or unreliable results due to the company's faulty technology, leading to misdiagnoses and, in some cases, delayed treatment (Jaffe, 2021). The misrepresentation of the efficacy of Theranos's technology is particularly egregious in healthcare, where patients' trust in the accuracy of diagnostic tests is paramount. The failure to provide reliable test results undermined this trust and put patients' health at risk. In a sector where lives are at stake, the ethical responsibility to provide accurate and reliable services is fundamental, and Theranos's inability to meet this responsibility represents a severe ethical breach (Ali *et al.*, 2022).

Theranos employees, particularly those in the research and development teams, faced significant internal pressure to remain silent about the company's technological shortcomings. Whistleblowers like Tyler Shultz and Erika Cheung raised concerns about the validity of the technology but were met with threats of legal action

and non-disclosure agreements (NDAs) aimed at silencing them (Trautman *et al.*, 2022). Many employees were put in a position where they had to choose between their ethical responsibility to report unsafe practices and their potential legal and professional consequences.

The case demonstrates how a toxic corporate culture, driven by fear and secrecy, can force employees into ethical dilemmas where they must choose between personal integrity and job security. The use of NDAs and intimidation tactics by Theranos leadership to suppress internal dissent further highlights the ethical failures of the company's leadership (Bratt, 2022).

Healthcare professionals, including doctors and nurses who used Theranos's tests, were also misled about the accuracy and reliability of the results. Many trusted the company's claims, and their patients suffered. Additionally, regulatory bodies like the Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services (CMS) were delayed in their investigations due to the company's lack of transparency. When they intervened, they found significant deficiencies in Theranos's laboratory practices, ultimately leading to its downfall (Lerman, 2021).

The failure of these regulatory bodies to detect and prevent fraud earlier raises questions about the need for more stringent oversight in the healthcare technology sector. While Theranos was able to evade detection for several years, the case underscores the importance of rigorous regulatory scrutiny to protect public health.

5. Ethical Analysis

The rise and fall of Theranos is a cautionary tale that exemplifies how unethical behavior can have far-reaching consequences in healthcare and beyond. This section explores the ethical dimensions of the Theranos scandal through different frameworks, including utilitarianism, deontology, virtue ethics, and a rights-based approach.

4.1. Utilitarian Perspective

From a utilitarian perspective, Theranos' actions resulted in a significant imbalance between potential benefits and overwhelming harm. The company presented itself as a revolutionary force in healthcare, claiming it could perform hundreds of diagnostic tests with drops of blood. This innovation could democratize healthcare by making diagnostic services more accessible, affordable, and less invasive (Straker *et al.*, 2021). In theory, the benefits of such a technology would have been vast, as it could have improved early detection of diseases, empowered patients to take control of their health, and lowered costs in an industry notorious for high expenditures (Tourish and Willmott, 2023). However, these hypothetical benefits were never realized because the technology did not work as claimed. Thus, the expected utility was never delivered (Diamandis *et al.*, 2021).

Theranos' failure caused considerable harm to multiple stakeholders. Patients who relied on inaccurate test results were put in jeopardy—some received false positives, while others were falsely reassured about their health conditions (Das and Drolet, 2022). This affected individual lives and created distrust in medical diagnostics and technological innovation. Holmes and Balwani's deceit compromised the healthcare system's integrity, leading to widespread skepticism about technological advancements in diagnostics, particularly point-of-care innovations (Jeske, 2020). As Tourish and Willmott (2023) argue, the damage to trust and credibility in healthcare innovations is a long-term consequence that may hinder future advancements, a point also stressed by Williams (2022), who highlights the cultural and structural impact of Theranos on the broader biotech industry. These widespread repercussions are far

more detrimental than the potential benefits of Theranos' technology, which were speculative at best.

One could argue that Theranos was driven by the ethos of Silicon Valley's "fake it till you make it" culture, where companies are encouraged to innovate rapidly and deliver transformative products, even when the underlying technology is not fully realized (Mcginn, 2022). However, while such an approach may be tolerated in industries like software development, its application in healthcare is ethically problematic due to its direct impact on human lives. Straker *et al.* (2021) contend that this practice is dangerous when applied to medical technologies, as the stakes are much higher. When patient lives and health outcomes are involved, as in the case of Theranos, the cost of failure is disproportionately more significant than the rewards of potential success. Thus, the utilitarian calculus shifts towards prioritizing patient safety over technological experimentation, a sentiment echoed by Das and Drolet (2022), who criticize the leniency of Silicon Valley's cultural norms when they permeate healthcare innovation.

A critical consideration in the utilitarian evaluation is the erosion of trust in investors and regulatory bodies like the FDA and CMS. Theranos received substantial financial backing from high-profile investors, many of whom were misled by the company's assurances about the efficacy of its technology (Griffin, 2020). This caused significant monetary loss to investors and demonstrated how the pursuit of rapid growth and disruption in the biotech industry could blind stakeholders to potential red flags (Williams, 2022). In turn, this led to a breakdown in regulatory oversight, as Holmes and Balwani successfully evaded scrutiny by exploiting regulatory loopholes, delaying accurate reporting on the state of their technology (Jeske, 2020). Diamandis *et al.* (2021) point out that the FDA and CMS, while responsible for protecting public health, failed to act swiftly enough to prevent the dissemination of Theranos' flawed tests. This failure had far-reaching consequences, as regulatory bodies now face tremendous pressure to enforce more stringent policies, potentially stifling innovation in the industry.

In weighing the potential benefits against the harm caused by Theranos, it becomes clear that the costs of the company's fraudulent practices extend far beyond financial losses and reputational damage. The harm to patients, the erosion of trust in healthcare innovation, and the strain on regulatory processes outweigh the hypothetical benefits that could have arisen had the technology worked. Tourish and Willmott (2023) stress that this case should be viewed as a pivotal lesson in the dangers of overpromising and underdelivering in healthcare, a sentiment echoed by Williams (2022), who advocates for greater accountability in biotech startups. While some argue that the vision of transforming healthcare was commendable, Theranos's path was fraught with ethical violations that undermined the integrity of the healthcare industry (Das and Drolet, 2022).

In contrast, Mcginn (2022) takes a slightly different stance, suggesting that the lessons learned from Theranos could lead to positive reforms in biomedical innovation, encouraging more ethical behavior and better regulatory practices. Jeske (2020) aligns with this view, positing that while the immediate consequences of Theranos were damaging, the long-term impact may lead to more robust industry standards and a more cautious approach to health technology innovation. This cautious optimism contrasts with the more critical perspectives of Tourish and Willmott (2023), who emphasize the irreparable harm caused to public trust and the healthcare system. Nevertheless, most agree that the utilitarian balance of Theranos' actions leans

towards more significant harm than benefit, particularly when considering the vulnerable populations directly affected by the company's deception.

From a utilitarian standpoint, the overall negative consequences of Theranos' actions far outweigh any potential benefit. While the company's vision may have been noble in theory, its unethical path, prioritizing rapid innovation and market disruption over patient safety and truthfulness, resulted in profound harm. The erosion of trust in healthcare innovation and the financial and emotional toll on patients, investors, and regulatory bodies underscores the failure of Theranos to deliver on its promises. As Straker *et al.* (2021) succinctly put it, the damage caused by this "dangerous unicorn" should be a critical reminder that in healthcare, the stakes are too high to tolerate deception.

4.2. Deontological Perspective

From a deontological perspective, the case of Theranos exemplifies a clear violation of the duties and ethical obligations expected of the company's leadership, particularly in the healthcare industry. Deontological ethics, which emphasize the importance of adherence to moral rules and duties, are particularly relevant in sectors like healthcare, where the well-being and safety of individuals are paramount. Elizabeth Holmes, as the founder and CEO of Theranos, and Ramesh "Sunny" Balwani, the COO, had an ethical responsibility to ensure that their company's operations and products adhered to principles of honesty, transparency, and patient safety (Guo *et al.*, 2024). Their failure to uphold these duties endangered lives and undermined the vital trust in healthcare. Holmes and Balwani's deliberate deception, which included falsifying test results and misrepresenting their technology's capabilities, represents a gross breach of professional ethics (Tourish and Willmott, 2023).

Healthcare companies are held to an exceptionally high standard of ethical conduct because their products and services directly impact human lives. In this context, Theranos had a duty to ensure that its blood-testing technology was safe and dependable before it was introduced to the market. Diamandis *et al.* (2021) highlight that the primary obligation of healthcare providers is to safeguard patient welfare, and any deviation from this responsibility is inherently unethical. Despite its flaws, Holmes and Balwani violated this central tenet of healthcare ethics by continuing to market and use the Edison machine. They placed their ambitions and the company's success above their duty to patients, resulting in misdiagnoses and incorrect treatments, potentially life-threatening consequences (Das and Drolet, 2022). This breach is compounded by the fact that patient safety should have been their highest priority, as Straker *et al.* (2021) argue, making their actions unethical and dangerous.

One of the most troubling aspects of Theranos' leadership was manipulating employees and creating a toxic, oppressive work environment that discouraged whistleblowing and fostered unethical behavior. According to Tourish and Willmott (2023), Holmes and Balwani used despotic leadership tactics to maintain control over employees, often pressuring them to remain silent about the technological failures they witnessed. Employees were ethically bound to report unsafe practices, but many feared retributions. This culture of fear and intimidation further illustrates the leadership's failure to uphold their duty to foster an environment of ethical integrity within the organization (Guo *et al.*, 2024). Williams (2022) emphasizes that leaders in any organization, especially in healthcare, must create a work culture that promotes transparency and ethical decision-making. In contrast, Theranos' leadership actively undermined these values, prioritizing their interests over the ethical obligations to their employees and patients.

Holmes' actions also violated the principles of informed consent and truthfulness, which are critical components of deontological ethics in healthcare. Jeske (2020) points out that in healthcare, informed consent is a foundational ethical obligation, meaning that patients must be given accurate and truthful information about the services they are receiving. By deliberately providing inaccurate test results, Theranos violated patients' rights to make informed decisions about their healthcare. Furthermore, Diamandis *et al.* (2021) argue that healthcare providers have a moral duty to be truthful, especially when patients' health is at stake. In this case, the misrepresentation of the accuracy and reliability of Theranos' technology directly harmed patients, who were led to believe they were receiving valid medical diagnoses when, in fact, the technology was incapable of delivering accurate results.

The deontological obligation of truth-telling is central to patient care and the relationships between companies and investors. Theranos' leadership consistently lied to investors about the efficacy of the company's technology. As Griffin (2020) notes, the magnitude of these lies led to significant financial losses for investors deceived into believing they were supporting a groundbreaking healthcare innovation. While investors have a certain level of responsibility to perform due diligence, Holmes and Balwani have an ethical obligation to provide truthful and transparent information about the state of their technology. In healthcare and business, the duty to tell the truth is non-negotiable, and their failure to do so resulted in financial and moral harm to both patients and investors (Das and Drolet, 2022).

From a deontological perspective, some might argue that Holmes believed she was acting in the best interest of future patients by pushing for the rapid development of a transformative technology (Straker *et al.*, 2021). However, deontology emphasizes that the morality of actions is judged by adherence to rules and duties, not by the potential future outcomes of those actions. Mcginn (2022) suggests that Holmes may have justified her actions through a utilitarian lens, believing that the eventual benefits of the technology would outweigh the short-term deception. However, deontologists like Kant argue that individuals must act according to ethical duties regardless of the outcomes, meaning that Holmes and Balwani's decisions were unethical when they deceived stakeholders, even if they believed their actions would lead to positive results.

4.3. Virtue Ethics

From the perspective of virtue ethics, the ethical failings in the Theranos case stem primarily from the leadership's lack of character, integrity, and moral responsibility, particularly Elizabeth Holmes and Ramesh "Sunny" Balwani. Virtue ethics emphasizes the importance of individual character in ethical decision-making, advocating for personal virtues such as honesty, courage, and integrity as guides for moral actions (Mcginn, 2022). In Theranos, however, the actions of Holmes and Balwani demonstrated a failure to embody these virtues, as they consistently prioritized ambition and success over ethical behavior and accountability (Guo *et al.*, 2024).

Holmes and Balwani's actions reveal a profound lack of honesty, a central virtue in business and healthcare ethics. According to Diamandis *et al.* (2021), the deliberate misrepresentation of their blood-testing technology's capabilities was a failure of technical leadership and a breach of the ethical principle of truthfulness. By continually promoting a product they knew did not work, Holmes and Balwani violated the trust of patients, investors, and employees. This lack of truthfulness had significant consequences, particularly for patients who received inaccurate medical diagnoses due to Theranos' defective tests (Tourish and Willmott, 2023). Integrity, which should

be the bedrock of ethical leadership, was conspicuously absent in their decision-making process, highlighting a critical flaw in their characters (Straker *et al.*, 2021).

Another critical element of virtue ethics is responsibility—particularly the responsibility of corporate leadership to act with transparency and accountability. Holmes and Balwani failed to uphold their responsibility to their stakeholders, especially patients directly affected by their actions. As Das and Drolet (2022) argue, the primary duty of healthcare innovators is to ensure that their products are safe and reliable before they reach the market. Nevertheless, rather than exercising this responsibility, Holmes and Balwani chose to conceal the failures of their technology, prioritizing corporate success and personal gain over patient safety. This behavior is antithetical to the principles of virtue ethics, which prioritize the well-being of others and the pursuit of moral excellence (Gildner *et al.*, 2022).

The case of Theranos also raises questions about the virtue of courage in corporate leadership. In the context of virtue ethics, courage refers to the ability to face challenges with integrity, even when doing so might result in personal or professional loss (Jeske, 2020). Rather than showing courage by admitting to the limitations of their technology and working to resolve these issues, Holmes and Balwani chose to deceive investors and the public. Their fear of failure and loss of status overrode their ethical obligations, leading them to perpetuate fraud that had devastating consequences (Williams, 2022). This lack of moral courage undermined the trust essential in healthcare and business, demonstrating the dangers of leaders prioritizing their interests over the common good (Rogal, 2020).

It is essential to confront the argument that Holmes might have believed she was acting in the best interest of society by trying to revolutionize healthcare. Some could argue that her successful vision would have significantly benefited patients by making diagnostic testing faster and more accessible (Straker *et al.*, 2021). However, from a virtue ethics perspective, intentions alone do not excuse unethical actions. As Mcginn (2022) emphasizes, leaders must act with virtues like honesty and integrity, regardless of their ultimate goals. In the case of Theranos, the means did not justify the ends, as the company's actions caused significant harm to patients and undermined trust in healthcare innovation (Das and Drolet, 2022). Holmes' failure to demonstrate ethical virtues throughout the decision-making process ultimately led to the company's downfall and her conviction.

Holmes and Balwani's leadership also failed to cultivate an ethical work environment that promoted transparency and accountability. In a company governed by virtue ethics, leaders would have fostered a culture where employees felt empowered to speak out about unethical practices or technical failures. However, as Tourish and Willmott (2023) note, Theranos was characterized by a toxic work culture that suppressed whistleblowing and discouraged ethical dissent. Employees who raised concerns were silenced or dismissed, creating an environment in which unethical behavior could flourish unchecked (Guo *et al.*, 2024). This failure of leadership to promote moral virtues within the organization exacerbated the company's ethical failings and caused significant harm to those who sought to act with integrity.

4.4. Rights-Based Approach

The rights-based approach to the Theranos case strongly emphasizes the fundamental rights of patients and investors, which were severely compromised by the actions of the company's leadership. This perspective examines the moral and legal obligations of organizations like Theranos to respect these rights, focusing on two primary groups: patients, who have the right to accurate and reliable medical

information, and investors, who have the right to truthful disclosures about the company's technology and progress.

Patients' rights in the healthcare system are paramount, particularly regarding diagnostic technologies directly affecting their health and well-being. Patients trust healthcare providers and companies to deliver reliable information, particularly regarding medical diagnoses. As Gildner *et al.* (2022) argue, patients rely on the accuracy of medical testing to make informed decisions about their health, and any deviation from this accuracy infringes on their fundamental right to receive truthful information. In the case of Theranos, patients were subjected to inaccurate blood test results, which led to incorrect diagnoses and treatment decisions, thereby violating their right to health and safety (Das and Drolet, 2022). Furthermore, as Diamandis *et al.* (2021) emphasize, the falsified results presented by Theranos were not just a technical failure but an ethical one, as they directly endangered the lives of individuals who depended on the technology for life-altering medical decisions.

In addition to patients, investors in Theranos were also victims of rights violations, as they were systematically misled about the company's progress and technological capabilities. According to Tourish and Willmott (2023), investors have a fundamental right to receive honest disclosures from companies in which they have a financial stake. This transparency is a moral and legal obligation, as investors base their financial decisions on the information companies provide. In the case of Theranos, Elizabeth Holmes and her team were engaged in fraudulent behavior by deliberately misrepresenting the functionality and progress of their blood-testing technology (Williams, 2022). This deception resulted in significant financial losses for investors who believed in the company's potential based on the false information they were provided (Mcginn, 2022). Straker *et al.* (2021) note that Holmes' consistent misrepresentation of Theranos' achievements was unethical and infringed on the rights of those who financially supported the company.

One of the central conflicts in the rights-based approach is the balance between the right to innovation and the right to truthful information. Holmes portrayed herself as a visionary leader aiming to revolutionize the healthcare industry, a claim that initially garnered widespread support from investors and the public alike (Das and Drolet, 2022). However, as Mcginn (2022) argues, innovation should not come at the cost of violating the rights of stakeholders. In the case of Theranos, the desire to push technological boundaries was pursued at the expense of patient safety and investor transparency. The rights-based framework suggests that the right to innovate must always be tempered by the duty to provide honest and accurate information, mainly when the stakes involve human lives and financial stability.

The role of regulatory bodies in safeguarding these rights cannot be overstated. Diamandis *et al.* (2021) highlight that organizations like the FDA and CMS ensure that companies adhere to ethical standards, particularly when patient safety is involved. The failure of Theranos to provide accurate test results should have been identified and rectified earlier by regulatory oversight. However, as Furlow (2022) points out, the secrecy surrounding Theranos' operations made it difficult for regulators and external stakeholders to assess the actual state of the company's technology. This lack of transparency violated the rights of patients and investors and undermined the role of regulatory bodies in maintaining public trust in healthcare innovations (Das and Drolet, 2022).

It is essential to address opposing views regarding the responsibility of investors in the Theranos case. Some may argue that investors bear partial responsibility for

failing to conduct thorough due diligence before investing in a company like Theranos. As Straker *et al.* (2021) suggest, the hype around innovative startups can sometimes cloud judgment, leading investors to make decisions based on emotion rather than complex data. However, from a rights-based perspective, this argument does not absolve Theranos of its ethical obligations. The onus remains on the company to provide truthful and accurate information to investors, regardless of market hype or investor enthusiasm (Guo *et al.*, 2024). Investors can make informed decisions based on facts, not fabricated or misleading claims.

6. Potential Responses

The Theranos scandal provides a significant case study of how unethical leadership and a lack of regulatory oversight can lead to large-scale fraud with far-reaching consequences. The responses taken by stakeholders, particularly Elizabeth Holmes and Sunny Balwani and regulators, were reactive and often insufficient to prevent the escalating situation. However, reflecting on the situation reveals numerous points at which different, more effective responses could have altered the course of events. This section explores the responses and those that internal and external stakeholders could have taken.

4.1. Responses Taken by Stakeholders

When the first signs of scrutiny emerged, Elizabeth Holmes and Sunny Balwani responded with defiance rather than transparency—rather than addressing concerns about the reliability of Theranos' blood-testing technology, Holmes and Balwani resorted to a combination of secrecy and manipulation to maintain control of the narrative. Tourish and Willmott (2023) highlight that their leadership was characterized by ideological manipulation, using the vision of revolutionizing healthcare to suppress dissent. This despotic leadership style fostered an environment where employees were discouraged from voicing concerns, thus exacerbating the ethical violations at the core of Theranos' operations.

Instead of admitting to the technical limitations of their product, Holmes and Balwani continued to propagate false claims about the capabilities of Theranos' technology, even as regulatory bodies and journalists began to question their accuracy (Diamandis *et al.*, 2021). According to Straker *et al.* (2021), this deliberate misrepresentation can be seen as an attempt to delay the company's inevitable collapse by misleading investors and the public. This defensive strategy ultimately compounded the damage when the full extent of the fraud was exposed.

Balwani, in particular, played a crucial role in enforcing a culture of secrecy and fear within the company. According to Mcginn (2022), his management style stifled dissent, creating a toxic work environment that contributed to the failure of employees to come forward earlier with concerns. When whistleblowers like Tyler Shultz came forward, the damage to patients and investors had already been done. The reactions of Holmes and Balwani were, therefore, emblematic of a leadership that prioritized self-preservation over corporate responsibility (Guo *et al.*, 2024).

Regulators and law enforcement agencies eventually took action against Theranos, but their responses were slow and fragmented. The U.S. Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services (CMS) did not intervene until after years of dubious practices had already taken place (Das and Drolet, 2022). When the CMS found that Theranos' operations posed an "immediate jeopardy" to patient health, the company had already caused significant harm through inaccurate test results (Richards, 2022). This delayed response highlighted the

weaknesses in regulatory oversight and raised questions about the efficiency of current healthcare regulations in preventing fraud (Furlow, 2022).

Law enforcement agencies became involved after whistleblowers and investigative journalists revealed the depth of the fraud. The U.S. Department of Justice charged Holmes and Balwani with multiple counts of fraud, leading to high-profile trials and eventual convictions (Dyer, 2022). However, the years-long delay in regulatory and legal actions against Theranos raises questions about how the system allowed such misconduct to continue for as long as it did. As Gildner *et al.* (2022) point out, the reactive nature of the responses from regulators and law enforcement underscores the need for more proactive measures to prevent similar incidents in the future.

4.2. Other Possible Responses

One of the critical failures within Theranos was the failure of internal stakeholders—board members, employees, and advisors—to challenge the unethical practices that were taking place effectively. Despite having high-profile individuals with experience in government and industry, the board of directors failed to exercise adequate oversight over Holmes and Balwani. According to Straker *et al.* (2021), the board was kept in the dark about the technical details of Theranos' operations, which enabled Holmes to maintain control and avoid scrutiny. The board's passivity is a clear example of the dangers of excessive trust in charismatic leadership without robust accountability mechanisms (Guo *et al.*, 2024).

Stronger oversight from the board could have significantly altered the trajectory of Theranos. By demanding more transparency from Holmes and Balwani and insisting on third-party technology validation, the board could have uncovered the fraud much earlier. Similarly, employees who suspected that the company's technology was not performing as advertised could have taken more decisive action, although it must be acknowledged that the toxic work environment created by Balwani made it difficult for employees to speak out (Mcginn, 2022). Companies should foster open communication and ethical accountability, where concerns can be raised without fear of retribution.

In hindsight, Theranos employees, particularly those in technical and managerial roles, could have sought external technology validation or raised concerns through more robust whistleblower mechanisms. Internal stakeholders had opportunities to halt the progress of the fraudulent activities, but their fears, combined with the manipulative leadership style, prevented them from doing so (Tourish and Willmott, 2023). A more robust organizational culture that encouraged ethical decision-making could have mitigated the damage caused by Theranos' faulty products.

The Theranos case underscores the need for stronger regulatory oversight, particularly in the healthcare and technology sectors, where new products can directly impact human health. Regulatory bodies like the FDA could implement more stringent monitoring processes for emerging technologies, particularly those claiming to offer revolutionary patient care advancements. As Das and Drolet (2022) argue, the speed at which new medical technologies are brought to market can outpace regulatory frameworks, allowing companies like Theranos to operate without sufficient scrutiny.

A key lesson from the Theranos case is the importance of independent third-party validation of medical technologies before they reach the market. Furlow (2022) suggests that stricter enforcement of regulatory requirements, such as clinical trials and third-party assessments, could have prevented Theranos from bypassing standard

procedures. Additionally, Mcginn (2022) notes that regulatory bodies could adopt more proactive measures, such as unannounced inspections or the requirement for continuous reporting of test accuracy, to ensure that companies do not deviate from ethical practices after initial approval.

Another potential regulatory reform could involve strengthening whistleblower protections, allowing employees to report unethical practices without fear of retaliation. Whistleblowers like Tyler Shultz were critical in exposing the fraud at Theranos, but the absence of formal whistleblower channels within the company delayed the exposure of the misconduct (Rogal, 2020). Regulatory bodies should mandate that companies establish formal, anonymous channels for employees to report concerns, particularly in healthcare industries where ethical violations can have life-threatening consequences (Guo *et al.*, 2024).

In addition to strengthening existing regulations, there is a clear need for collaboration between regulatory bodies and independent watchdog organizations to monitor the conduct of companies in high-risk industries like biotechnology. As Diamandis *et al.* (2021) point out, the lack of transparency in Theranos' operations allowed it to avoid regulatory scrutiny for years. More rigorous collaboration between regulatory bodies, journalists, and other stakeholders could facilitate early detection of potential fraud and prevent harm to patients and investors.

7. Critical Evaluation of Most Appropriate Response

The collapse of Theranos and its subsequent legal proceedings offer a rich case study for evaluating how regulatory bodies, the justice system, and corporate leadership responded to a large-scale health technology scandal. Examining these responses sheds light on the shortcomings in overseeing emerging technologies and the lessons that can be learned to prevent future ethical failures. This section critically analyzes the effectiveness of the responses by regulatory bodies and the justice system, as well as the broader implications for the health technology sector. It also offers recommendations for the actions that could have been taken by Theranos leadership and other stakeholders.

6.1. Analyzing Responses and Consequences

The role of regulatory bodies, such as the U.S. Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services (CMS), was crucial but reactive in addressing the misconduct at Theranos. One of the main criticisms of the regulatory response is the delay in taking decisive action against the company. Theranos was able to operate for years without proper oversight, during which time its faulty technology jeopardized the health and safety of countless patients (Das and Drolet, 2022). The CMS, responsible for overseeing clinical laboratories, found 2016 that Theranos' practices posed an "immediate jeopardy" to patients, but the damage was already extensive (Richards, 2022). This highlights the reactive nature of the regulatory response and underscores the need for more proactive and continuous monitoring mechanisms in the health technology sector.

While the justice system eventually took action against Elizabeth Holmes and Sunny Balwani, resulting in their conviction on multiple counts of fraud, this too came only after the media and whistleblowers, such as Tyler Shultz, had exposed the depth of the misconduct (Tourish and Willmott, 2023). The fact that whistleblowers had to take their concerns to journalists instead of regulatory authorities suggests a gap in the system for reporting and addressing internal ethical concerns. The trial of Holmes and Balwani brought public attention to the dangers of unchecked leadership in health

technology startups, but it also exposed the shortcomings of a regulatory environment that failed to act promptly (Diamandis *et al.*, 2021).

Despite these shortcomings, the legal proceedings against Holmes and Balwani warn other corporate leaders about the consequences of engaging in fraudulent practices. The conviction of Theranos executives represents a milestone in holding individuals accountable for corporate fraud, but as Furlow (2022) argues, it also raises questions about how similar cases could be prevented in the future. The justice system's response was appropriate regarding legal accountability, but it was reactive rather than preventive, highlighting the need for earlier intervention by regulators and internal stakeholders.

The Theranos case offers critical lessons for the broader health technology sector, particularly in transparency, accountability, and ethical governance. One of the primary lessons is the importance of independent validation and third-party oversight of new technologies before they are introduced to the market. Theranos bypassed these essential safeguards by exploiting loopholes in regulatory oversight, which allowed its technology to be used on patients without sufficient validation (Mcginn, 2022). This highlights the need for stricter enforcement of regulatory standards, particularly in high-risk industries like healthcare, where the consequences of failure can be life-threatening.

Another critical lesson is the role of corporate governance in preventing ethical failures. Theranos' board of directors, despite being composed of high-profile individuals, failed to exercise adequate oversight of the company's operations. According to Straker *et al.* (2021), the board's lack of technical expertise in health technology allowed Holmes to maintain control without being questioned. This underscores the importance of having board members with diverse expertise who can provide meaningful oversight, particularly in technology-driven industries where innovation can outpace regulatory frameworks (Guo *et al.*, 2024).

The case also highlights the importance of fostering an organizational culture that encouraging ethical behavior and whistleblowing. The toxic work environment at Theranos and the authoritarian leadership style of Holmes and Balwani stifled dissent and made it difficult for employees to raise concerns internally (Tourish and Willmott, 2023). This suggests that companies should implement robust whistleblower protection mechanisms and create an environment where ethical concerns can be addressed without fear of retaliation.

6.2. Recommendation

One of the most significant failures of Theranos' leadership was the decision to prioritize secrecy and self-preservation over transparency and accountability. Had Holmes and Balwani adopted a more transparent approach to addressing the limitations of their technology, they might have been able to salvage the company's reputation and avoid the catastrophic legal and financial consequences that followed. Straker *et al.* (2021) argue that transparency is essential in maintaining the trust of both investors and the public, particularly in industries like healthcare where the stakes are high. The decision by Holmes and Balwani to deceive investors and patients about the capabilities of their technology represents a clear violation of ethical standards, and a more transparent approach could have mitigated the damage.

Another crucial step that the board of directors could have taken was to insist on independent validation of the technology before it was widely deployed. As Das and Drolet (2022) suggest, the failure of the board to demand third-party assessments of

Theranos' products allowed the company to operate without proper checks and balances. By insisting on independent validation and engaging external experts, the board could have played a critical role in preventing the widespread use of faulty technology and the resulting harm to patients.

Employees also had a potential role in preventing the escalation of fraud, but they were constrained by the hostile work environment created by Balwani. Companies should foster a culture of open communication where employees feel empowered to raise concerns about ethical issues. Implementing formal, anonymous whistleblower channels could have provided employees with a safer avenue for reporting concerns, allowing the fraud to be exposed earlier (Mcginn, 2022). Regulators should also consider mandating whistleblower protections for companies in high-risk sectors like healthcare, ensuring employees can report misconduct without fear of retaliation.

More proactive measures could have been implemented from a regulatory perspective to prevent the scandal. Regulatory bodies like the FDA and CMS could adopt a more continuous monitoring approach for emerging technologies, particularly those directly affecting patient safety. As Richards (2022) points out, the reliance on periodic inspections and reporting allowed Theranos to operate under the radar for years, during which time it caused significant harm. More frequent inspections and mandatory third-party validation could have mitigated the risks posed by unproven technologies.

In addition to strengthening existing regulations, regulators could work more closely with independent watchdog organizations and the media to monitor corporate conduct. The role of investigative journalists, particularly John Carreyrou, was crucial in exposing the fraud at Theranos, but this should not have been necessary. Regulatory bodies should collaborate with independent organizations to ensure that companies like Theranos cannot avoid scrutiny by keeping their operations secretive (Diamandis *et al.*, 2021).

8. Conclusion

The Theranos case is a significant example of the ethical challenges that can arise when the drive for innovation and financial success overshadows transparency, accountability, and responsibility. At the heart of this case was the deliberate misrepresentation of a health technology that promised revolutionary advancements but, in reality, delivered unreliable and dangerous results. The ethical dilemma centered on the actions of Theranos' leadership, particularly Elizabeth Holmes and Sunny Balwani, who prioritized personal and corporate gain over the well-being of patients and the integrity of healthcare.

Throughout this analysis, critical ethical frameworks such as utilitarianism, deontology, virtue ethics, and rights-based approaches were applied to understand the severity of the actions taken by Theranos' leadership. From a utilitarian perspective, the potential benefits of Theranos' technology were outweighed by the substantial harm caused to patients, investors, and the healthcare industry at large. Deontologically, the leadership violated their fundamental duty to act in patients' best interest and uphold the standards of honesty and transparency expected in healthcare. Virtue ethics further underscored the lack of moral integrity and ethical character in the decision-making processes at Theranos. Lastly, a rights-based analysis emphasized the failure to respect patients' rights to accurate medical information and the investors' right to truthful disclosures about the company's progress.

Responses to the growing scrutiny of Theranos varied. While regulators and the justice system eventually took action against Holmes and Balwani, their interventions came too late to prevent the widespread harm caused. Other internal stakeholders,

including board members and employees, could have been more active in addressing the company's ethical lapses earlier. The lack of robust internal oversight and a culture of fear within the company stifled opportunities for whistleblowers and further exacerbated the damage.

The lessons learned from the Theranos case are profound and far-reaching. For the broader health technology sector, it is a cautionary tale about the importance of independent validation, transparency, and ethical leadership. Regulatory bodies must adopt a more proactive stance in monitoring new technologies to prevent such scandals from occurring. Meanwhile, companies must foster a culture where ethical concerns can be raised and addressed without fear of retaliation and where accountability is built into every level of governance.

Ultimately, the Theranos case highlights the critical need for ethical leadership in driving innovation responsibly. As healthcare evolves with new technologies, maintaining public trust will depend on the industry's ability to balance progress with ethical principles. The consequences of Theranos' downfall extend beyond the company itself, as a stark reminder of the damage that can be caused when ethics are neglected in pursuing innovation. Future practices must integrate ethical considerations at their core to avoid similar disasters and ensure that progress in healthcare remains aligned with the values of honesty, transparency, and accountability.

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