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# THE CONSEQUENCES OF BREAKING UNWRITTEN MORAL RULES: THE SOCIAL IMPACT OF UNETHICAL DECISION-MAKING IN THE HEALTHCARE SEGMENT

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**Abstract:** ***This article examines the critical role of individual and situational factors in fostering unethical corporate behaviour within the highly regulated healthcare sector. Utilising two landmark cases—the Theranos technological fraud and the Purdue Pharma opioid crisis—the study analyses how leadership character traits, cognitive biases, and systemic governance failures converge to produce catastrophic social harm. The analysis is grounded in Schwartz's Integrated Ethical Decision-Making Model (I-EDM), focusing on 'moral capacity' as a decisive individual moderator. The analysis indicates that the leadership styles of both Elizabeth Holmes and the Sackler family aligned with distinctive behavioural archetypes—characterised by self-centredness, strategic manipulation, and a lack of interpersonal empathy—which served to foster institutionalised moral disengagement and 'ethical blindness'. These behavioural tendencies were compounded by pervasive cognitive biases, specifically overconfidence and confirmation bias, which created a psychological framework for leaders to rationalise deceptive commercial practices as necessary instruments for achieving broader visionary or altruistic objectives. Situational analysis highlights how these companies exploited regulatory loopholes, such as 'trade secret' protections and flaws in FDA oversight, to shield technological failures and deceptive marketing from public scrutiny. Furthermore, both organisations suffered from insular governance models; boards lacked technical expertise and functioned primarily to validate executive strategy rather than provide independent oversight. To mitigate the recurrence of such scandals, the author advocates for a hybrid governance approach. This model integrates enforceable 'hard law' mandates, such as clinical trial transparency and whistleblower protections, with adaptive 'soft law' frameworks. Specific recommendations include mandating independent board protocols, enhancing conflict-of-interest disclosures, and providing ethical leadership training to sensitise decision-makers to cognitive biases. Ultimately, the article argues that aligning technological ambition with moral responsibility is essential to safeguarding public welfare.***

**Key words:** ***Healthcare Scandal; Opioid Crisis; Ethical Challenges; Hard Law; Soft Law; Cognitive Bias***

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## 1. INTRODUCTION

The pharmaceutical industry is one of the most heavily regulated industries, which can be run under strict conditions. This is not coincidental. The products are chemicals that cause serious environmental and human impacts. Product development,

production, and distribution of medicines require significant corporate social responsibility.

This article aims to explore the importance and relevance of moderating factors that influence (un)ethical decision-making, highlighting the role of soft-law elements in governance models and arguing for more extensive soft-law regulation in preventing corporate misconduct.

The analysis of the cases is based on Schwartz's I-EDM (Integrated Ethical Decision-Making Model), focusing particularly on the role of the moderating factors emphasised in this model. These moderating factors include individual and situational factors. The individual factors are termed 'moral capacity.' '*Moral capacity is defined as the ability of an individual to avoid moral temptations, engage in the proper resolution of ethical dilemmas, and ultimately act morally.*'[1] Variables at the individual level can be demographic, personality/psychological traits, or ethical experiences.[2] Moral character is a part of moral capacity and is described as '*one's level of moral maturity based on their ethical value system, stage of moral development, and sense of moral identity.*'[3] The model incorporates Trevino's interactionist model, which identifies Kohlberg's cognitive moral development (CMD) stage, ego strength, field dependence, and locus of control as key individual factors in ethical decision-making.[4]

The analysis links theoretically defined factors that influence ethical decision-making with scientifically researched character traits and behavioural patterns. It aims to show how these individual factors, such as poor moral capacity and character, have played a significant role in the scandals examined. Beyond personality traits, the article also discusses how cognitive biases[5] affect the decision-making process.

Situational factors – the other main group of moderating factors in Trevino's and Schwartz's model - are also discussed with special attention to the organisational and legal environment.[6]

There are competing arguments and practices about what corporate responsibility is. Caroll's perspective is that society expects the leaders of a company to act ethically and morally right[7] and ensure that the impacts of their decisions focus not only on profit but also on the interests of a wider stakeholder group, including patients, communities, and the environment. Stakeholder theory also argues for a wider context

[1] Mark S Schwartz, 'Ethical Decision-Making Theory: An Integrated Approach' (2016) 139 *Journal of Business Ethics* 755, 761 https://doi.org/10.1007/s10551-015-2886-8 accessed 26 April 2025.
[2] Ibid, 762-763.
[3] Ibid, 762.
[4] Ibid, 762.
[5] Cognitive biases are systematic and predictable patterns of deviation from norms of rationality in judgment, inferential reasoning, and evaluation. They serve as mental shortcuts, or heuristics, which allow individuals to process information and make quick, efficient decisions, particularly in conditions of information overload or time constraint (See Amos Tversky and Daniel Kahneman, 'Judgment under uncertainty: heuristics and biases' (1974) 185(4157) *Science* 1124 https://www.jstor.org/stable/1738360 accessed 26 April 2025). While often functional for rapid judgment, these heuristics can lead to systematic errors, resulting in suboptimal or irrational choices across various domains, including business, healthcare, law, and public policy (See Devaki Rau and Philip Bromiley, 'A review of cognitive biases in strategic decision making' (2025) 58(3) *Long Range Planning* 102529 https://doi.org/10.1016/j.lrp.2025.102529 accessed 26 April 2025).
[6] Schwartz's I-EDM model lists these three factors as a situational context (issue, organisational environment and personal situation). See Schwartz (n 1) 763.
[7] Caroll's model of Corporate social responsibility illustrates corporations' social responsibility as a multi-layered concept that has four interrelated layers: economic, legal, ethical, and philanthropic. The economic and legal aspects are required by society, ethical is expected, and philanthropic are desired by society. See Archie B Carroll, 'Carroll's pyramid of CSR: taking another look' (2016) 1 *International Journal of Corporate Social Responsibility* 1, 5 https://doi.org/10.1186/s40991-016-0004-6 accessed 26 April 2025.

of the corporation's responsibility.[8] Government regulations provide strict guidelines for legal operations, and the corporation's governance model creates the framework that represents the corporation's values and demonstrates intent for good. However, even the most thorough and carefully designed governance model cannot fully prevent misconduct. Cognitive bias and blind spots, combined with poor character traits, can lead to morally questionable decisions. In addition to character traits, the proximal and distal context (such as corporate culture) can also increase the possibility of ethical blindness and unethical decision-making.[9]

The author argues that a better understanding of human nature and human behaviour and the situational importance can play a pivotal role in using soft-law measures to create a stronger framework for ethical decision-making in business.

The industry and the selected cases have been carefully chosen. The healthcare sector is a high-risk and high-impact factor in many aspects. Its operation has a significant impact on society's physical and mental health. The industry has several stakeholders who are influenced and impacted by its business conduct. The pharmaceutical and medical device sectors are supposed to safeguard public health and contribute to social and individual welfare. It is an especially sensitive sector, since the health-care system is financed by tax income from citizens or health insurance institutions, but in most cases not directly by the 'end-user', namely the patient. The end-users (the patients) cannot make informed choices because they lack professional medical expertise. The regulatory authorities determine the availability of a treatment or device; financial accessibility depends on the country's healthcare system (whether centrally financed from tax or through private health insurance). The decision-makers regarding financing and availability do not directly face the consequences of their decision.

Ethical failures in the healthcare system have serious, long-term, and high-impact consequences. It is not 'only' a financial, economic, and business question.

Despite all the central efforts in regulation, systemic vulnerability in corporate governance and regulatory oversight is apparent. The Theranos case, for instance, shows how a company exploited a loophole in FDA oversight for laboratory-developed tests, while the Purdue Pharma case reveals how a company leveraged flawed regulatory approvals to legitimise deceptive marketing. These two landmark cases also illustrate how the ethical blindness of the leader and institutionalised moral disengagement can lead to catastrophic consequences. These scandals reveal a troubling pattern: visionary ambitions and profit motives often eclipse ethical rigour, enabled by gaps in traditional regulatory frameworks. As technological innovation accelerates, the need for adaptive governance models becomes urgent. Soft-law, non-binding guidelines, industry standards, and collaborative frameworks emerge as a critical tool to bridge ethical voids, fostering accountability while accommodating rapid advancements in healthcare technology.

[8] R. Edward Freeman's stakeholder theory, introduced in his 1984 book 'Strategic Management: A Stakeholder Approach,' is a business and ethics concept that argues a company's success depends on creating value for all stakeholders, not just its shareholders. The theory challenges the traditional view of a corporation (often associated with economist Milton Friedman), which holds that a company's primary and sole responsibility is to maximise profits for its owners or stockholders. According to the theory, the role of management is to balance the often-competing interests of all stakeholders. This involves fostering strong relationships built on trust, transparency, and a shared sense of purpose. By doing so, managers can create a more resilient and sustainable business. See R Edward Freeman, *Strategic Management: A Stakeholder Approach* (Pitman 1984).

[9] Guido Palazzo, Franciska Krings and Ulrich Hoffrage, 'Ethical Blindness' (2012) 109 *Journal of Business Ethics* 323, 328 https://doi.org/10.1007/s10551-011-1130-4 accessed 26 April 2025.

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The presented and discussed cases provide a comprehensive overview of the root causes, systemic and individual parts of failures from the central actor's perspective. The part of individual factors describes certain character traits and attempts to identify some cognitive biases that might have limited the actors' decision-making scope. The article focuses on the role and responsibility of the company and its leaders.

## 2. THE THERANOS CASE

### *2.1 Company History*

Theranos Inc. was founded in 2003 by 19-year-old Elizabeth Holmes after she dropped out of Stanford University. The company was named 'Real-Time Cures' in the beginning, and later renamed to Theranos (the combination of words 'therapy' and 'diagnosis'). Founded in Palo Alto, California as a privately held corporation, Theranos positioned itself from the start as a health-technology innovator in the diagnostic blood-testing sector. The company claimed to have developed proprietary devices that could run hundreds—eventually more than 1,000—tests from only a few drops of finger-prick blood rather than larger venous draws.[10]

Corporate leadership initially centred around Holmes as founder and CEO, with Ramesh 'Sunny' Balwani joining in 2009 as President and Chief Operating Officer. He was responsible for the day-to-day business but had no knowledge of biomedicine and had never worked in a tech start-up. The employees quickly realised he did not understand the processes and technologies in the lab. Holmes hid the fact that she was in a relationship with Balwani from the staff and the board.[11]

The company assembled an impressive board of directors. One of her first and most important advocates was Stanford professor Channing Robertson, who became her mentor and later the first board member at Theranos. His expertise in bioengineering supported Theranos in gaining external scientific credibility. Holmes met former US Secretary of State George Shultz in 2011, and shortly afterwards, he became a Theranos board member. With the help of his connections, the board was filled with influential people from politics and business, including former Secretary of State Henry Kissinger, former Secretary of Defense William Perry, General Jim Mattis, and former Wells Fargo Bank CEO Richard Kovacevich.[12] Holmes also received money from the Walton family (owners of Walmart). They invested $150 million, Rupert Murdoch, media mogul, put in more than $120 million, and former Secretary of Education Betsy DeVos contributed $100 million.[13]

Elizabeth Holmes was not only the majority owner but also played a key role in shaping Theranos' corporate culture. The background on her family is useful for context on her character. Her grandparents were one of the wealthiest American families; her grandfather founded the Fleischmann Yeast Companies.[14] She gained experience from a

[10] Cait Caffrey, 'Theranos' (2024) *EBSCO Research Starters* https://www.ebsco.com/research-starters/technology/theranos accessed 26 April 2025.
[11] Integrity Line, EOS Editorial Team, 'Elizabeth Holmes and the Theranos Case: History of a Fraud Scandal' (2023) https://www.integrityline.com/expertise/blog/elizabeth-holmes-theranos/ accessed 26 April 2025.
[12] Integrity Line (n 11).
[13] Integrity Line (n 11).
[14] Judit Chrenóczy-Nagy and Zsolt Bujtár, 'Corporate governance implications of the Theranos scandal' in Zsolt Bujtár and others (eds), *A válságkezelés, gazdasági és jogi eszközei: konferenciakötet – válogatott tanulmányok* [Crisis, economy, technology and law Conference Proceedings – Selected Studies] (Pécsi Tudományegyetem Állam- és Jogtudományi Kar 2023) 101 https://pea.lib.pte.hu/server/api/core/bitstreams/db156d01-3737-48d3-9995-e83ca8982643/content accessed 26 April 2025.

very early age on how making a difference as an outsider in business is possible. She was stubborn and persistent. During her studies at the university, she could study continuously with 4 to 5 hours of sleep a day.[15] Elisabeth Holmes was a visionary; her fear of needles drove her design philosophy and goals. Holmes envisioned and developed a system that would use only a finger prick to collect a tiny blood sample, rather than requiring large vials drawn through venipuncture.[16]

Theranos quickly attracted significant venture capital and private investment. By 2004, it had raised nearly $7 million, and its valuation continued to rise rapidly, reaching $30 million in 2004, almost $200 million by 2007, and $1 billion by 2010. By 2014, Theranos had raised more than $400 million, achieving a peak valuation close to $9–10 billion, while keeping its technology secret and aggressively marketing its capabilities.[17]

*2.2 The Scandal*

Doubts about Theranos's technology began surfacing in 2015. Whistleblowers, including Tyler Shultz (grandson of board member George Shultz) and Erica Cheung, provided information to journalist John Carreyrou of The Wall Street Journal. Carreyrou's investigative report revealed that Theranos's technology was unreliable and that the company used conventional machines for most tests, despite claiming otherwise.[18]

In 2016, following media reports, the Centers for Medicare & Medicaid Services (hereinafter also referred to as 'CMS') sent an official notice of proposed sanctions to Theranos. CMS revoked the laboratory's certificate for 60 days due to a lack of credibility in the lab's compliance. Holmes was banned from owning or operating a lab for two years, and Theranos shut down its labs and testing centres by October 2016.[19]

In March 2018, the US Securities and Exchange Commission charged Silicon Valley-based private company Theranos Inc., its founder and CEO Elizabeth Holmes, and its former President Ramesh 'Sunny' Balwani with raising more than $700 million from investors through an elaborate, years-long fraud in which they exaggerated or made false statements about the company's technology, business, and financial performance. Holmes has agreed to resolve the charges against them, to give up majority voting control over the company, and reduce her equity.[20] In June 2018, both were indicted on federal wire fraud and conspiracy charges, accused of defrauding investors and patients.[21] Holmes stepped down as CEO, and by September 2018, Theranos announced it would dissolve after failing to find a buyer.[22]

Holmes's trial concluded in January 2022 with her conviction on four counts of fraud and conspiracy to defraud investors. She was sentenced to over 11 years in

[15] John Carreyrou, *Bad Blood: Secrets and Lies in a Silicon Valley Startup* (Alfred A Knopf 2018) 26.
[16] Integrity Line (n 11); Yasmin Khorram, 'Theranos whistleblower testifies blood-test machines were about as accurate as a coin toss' *CNBC* (15 September 2021) https://www.cnbc.com/2021/09/15/former-theranos-employee-erika-cheung-edison-machines-failed-tests.html accessed 26 April 2025.
[17] Caffrey (n 10).
[18] Khorram (n 16).
[19] Centers for Medicare & Medicaid Services, 'Theranos Enforcement Letter' (12 April 2016), www.wsj.com/public/resources/documents/cms20160412.pdf accessed: 26 April 2025
[20] US Securities and Exchange Commission, 'Theranos, CEO Holmes, and Former President Balwani Charged With Massive Fraud' (2018) https://www.sec.gov/newsroom/press-releases/2018-41 accessed 26 April 2025.
[21] United States Department of Justice, 'U.S. v. Elizabeth Holmes, et al.' (2022) https://www.justice.gov/usao-ndca/us-v-elizabeth-holmes-et-al accessed 26 April 2025.
[22] Sara Ashley O'Brien, 'The rise and fall of Theranos: A timeline' *CNN* (7 July 2022) https://edition.cnn.com/2022/07/07/tech/theranos-rise-and-fall/index.html accessed 26 April 2025.

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prison.[23] Balwani's trial followed in 2022, resulting in his conviction on 12 counts of fraud and conspiracy, and a sentence of nearly 13 years.[24]

*2.3 Root Causes of Theranos' Misconduct*

Theranos' failure is a striking example of where a negative constellation of regulatory loopholes, certain personal characteristics, and a business opportunity can lead. In addition to the evident legal loopholes, it is worthwhile exploring and analysing the individual factors that influenced Elisabeth Holmes' (un)ethical decision-making and the gaps in Theranos' corporate governance structure to gain a deeper understanding of the case.

2.3.1 Individual Factors That Influenced Elisabeth Holmes' Decision-Making and Her Cognitive Biases

Several academic publications explore how to measure moral character and individual moral capacity.[25] This section describes Elisabeth Holmes' character and compares these observations with key findings from a well-known empirical study on narcissistic leadership.[26]

The traits presented are drawn from investigative journalism and other academic studies, and their purpose is to highlight how the excessive presence of certain traits and cognitive biases can reduce moral sensitivity.

Academic studies and investigative journalism described Elisabeth Holmes as follows:

Holmes exhibited traits characterised by grandiosity, a need for admiration, and a lack of empathy. She cultivated a charismatic persona, leveraging her vision of revolutionising healthcare to inspire loyalty and silence dissent .[27] She framed Theranos as a 'religion,' demanding absolute devotion from employees and dismissing critics as non-believers ).[28] She styled herself as a Steve Jobs-like visionary, adopting his signature

[23] United States Department of Justice, 'Theranos Founder Elizabeth Holmes Found Guilty Of Investor Fraud' (2022) https://www.justice.gov/usao-ndca/pr/theranos-founder-elizabeth-holmes-found-guilty-investor-fraud accessed 26 April 2025.

[24] United States Department of Justice, 'Theranos President Sentenced To More Than 12 Years For Fraud That Jeopardized Patient Health And Bilked Investors Of Millions' (2022) https://www.justice.gov/usao-ndca/pr/theranos-president-sentenced-more-12-years-fraud-jeopardized-patient-health-and-bilked accessed 26 April 2025.

[25] Lawrence Kohlberg and Anne Colby about CMD, see Georg Lind, 'Measuring Moral Judgment: A Review of "The Measurement of Moral Judgment" by Anne Colby and Lawrence Kohlberg' (1989) 32 *Human Development* 388 https://doi.org/10.1159/000276491 accessed 26 April 2025; Robert Hogan about moral conduct and moral character, see Robert Hogan, 'Moral conduct and moral character: A psychological perspective' (1973) 79(4) *Psychological Bulletin* 217 https://doi.org/10.1037/h0033956 accessed 26 April 2025.

[26] The article 'Leader Narcissism and Outcomes in Organizations: A Review at Multiple Levels of Analysis and Implications for Future Research' by Susanne Braun is a systematic literature review that explores the positive and negative impacts of leader narcissism. The review categorised findings from 45 research articles into three levels of analysis: dyadic (leader-follower relationships), team, and organisational. See Susanne Braun, 'Leader narcissism and outcomes in organizations: A review at multiple levels of analysis and implications for future research' (2017) 8(773) *Frontiers in Psychology* https://doi.org/10.3389/fpsyg.2017.00773 accessed 26 April 2025.

[27] Dennis Tourish, 'The Leadership of Elizabeth Holmes: Lessons From the Dark Side of Silicon Valley' (2023) *International Leadership Association* https://ilaglobalnetwork.org/the-leadership-of-elizabeth-holmes-lessons-from-the-dark-side-of-silicon-valley/ accessed 26 April 2025.

[28] Carreyrou (n 15) 183.

black turtleneck and trousers,[29] and subsequently changed her voice inflexion and the depth of her voice.[30] She concealed technological flaws and retaliated against whistleblowers, prioritising her image over patient safety.[31]

She used abstract, aspirational language (e.g., 'democratising healthcare') to obscure the lack of scientific validation.[32]

In the centre of Theranos's downfall was confirmation bias, the tendency to seek, interpret, and remember information that confirms one's pre-existing beliefs while ignoring contradictory evidence. Elizabeth Holmes and her leadership team were so invested in the vision of revolutionary blood testing that they systematically dismissed or rationalised the shreds of evidence of failure. Despite repeated warnings from scientists and engineers, Holmes and her inner circle focused only on data that supported their narrative, downplaying or concealing negative test results and technical flaws.[33]

Holmes demonstrated extreme overconfidence in her technology and ethical judgment, despite mounting evidence of its failures. This bias resulted in her dismissing internal warnings and external scrutiny, believing she could overcome technical limitations through sheer will. She continued to market the Edison device as revolutionary, even after employees documented its inaccuracies.[34] Investors and partners were misled by claims of profitability and capabilities that Theranos could not deliver.[35] Holmes rationalised her actions through a mission-driven mindset, arguing that the ends (revolutionising healthcare) justified deceptive means.[36]

Holmes' conduct displays traits commonly associated with a narcissistic personality, although this observation does not constitute a formal clinical diagnosis. Drawing on Braun's framework, narcissism may be understood as marked by grandiosity and self-affirmation combined with interpersonal disregard, producing a paradoxical reliance on external approval that incentivises power-seeking, influence strategies, and risk-taking or creative initiatives. In leadership contexts, these dynamics can yield organisational benefits—such as visionary direction and innovation—while also giving rise to substantial legal and governance risks, including ethical breaches, deficient oversight, and harms to stakeholder interests.[37]

The excessive presence of the behavioural patterns listed above may have contributed to Elizabeth Holmes's decline in moral sensitivity.

The other actors or stakeholders in the Theranos case have their own cognitive biases, such as authority bias, availability bias, and avoidance of inconsistency bias. The analysis of their biases is beyond the scope of this paper.

[29] Carreyrou (n 15) 218.
[30] The Guardian News, 'How Elizabeth Holmes' rhetoric changed over time' (YouTube, 4 January 2022) https://www.youtube.com/watch?v=uLwtxDxWxUM accessed 26 April 2025.
[31] Integrity Line (n 11).
[32] Inês Martins and others, 'A Review on Elizabeth Holmes and her Sinking Ship's Backstory' (2024) 19(1) *European Conference on Innovation and Entrepreneurship* 469, 473 https://doi.org/10.34190/ecie.19.1.2661
[33] Carrie Cabral, 'Theranos Investors: How Bias Led to Fraud' (*Shortform,* 5 March 2021) https://www.shortform.com/blog/theranos-investors/ accessed 26 April 2025.
[34] Integrity Line (n 11).
[35] Daniel Thomas, 'Theranos founder Elizabeth Holmes "lied and cheated", trial hears' *BBC News* (8 September 2021) https://www.bbc.com/news/business-58494912 accessed 26 April 2025.
[36] Caterina Bulgarella, 'Mirage or Vision? Four Blind Spots at the Core of Theranos' Failure' (*Ethical Systems*, 3 May 2019*)* https://www.ethicalsystems.org/mirage-or-vision-four-blind-spots-at-the-core-of-theranos-failure/ accessed 26 April 2025.
[37] Braun (n 26) 773.

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2.3.2 Situational Factors – Regulatory Loopholes

The main critical legal dimension of the Theranos case was its exploitation of a regulatory loophole. Theranos leveraged to circumvent standard FDA review processes for LDT (laboratory-developed tests). Theranos brought its testing panel to market without the pre-market review or peer-reviewed scientific validation typically required for diagnostic technologies.[38]

Theranos has used the UTSA[39] as a 'shield' to withhold technological information from the authorities and the public. When the Centers for Medicare & Medicaid Services (CMS) inspected the Theranos lab in 2015, the company prevented inspectors from entering the 'Edison' lab. They claimed that the Edison machines were proprietary trade secrets and that allowing an inspection of the device's internal mechanics would compromise their intellectual property.[40]

Theranos secretly ran most of its tests on modified Siemens machines instead of its own technology. They classified these modifications as 'trade secrets' to justify why business partners (like Walgreens) and regulators were not allowed to see the laboratory floor or the testing process.[41]

Legal loopholes or regulatory arbitrage and forum shopping are those situations that can be addressed with strong moral character and/or clear soft-law regulations.

2.3.3 Situational Factors – Gaps in Theranos' Governance Structure and Company Culture

There are at least three major areas where existing gaps in the system created opportunities for ongoing and permanent misconduct.

The composition of the board was highly homogeneous and notably deficient in medical expertise. The board was composed predominantly of political, military, and financial figures—former politicians, senior military officers, and business executives—resulting in a governance body largely lacking professional medical-device, scientific, or healthcare-sector expertise. There were 14 members, including former influential politicians (Henry Kissinger – Former U.S. Secretary of State; William Perry – Former U.S. Secretary of Defense; George Shultz – Former U.S. Secretary of State; Sam Nunn – Former U.S. Senator; Bill Frist – Former U.S. Senator and heart-transplant surgeon; Gary Roughead – Retired U.S. Navy Admiral; James Mattis – Retired U.S. Marine Corps General (later U.S. Secretary of Defense)) and former wealthy business people (Richard Kovacevich – Former CEO and Chairman of Wells Fargo; Riley Bechtel – Former CEO of Bechtel Group; William Foege – Former Director of the Centers for Disease Control and Prevention (CDC); David Boies – Founder and Chairman of Boies Schiller Flexner (joined later); Fabrizio Bonanni – Former Executive Vice President of Amgen (joined later)). The composition of the board of directors should have been a warning sign to investors since

[38] Mario Plebani, 'Evaluating and using innovative technologies: a lesson from Theranos?' (2015) 53(7) *Clinical Chemistry and Laboratory Medicine* 961, 962 https://doi.org/10.1515/cclm-2015-0411 accessed 26 April 2025.

[39] Uniform Trade Secrets Act (with 1985 amendments) https://www.uniformlaws.org/committees/community-home/librarydocuments accessed 21 January 2026.

[40] Carreyrou (n 15) 199.

[41] Andrea Park, 'Elizabeth Holmes admits to OK'ing shady practices at Theranos' (*Fierce Biotech*, 24 November 2021) https://www.fiercebiotech.com/medtech/theranos-trial-elizabeth-holmes-admits-to-using-altered-siemens-analyzers-for-blood-tests accessed 21 January 2026.

they were former politicians and military leaders without professional experience in the medical device sector. Leadership also lacked scientific expertise.[42]

The organisation lacked an effective whistleblowing mechanism, leaving concerns about product performance and governance channels largely unreported and unaddressed. Neither Erika Cheung's nor Tyler Shultz's concerns were taken seriously by the company. Their concerns were not only ignored, but they were threatened with legal consequences.[43] Employees were faced with surveillance, legal threats, and non-disclosure agreements if they raised concerns.[44]

Theranos's toxic culture, characterised by secrecy and retaliation against whistleblowers, created an environment in which cognitive biases could flourish unchecked. The employees faced intense pressure to conform, and moral disengagement allowed leaders to rationalise unethical behaviour as necessary for a greater good.[45] Theranos' culture was marked by paranoia, surveillance, and suppression of information. Holmes and CEO Sunny Balwani enforced strict secrecy. Employees were prohibited from discussing work between teams.[46] Security cameras monitored staff, and dissenters faced termination or legal threats.[47]

## 3. THE PURDUE CASE

The Purdue Pharma case constitutes one of the most significant legal and public health crises in contemporary United States history, illuminating profound and systemic shortcomings in pharmaceutical regulation, corporate governance, and bankruptcy jurisprudence. This analysis critically evaluates Purdue Pharma's leadership and governance system, which played an instrumental role in precipitating and exacerbating the opioid epidemic.

### *3.1 Company History*

Purdue Pharma was founded in 1892 in New York City by medical doctors John Purdue Gray and George Frederick Bingham as the Purdue Frederick Company. The company underwent a significant transformation in 1952 when it was purchased by the three Sackler brothers – Arthur, Mortimer, and Raymond.[48] All three brothers had medical backgrounds, having worked together at the Creedmoor Psychiatric Center in Queens, where they were recognised as pioneers in medication techniques that offered alternatives to controversial procedures like lobotomies.[49] At that time, it was a modest company.[50] At that time, the company began establishing its presence in the pharmaceutical industry. Raymond and Mortimer directly managed Purdue's operations, while Arthur, the eldest brother, developed the marketing approach that would later define the company's business strategy. He applied a new sales approach focusing on directly

[42] Integrity Line (n 11).
[43] Chrenóczy-Nagy and Bujtár (n 14) 112.
[44] Integrity Line (n 11).
[45] Bulgarella (n 36).
[46] Tourish (n 27).
[47] Martins and others (n 32).
[48] Colin White, *The Rise of OxyContin: How Purdue Pharma and the Sackler Family is Responsible For the Epidemic Behind the Pandemic* (Senior Thesis, Dominican University 2022) 8–12 https://doi.org/10.33015/dominican.edu/2022.HIST.ST.04 accessed 26 April 2025.
[49] Patrick Radden Keefe, *Empire of Pain: The Secret History of the Sackler Dynasty* (Doubleday 2021) 48.
[50] Tyler Biscontini, 'Purdue Pharma' (2024) *EBSCO Research Starters* https://www.ebsco.com/research-starters/history/purdue-pharma accessed 26 April 2025.

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contacting doctors, winning over prominent, leading physicians, and changing society's attitudes to medicines by reinforcing the credibility of the medical literature.[51] In 1991, the company was officially renamed Purdue Pharma, with Raymond serving as president until 1999, when his son Richard Sackler took over the position. Purdue Pharma manufactured various pain medications, including hydromorphone, fentanyl, codeine, and hydrocodone. Several of these drugs were sold under the names OxyContin, Ryzolt, and MS Contin.[52] The aim was to ensure that the drug would allow patients to receive treatment in their own homes or a hospice facility, without having to resort to sterile, alienated hospital care in the final stages of their lives. The solution was a 12-hour absorption morphine capsule. As this drug was still only intended for terminally ill patients, the issue of addiction was not raised.[53] The company noted that pain was one of the most significant negative parts of the human experience and it had decades of practice in manufacturing pain-relieving medications. Its breakthrough drug, OxyContin, was marketed as a reliable treatment for chronic pain. The drug releases oxycodone gradually over twelve hours. Introduced to the market in the 1990s, OxyContin has become the company's most profitable product and the centre of its controversies.[54]

Purdue marketed the drug to doctors and claimed that this would reduce the possibility of users abusing the drug. Later, it was revealed that this claim was false and Purdue Pharma was aware that many users were abusing the medication.[55]

### *3.2 The Opioid Crisis*

When MS Contin's patent expired, the goal was to create a product that would be far more profitable than this drug, to surpass MS Contin, which had sales of $400 million in its peak year. This goal could only be achieved by launching a drug that would reach a much larger market, not only for terminally ill patients.[56] OxyContin was produced in capsule form to ensure 12 hours of absorption. However, if someone chewed it or dissolved it in water, a significant amount of the morphine-containing drug was immediately absorbed. Thus, the capsule format has greatly increased the risk of misuse of the drug. [57]

The opioid crisis had three waves in the US. Purdue triggered an opioid crisis in 1995 by engaging in a highly aggressive and profitable marketing of OxyContin with FDA approval. The first wave of the crisis began in the 1990s with the sale of OxyContin as a prescription drug. As a result, the heroin market started to grow in the second wave due to the emergence of already addicted patients. The third wave culminated in the use of illicit synthetic opioids. It led to a 60-fold increase in the death rate in this drug use segment by the early 2000s. By 2022, this crisis threatened the lives of 1.2 million people, costing them their lives through opioid overdose.[58] The analysis focuses on the first wave, mainly the role of Purdue and its leadership in the crisis. It explores what the main psychological traits, cognitive biases, and corporate governance gaps contributed to the opioid crisis.

[51] Zsolt Bujtár and Judit Chrenóczy-Nagy, 'The opioid crisis, or the rise and fall of Purdue Pharma' (Crisis, economy, technology and law, Pécs, 17 November 2023) 66.
[52] Biscontini (n 50).
[53] Bujtár and Chrenóczy-Nagy (n 51) 67.
[54] Bujtár and Chrenóczy-Nagy (n 51) 67.
[55] United States v The Purdue Frederick Company, Inc No 1:07-cr-00029 (WD Va 2007).
[56] White (n 48) 11.
[57] Bujtár and Chrenóczy-Nagy (n 51) 68.
[58] Bujtár and Chrenóczy-Nagy (n 51) 65.

*3.3 Root Causes of the Purdue Opioid Crisis*

The opioid crisis precipitated by Purdue Pharma represents a multifaceted synthesis of corporate malfeasance, aggressive marketing strategies, and institutional regulatory capture. This phenomenon was further exacerbated by specific legislative lacunae that allowed a catastrophic misalignment between corporate profit motives and public health outcomes. Beyond these structural failures, however, the crisis was profoundly shaped by the distinctive personal traits of the Sackler dynasty.

This section provides a critical analysis of these interlocking factors, illustrating how the convergence of negative personality traits and systemic failure established the structural conditions for one of the most significant public health crises in the history of the United States.

3.3.1 Individual Factors That Influenced the Sackler Brothers' Decision-Making and Their Cognitive Biases

Character traits of Sackler brothers can be drawn on the basis of their actions and behaviours.

Arthur Sackler, the family patriarch, pioneered aggressive pharmaceutical marketing tactics, including direct-to-physician promotion and paid advocacy networks. He combined medical expertise with a 'profit-first' ethos, viewing physicians as tools to 'always keep on closing' sales. The families strictly controlled the company's sales performance. They demanded quarterly sales growth.[59]

Richard Sackler (Raymond's son) demonstrated a lack of empathy in his actions. He dismissed early warnings about risks of OxyContin and considered them PR challenges. In internal emails, he framed addiction as a problem of 'criminals' rather than systemic corporate misconduct. He dismissed 59 OxyContin-linked deaths as 'not too bad'.[60]

Richard Sackler displayed delusions of medical altruism, claiming that OxyContin 'mobilised' patients in pain, despite evidence of widespread addiction. This self-aggrandising belief in their own benevolence, despite mounting evidence to the contrary, is a classic sign of poor moral character. The blind commitment to their vision allowed them to justify any means. This falls into the personality trait called Dark-Triad (Narcissism, Machiavellianism, and Psychopathy).[61]

The Sackler's cultivated a public image as philanthropists while concealing their role in the opioid crisis. Their donations to museums, universities, and medical institutions served as reputational shields.[62] It created a perception of benevolence that obscured their role in the epidemic. This indicates that the family consciously built on the

[59] *Harrington, United States Trustee, Region 2 v Purdue Pharma LP and others* (US Supreme Court, 27 June 2024) https://www.supremecourt.gov/opinions/23pdf/23-124_8nk0.pdf accessed 26 April 2025.
[60] State of Minnesota v Purdue Pharma LP (First Amended Complaint), Hennepin County District Court, 5 August 2019. https://www.thomsonreuters.com/en-us/posts/investigation-fraud-and-risk/sackler-family-opioid-crisis/ accessed 26 April 2025.
[61] Delroy L Paulhus and Kevin M Williams, 'The dark triad of personality: Narcissism, Machiavellianism, and psychopathy' (2002) 36 *Journal of Research in Personality* 556, 559.
[62] Bujtár and Chrenóczy-Nagy (n 51) 66.

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moral 'halo effect'.[63] The family's public image as philanthropists served as a 'reputational shield' while actively concealing their role in the opioid crisis.

The Sacklers leveraged insider connections at the FDA—specifically through Dr. Curtis Wright—to assist in drafting the medical review for OxyContin's approval.[64] Simultaneously, internal correspondence revealed a strategy to stigmatise victims by attributing addiction to 'abusive personalities' and criminal intent rather than the potency of the drug.[65] Most controversially, internal documents from 'Project Tango' indicate that the family sought to vertically integrate their business model by secretly planning to profit from the burgeoning addiction treatment market.[66]

The Sackler family created a closed group and all their decisions were hidden from the employees. Their company culture can be described as a culture of fear dominated by aggressive sales targets and a demanding style.[67]

Moral detachment is the leading motive of the case. The Sacklers reframed addiction as a moral failure of 'abusers' rather than a systemic issue. Richard Sackler described users as 'reckless criminals' and 'culprits,' deflecting accountability from Purdue's deceptive practices.[68]

The Sacklers' overconfidence acted as a catalyst for a profound moral myopia,[69] systematically narrowing their field of ethical vision. This cognitive distortion functioned as an intellectual firewall, allowing the owners to interpret escalating clinical warnings not as evidence of product risk, but as external 'noise' or interference. Consequently, their unwavering belief in their own clinical and commercial infallibility facilitated a psychological decoupling from the bioethical consequences of their distribution strategies.

### 3.3.2 Regulatory Loopholes

Purdue Pharma leveraged the FDA's permissive labelling standards, revolving-door relationships, and lack of post-marketing oversight to perpetuate deceptive marketing of OxyContin.[70] The FDA's failure to detect risks stemmed from regulatory capture, inadequate evidence requirements, and reliance on industry-controlled data.

[63] 'The halo effect refers to the tendency of overall evaluations of a person/object to influence evaluations of the specific properties of that person/object in a way that is consistent with the overall evaluation (Asch 1946; Nisbett and Wilson 1977; Thorndike 1920; Wells 1907) …the halo effect stemming from the moral undertone of the company's socially responsible activities can influence not only the overall company image but also the perceived performance of company products, such that the products made by companies engaged in prosocial activities are perceived to have superior performance.' See Alexander Chernev and Sean Blair, 'Doing Well by Doing Good: The Benevolent Halo of Corporate Social Responsibility' (2015) 41(6) *Journal of Consumer Research* 1412, 1413 https://doi.org/10.1086/680089 accessed 26 April 2025.

[64] Keefe (n 49) 255.

[65] Harvard T.H. Chan School of Public Health, 'What led to the opioid crisis—and how to fix it' (9 February 2022) https://hsph.harvard.edu/news/what-led-to-the-opioid-crisis-and-how-to-fix-it/ accessed 26 April 2025.

[66] *New York v Purdue Pharma LP* (Amended Complaint) [2019] NY Misc (Index No 451749/2017) paras 540–545.

[67] Hearing before the Committee on Oversight and Reform House of Representatives, 116th Cong, 2nd Sess (17 December 2020) 1.

[68] *Commonwealth of Massachusetts v Purdue Pharma LP and others* (Mass Super Ct, 1884CV01808) 59.

[69] Moral myopia is a cognitive distortion whereby ethical issues are obscured to the point of being invisible to the decision-maker. See Minette E Drumwright and Patrick E Murphy, 'How Advertising Practitioners View Ethics: Moral Muteness, Moral Myopia, and Moral Imagination' (2004) 33(2) *Journal of Advertising* 7, 11.

[70] Andrew Kolodny, 'How FDA failures contributed to the opioid crisis' AMA *Journal of Ethics* (2020) 22(8) E743 https://journalofethics.ama-assn.org/article/how-fda-failures-contributed-opioid-crisis/2020-08 accessed 26 April 2025

These systemic flaws enabled a public health catastrophe, underscoring the need for reforms such as stricter conflict-of-interest rules, mandatory long-term safety trials, and independent post-market surveillance.[71]

Purdue Pharma exploited weaknesses in FDA regulations to aggressively market OxyContin. The FDA approved OxyContin in 1995 with a label stating its delayed-release mechanism 'is believed to reduce the abuse liability' of oxycodone, despite no long-term studies or evidence supporting this claim. The company framed the FDA's tentative wording as definitive proof of safety, directly contributing to overprescribing.[72]

The FDA approved OxyContin after a single 2-week clinical trial in osteoarthritis patients, ignoring historical evidence of opioid risks. No studies evaluated long-term use or addiction potential, violating standard efficacy requirements.[73]

Dr. Curtis Wright IV, the FDA medical officer who approved OxyContin, later joined Purdue Pharma as a consultant. Internal documents reveal that Wright allowed Purdue to draft key sections of the drug's FDA review, creating a conflict of interest.[74]

Purdue Pharma argued that internal documents, including Sackler's testimony and marketing strategies, contained 'proprietary trade secrets' and 'confidential business information.'[75]

Purdue designated its 'Targeting' lists (spreadsheets of doctors who were high-volume prescribers) and its 'Turbocharging' marketing plans (developed with McKinsey & Co.) as highly confidential trade secrets. This prevented state health authorities from seeing that Purdue was specifically targeting doctors in 'pill mill'[76] regions.[77]

Moreover, the FDA failed to correct misleading claims or restrict OxyContin's broad indication for moderate-to-severe pain, despite mounting evidence of abuse.[78]

The FDA relied on Purdue's self-reported data rather than independent studies to monitor OxyContin's safety. Purdue withheld reports of early abuse (noted as early as 1997) and manipulated educational programmes to downplay risks.[79] There were several examples of ignoring and managing conflict-of-interest situations. In 2002, when the FDA convened a panel to reconsider OxyContin's broad label, eight of the 10 panellists had financial ties to opioid manufacturers, including Purdue, leading to a decision against

[71] Harvard T.H. Chan School of Public Health (n 65).
[72] Harvard T.H. Chan School of Public Health (n 65).
[73] Jessie Pappin, Itai Bavli and Matthew Herder 'On what basis did Health Canada approve OxyContin in 1996? A retrospective analysis of regulatory data' (2022) 19(5) *Clinical Trials* 584, 587. https://doi.org/10.1177/17407745221108436 accessed 26 April 2025.
[74] Bujtár and Chrenóczy-Nagy (n 51) 68.
[75] *Purdue Pharma LP v Boston Globe Life Sciences Media (STAT)* (Kentucky Court of Appeals, 2018) https://law.justia.com/cases/kentucky/court-of-appeals/2018/2016-ca-000710-mr.html accessed 26 April 2025.
[76] A ‚pill mill' is a healthcare provider or facility that operates as a front for the illegal distribution of controlled substances. These establishments typically prioritise profit over patient care, characterised by high-volume prescribing of high-dose opioids, 'cash-only' payment models, and minimal medical documentation. In the context of the Purdue case, 'pill mill regions' refers to geographic areas (such as parts of Appalachia) where a disproportionately high number of these clinics operated, leading to extreme rates of addiction and overdose. See Yuichi Mizushima and others, 'Regulating quasi-legal markets: Evidence from pain management clinic laws' (2025) 252 *Journal of Public Economics* 105515 https://doi.org/10.1016/j.jpubeco.2025.105515 accessed 26 April 2025.
[77] *Purdue Pharma* (Mass Super Ct, 16 September 2019, No 1884-cv-01808 (BLS2)).
[78] Kolodny (n 70) 744.
[79] New York State Attorney General, Summons and Complaint, The People of the State of New York v Purdue Pharma L.P. et al, Supreme Court, Suffolk County, Index No 400016/2018 (2019) https://ag.ny.gov/sites/default/files/court-filings/oag_opioid_lawsuit.pdf accessed 26 April 2025.

narrowing the indication.[80] The FDA did not enforce cooling-off periods for staff transitioning to industry roles.

### 3.3.3 Gaps in Purdue's Governance Structure and Company Culture

The following gaps can be identified in Purdue's internal governance structure.

The governance structure of Purdue's board, which was predominantly composed of the members of the Sackler family, exhibited a systemic misalignment between fiduciary duties and bioethical obligations. This insular composition created a confirmation bias within the firm's leadership; despite the presence of external directors, the board effectively functioned as a mechanism to validate executive strategy rather than providing independent oversight. Consequently, the board repeatedly endorsed compliance reports that contradicted burgeoning internal data regarding the widespread misuse of OxyContin.[81] The board failed to audit Purdue's fraudulent marketing tactics, such as paying doctors to promote OxyContin and manipulating electronic health records (EHRs) to encourage opioid prescriptions.[82] The company had a weak compliance programme. They did not control, supervise, or screen the hiring process. They hired ex-government officials, and by allowing a revolving-door dynamic, they have compromised regulatory integrity.

The company culture was competitive, aggressive, and sales-focused. Sales teams were rewarded for maximising OxyContin prescriptions, with quotas tied to high-dose sales despite known addiction risks. This aggressive sales focus depresses the moral sensitivity of employees. Purdue's sales teams aggressively marketed opioids to high-prescribing doctors, nurse practitioners, and rural communities, ignoring red flags about overprescribing.[83] Corporate culture encouraged and normalised aggressive, non-emphatic language. Executives like Richard Sackler dismissed addiction as a moral failure.[84]

The company has used unethical tools to manipulate public opinion. Purdue hired PR firms like Dezenhall Resources to discredit critics, funded biased research, and settled lawsuits with nondisclosure agreements to conceal evidence.[85]

Purdue Pharma's governance gaps, strong family control, and legal loopholes enabled a corporate culture of deception and profit maximisation at the expense of public health. The authoritarian leadership and moral disengagement of the Sacklers normalised unethical practices, perpetuating the opioid crisis.

## 4. THE COMMONALITIES AND RED FLAGS IN THESE CASES

The article analysed the systemic parallels between the Theranos and Purdue Pharma scandals, focusing on the individual factors such as certain character traits and

[80] Kolodny (n 70) 744.
[81] United States Government Publishing Office, *The Role of Purdue Pharma and the Sackler Family in the Opioid Epidemic*(Hearing before the United States House of Representatives, 116th Congress, 2020) https://www.govinfo.gov/content/pkg/CHRG-116hhrg43010/html/CHRG-116hhrg43010.htm accessed 26 April 2025.
[82] Jonathan H Marks, 'Lessons from Corporate Influence in the Opioid Epidemic: Toward a Norm of Separation' (2020) 17(2) *Journal of Bioethical Inquiry* 173, 175. https://doi.org/10.1007/s11673-020-09982-x accessed 26 April 2025.
[83] Washington State Office of the Attorney General, 'Ferguson: New details unsealed in lawsuit against one of the nation's largest opioid manufacturers' (5 January 2018) https://www.atg.wa.gov/news/news-releases/ferguson-new-details-unsealed-lawsuit-against-one-nation-s-largest-opioid accessed 26 April 2025.
[84] *Commonwealth of Massachusetts v Purdue Pharma LP and others* (Mass Super Ct, 1884CV01808) 59.
[85] Keefe (n 49).

cognitive biases and the situational factors such as governance failures, and legal loopholes.

The intersection of idiosyncratic leadership traits and cognitive biases within the management of Theranos and Purdue Pharma created a psychological environment that facilitated systemic ethical erosion. When coupled with structural vulnerabilities in corporate oversight, these factors converged to undermine regulatory safeguards, ultimately resulting in significant public health consequences and corporate malfeasance.

The behavioural pattern and leadership styles of Elizabeth Holmes and the Sackler family, when viewed through the lens of cognitive bias, appear to have functioned as catalysts for systemic ethical erosion. When these individual traits intersected with structural vulnerabilities in corporate oversight, they created a permissive environment that compromised regulatory efficacy and facilitated the progression of corporate malfeasance. Elizabeth Holmes cultivated a charismatic, messianic persona that could attract investors. Her leadership style relied on secrecy, intimidation, and a delusional belief in her mission to 'revolutionise healthcare'.[86] Her internal moral judgement was suppressed. Holmes scapegoated employees for Theranos' failures, and whistleblowers were threatened with legal action.

The Sacklers, particularly Richard Sackler, framed OxyContin as a medical breakthrough while dismissing addiction risks as moral failures of 'reckless criminals'. Their philanthropic donations to museums and universities served as reputational shields by building on the 'halo effect', obscuring their role in the opioid crisis.

Both intensively donated to universities and cultural institutions to burnish reputations while concealing misconduct. Both leadership groups exhibited victim-blaming, profit-driven aggression, and philanthropic whitewashing, reflecting a transactional view of ethics, prioritising ambition over accountability. Both have hidden behind the mask of altruism. Holmes claimed to revolutionise healthcare; the Sacklers positioned themselves as pain-management pioneers.

Both leaders prioritised growth over safety. Theranos faked demonstrations for investors and Purdue incentivised sales representatives to target high-prescribing clinicians.

Confirmation bias can be detected in both cases. Holmes ignored engineers' warnings about faulty technology, while the Sacklers dismissed internal reports of OxyContin misuse.

They both built on authority bias. Theranos leveraged endorsements from Henry Kissinger and George Shultz; Purdue paid 3,000+ doctors to promote OxyContin as safe.

Both companies overstated the benefits of their products. Theranos positioned their device as 'revolutionary' in blood testing, and Sacklers positioned OxyContin as a 'low risk of addiction' medicine and downplayed its harms.

Both Theranos and Purdue Pharma demonstrate how cognitive biases are not just individual failings but can become systemic, especially when reinforced by organisational culture, financial incentives, and social dynamics.

Cognitive biases thus contributed to the normalisation of unethical behaviour and the suppression of dissent, resulting in massive harm to patients, investors, and public trust.

There were structural and systematic problems with the composition of the Board and the whistleblowing system in both cases. These systems existed only in

[86] Carreyrou (n 15) 496.

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principle and did not operate in practice. The main reasons for this were the threatening, aggressive language in the company, and the poor company culture.

In the case of Theranos, the Silicon Valley's 'fake it till you make it' ethos normalised unethical behaviour.

Ethical blindness, the failure to recognise the moral implications of decisions, played a central role in the Theranos and Purdue Pharma scandals. Both cases reveal systemic patterns of ignoring red flags, suppressing dissent, and prioritising organisational goals over ethical accountability. The detectable signs of ethical blindness were suppression of dissent, exploitation of regulatory gaps, moral rationalisation, data manipulation, creating the illusion of legitimacy while concealing risks by manipulating data, and misrepresenting studies.

## 5. SUGGESTED ACTIONS FOR SOFT LAW AND CORPORATE GOVERNANCE REFORM IN THE HEALTHCARE SECTOR

In the wake of the Purdue Pharma and Theranos scandals, several legal and regulatory 'enhancements' were enacted or proposed to prevent the misuse of trade secrets as a shield against public safety oversight. These reforms focus on three pillars: whistleblower immunity, regulatory closure of loopholes, and transparency in litigation.

The Defend Trade Secrets Act (DTSA) of 2016 introduced a federal 'Whistleblower Immunity' provision (18 U.S.C. § 1833(b)). It provides immunity from civil or criminal liability for disclosing a trade secret '*in confidence to a Federal, State, or local government official… solely for the purpose of reporting or investigating a suspected violation of law.*'[87]

The VALID Act (Verifying Accurate Leading-edge IVCT Development Act) was introduced to create a new category of 'in vitro clinical tests' (IVCTs), specifically requiring FDA oversight for all tests, regardless of where they are developed to mitigate classification loophole that has been exploited by Theranos. The VALID Act has faced legislative delays (reintroduced in 2023 and 2025), and finally FDA issued a Final Rule in 2024 to phase out its 'enforcement discretion' over LDTs.[88]

Several states have recepted the Sunshine in Litigation Acts (e.g., New York Senate Bill S3837, 2025). These laws prohibit court orders or settlement agreements that have the effect of concealing 'public hazards' or information vital to public safety.

The legal system has shifted towards mandatory, permanent public archives for documents once claimed as 'proprietary.' The Opioid Industry Documents Archive (OIDA) was established as part of global settlements. It houses over 30 million pages of internal records from Purdue and other manufacturers.[89]

These scandals highlight the question of whether soft law can mitigate the risks of unethical business decisions arising from certain human characteristics or behaviours. Probably not. The original role of soft law and corporate governance is to create a framework for more transparent and structured corporate operations.

However, soft law guidelines can be extended to areas that involve a deeper understanding of human behaviour and decision-making. Increased awareness

[87] *Defend Trade Secrets Act of 2016*, Pub. L. No. 114-153.

[88] United States Food and Drug Administration, 'Medical Devices; Laboratory Developed Tests; Implementation' (19 September 2025) https://www.federalregister.gov/documents/2025/09/19/2025-18239/regulation-identification-number-0910-aj05-medical-devices-laboratory-developed-tests-implementation accessed 21 January 2026.

[89] UCSF–Johns Hopkins University Opioid Industry Documents Archive https://www.industrydocuments.ucsf.edu/opioids/ accessed 21 January 2026.

sensitises the decision-makers' environment to recognise warning signs earlier. Soft law regulation can also support the development of reporting channels through which these perceptions can be escalated, thereby preventing greater damage originating from unethical business conduct.

The Theranos and Purdue Pharma scandals illustrate the urgent need for comprehensive reforms, including stricter conflict-of-interest rules, independent board oversight, and robust post-market surveillance to ensure ethical leadership and safeguard public welfare in healthcare and beyond. The Purdue case demonstrates how profit-driven practices, abetted by regulatory inertia, can have devastating consequences for public health. These dynamics underscore the need for enhanced oversight and legislative reform to close loopholes in drug approval and mitigate conflicts of interest between regulators and industry actors.

A robust soft law framework is essential to promote transparency, accountability, and ethical conduct in healthcare. Scholars and global institutions such as the UN Global Compact, WHO and OECD have developed some recommendations to improve soft law regulations and corporate governance models to mitigate the recurrence risk of such cases. These recommendations include elements in the following paragraphs.

Setting an independent board protocol as an internal process that requires that the majority of board members be truly independent existentially and professionally from the owners (especially if they are members of the same family) can increase more independent governance oversight. This protocol would mandate that these independent directors have a direct say in key ethical and public health decisions.[90]

An industry-specific best practice guideline for corporate board composition could recommend that boards of directors for companies in highly technical or regulated fields like medical devices include a certain percentage of members with relevant scientific, medical, or technical expertise. Such a guideline, while not legally binding, would create a professional standard.[91] Investors and the public could use this publicly available standard to assess the credibility and risk of a company's leadership. It would signal the lack of credibility, potentially deterring major investments.

A Code of Ethics document could establish a clear, voluntary policy against hiring former government regulators with direct oversight of the company's industry for a defined period. This would be a self-imposed measure to avoid conflicts of interest and the appearance of compromising regulatory integrity.[92]

Enhance the current conflict of interest disclosures to require comprehensive and public disclosures of financial and professional ties among corporate boards, regulators, and industry stakeholders to reduce the risk of regulatory capture.[93]

Establish independent, confidential whistleblowing channels for employees to report concerns without fear of reprisal. Mandating a clear, public commitment from corporate leadership to protect whistleblowers and seriously investigate their claims.[94] Furthermore, the efficacy of soft law frameworks in the healthcare sector is significantly bolstered by existing statutory protections designed to dismantle cultures of enforced silence. A critical mechanism to enhance transparency is the whistleblower immunity

[90] OECD, *G20/OECD Principles of Corporate Governance 2023*(OECD Publishing 2023) 39 https://doi.org/10.1787/ed750b30-en accessed 21 January 2026.
[91] OECD (n 90) 42.
[92] Transparency International, *Regulating the Revolving Door* (Working Paper No 06/2010, 2010).
[93] United Nations Conference on Trade and Development, *Guidance on Good Practices in Corporate Governance Disclosure* (2006) 22 https://unctad.org/system/files/official-document/iteteb20063_en.pdf accessed 26 April 2025.
[94] United Nations Conference on Trade and Development (n 93) 17.

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provision established under 18 U.S.C. § 1833(b), introduced by the Defend Trade Secrets Act (DTSA) of 2016.[95] This federal statute provides a 'safe harbour' for individuals who disclose trade secrets to government officials or attorneys solely for the purpose of reporting or investigating a suspected violation of the law. By integrating this 'hard law' immunity into corporate ethical charters, healthcare organisations can effectively neutralise the 'trade secret' defence—a tactic notably exploited in the Theranos case—thereby empowering internal stakeholders to act as ethical guardians without fear of retaliatory litigation.

A Transparency Framework document could encourage companies to adopt and publicly commit to principles of ethical behaviour and open communication. It could recommend practices such as open-door policies and regular, transparent communication between leadership and all levels of employees; introduction of an anonymous feedback system that is reviewed and acted upon by a designated ethics officer or committee; or providing training on cognitive biases and how to foster moral courage to speak up against wrongdoing.[96]

Company's governance model can encourage voluntary certification schemes in ethics that signal adherence to best practices in data integrity and patient safety, like the World Health Organisation's soft law approaches.[97]

The limitations of Friedman's shareholder theory should be critically assessed in contexts where public health is at stake. Extend 'net harm' liability to consultants and secondary actors that facilitate corporate misconduct.[98]

Independent, mandatory peer review processes could be implemented for medical technologies and pharmaceutical products to ensure claims are substantiated by objective evidence rather than corporate interests.[99]

The company would be required to commit to release all its clinical trial data and research findings that would conceal evidence of public health risks. This measure would make it difficult for the company to manipulate public opinion and would hold them accountable to scientific integrity.[100]

Pharmaceutical and medical companies can develop frameworks that incorporate perspectives from clinicians, patients, and ethicists.[101] They could mandate transparent audits of AI and machine learning technologies to assess bias, accuracy, and clinical validity, drawing on evolving FDA guidance as a model.[102]

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[95] 18 USC § 1833(b) (Immunity from Liability for Confidential Disclosure of a Trade Secret to the Government or in a Court Filing).

[96] Paul Lindhout and Genserik Reniers, 'The "Transparency for Safety" Triangle: Developing a Smart Transparency Framework to Achieve a Safety Learning Community' (2022) 19(19) *International Journal of Environmental Research and Public Health* 12037 https://doi.org/10.3390/ijerph191912037 accessed 26 April 2025.

[97] WHO, *Technical Report Series No 1033* (2021) 142 https://www.who.int/publications/m/item/annex-4-trs-1033 accessed 26 April 2025

[98] Lynn Stout, *The Shareholder Value Myth: How Putting Shareholders First Harms Investors, Corporations, and the Public* (Berrett-Koehler 2012).

[99] European Medicines Agency, 'How EMA evaluates medicines for human use https://www.ema.europa.eu/en/about-us/what-we-do/authorisation-medicines/how-ema-evaluates-medicines-human-use accessed 26 April 2025.

[100] World Health Organization, *Ethics and Governance of Artificial Intelligence for Health: Guidance on Large Multi-Modal Models* (25 March 2025) 47 https://www.who.int/publications/i/item/9789240084759 accessed 26 April 2025.

[101] World Health Organization (n 100) 40.

[102] United States Food and Drug Administration, *Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan* (January 2021)
7 https://www.fda.gov/media/145022/download?attachment accessed 26 April 2025.

The current hard law and soft law regulations should be continuously improved to address the ethical complexities of contemporary healthcare. A hybrid governance model is warranted, integrating enforceable regulatory mandates, such as clinical trial transparency and robust whistleblower protections, with the flexibility of soft law, including industry-developed standards for emerging technologies.[103] This approach should be complemented by ethical leadership training designed to mitigate cognitive biases such as overconfidence and profit-driven reasoning.

Lessons of Theranos and Purdue Pharma emphasise the importance of transparency mechanisms, including independent audits, third-party validations, and open-data policies to counteract confirmation bias. Legal and cultural reforms should encourage internal reporting and protect whistleblowers, fostering an environment where ethical concerns can be raised without fear of retaliation.

In conclusion, as healthcare innovation accelerates, the sector must prioritise preventive ethics and shared accountability. Soft law provides a viable pathway to align technological ambition with moral responsibility and ensures that patient welfare remains central to medical progress. But only when integrated with enforceable regulations and grounded in continuous stakeholder dialogue.

## 6. CONCLUSIONS

The Theranos and Purdue Pharma cases provide compelling evidence of how narcissistic leadership, cognitive biases, and governance failures can converge to produce systemic harm within the healthcare sector. Both cases underscore the dangers inherent in prioritising the illusion of innovation and profit over transparency and accountability. The scandals caused significant devastation and served as stark warnings: unchecked corporate power, especially with pathological leadership, seriously threatens public trust and health.

A critical examination of these cases reveals vulnerabilities in hard and soft laws and ethical norms. Gaps in binding and non-binding standards and the failure to institutionalise ethical imperatives enabled systemic harm, even in the presence of formal legal frameworks. These were not isolated incidents of individual wrongdoing or technical oversight; rather, they were the culmination of excessive success orientation accompanied by deeply rooted cognitive biases that distorted decision-making across all organisational levels, from corporate leadership to investors, medical professionals, and regulators.

Cognitive biases, such as overconfidence in unproven technologies at Theranos and confirmation bias in Purdue's selective use of data, were powerful and often invisible drivers of unethical business decisions. Addressing these biases requires more robust checks and balances, transparent communication, and a culture that values dissent and evidence over charisma and authority. Only by confronting these psychological pitfalls can organisations hope to prevent the recurrence of such damaging crises.

Central to the downfalls of Theranos and Purdue Pharma was the phenomenon of ethical blindness, where leaders and employees rationalised deceit as a necessary means to achieve transformative objectives. Whistleblowers who raised concerns encountered intimidation and legal threats, fostering an environment where dissent was suppressed and unethical practices became normalised. Similarly, Purdue Pharma

[103] Joy Furnival, Kleran Walshe and Ruth Boaden, 'Emerging hybridity: comparing UK healthcare regulatory arrangements' (2017) 31(4) *Journal of Health Organization and Management* 517 https://doi.org/10.1108/JHOM-06-2016-0109 accessed 26 April 2025.

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minimised the addictive risks of OxyContin by cherry-picking research, obscuring adverse data, and aggressively marketing the drug to vulnerable populations. Executives justified these actions through a distorted narrative of serving patient needs, even as overdose deaths surged.

The consequences of these ethical lapses extended beyond financial losses. Theranos's inaccurate blood tests led to patient misdiagnoses and delayed treatments, undermining trust in medical innovation. Purdue's manipulation of opioid research contributed to a national epidemic, resulting in more than 500,000 deaths from overdose in the United States and disproportionately harming vulnerable populations.

Both cases also highlight the inadequacy of relying solely on individual moral courage to counteract institutional corruption. Whistleblowers played pivotal roles in exposing these scandals, yet their efforts were often met with retaliation, further illustrating the need for systemic reforms.

Existing regulatory frameworks failed to prevent these crises. Theranos exploited loopholes in FDA oversight, while Purdue leveraged flawed regulatory approvals to legitimise deceptive marketing. These failures reveal how binding regulations and hard law often lag behind technological and corporate innovation, allowing companies to exploit ethical grey zones.

Soft law presents a dynamic alternative to rigid regulatory frameworks by emphasising collaboration, transparency, and adaptive governance. Earlier adoption of industry standards for third-party validation and conflict-of-interest disclosures could have mitigated the risks posed by both companies.