BPP Business School

Coursework Cover Sheet

Please use this document as the cover sheet of for the 1st page of your assessment.

Please complete the table below – the grey columns

Module Name	Executive Leadership and Governance.
Programme Name	
Student Reference Number (SRN)	
Assessment Title	An Analysis of Pfizer Inc.'s Executive Leadership and Governance

Declaration of Original Work:

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The word count, excluding contents table, bibliography and appendices, is 4908 words.

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Task 1 – Leadership and Management

Leadership is the ability of an individual to influence, motivate and enable others to contribute to the success of an organisation (Moon, 2021). On the other hand, management is responsible for controlling an organisation group to achieve specific objectives. According to the Goleman leadership style there are mainly six leadership styles. As per this model, leadership style is in which decision-making is shared among team members (Fitra *et al.* 2024). In this report, the leadership and management style of Pfizer Inc. is discussed.

Leadership Style of Pfizer Inc.

The leaders of Pfizer mainly follow a ***transformational leadership style***. The transformational leadership style inspires employees to strive beyond required expectations to work towards a shared vision (Zeineddine *et al.,* 2023). This leader drove cultural changes and ensured cross-divisional collaboration. These elements were significant in the turnaround of the company under the guidance of the CEO. He prioritised trust within the Executive Leadership Team (ELT) through clear expectations. An initial offsite focused on team norms and feedback encouraged transparency and commitment (Ian, 2024). For example, after the FDA refused to review a drug application, the CEO used the incident as a learning opportunity. It highlights accountability and clear ownership across functions. The leadership of Pfizer recognised that cultural transformation was essential to organisational success (Salazar-Rebaza *et al.* 2022). The CEO emphasised creating an "Own-It Culture" that encouraged faster decision-making and stronger ownership (Ian, 2024). In this case, engagement surveys painted a clear picture of organisational alignment and their results were translated into actionable plans. The engagement surveys painted a clear picture of organisational alignment, and their results were translated into actionable plans (Antonopoulou *et al*. 2021). The main focus of leadership on emotional intelligence further strengthened teamwork. It prioritised it over technical competence when necessary.

The CEO restructured ELT meetings, differentiating between tactical weekly discussions and strategic monthly sessions. This ensured focus on enterprise-level decisions. For example, a collaboration between Pfizer and BioNTech leaders was marked by a strategic partnership to develop mRNA-based influenza vaccines (Biotech, 2018). This multi-year agreement supports the expertise of BioNTech in mRNA technology and clinical development and commercialisation of Pfizer. BioNTech received $120 million in upfront and near-term payments with potential milestones of $305 million and tiered royalties on global sales (Biotech, 2018). Moreover, this leadership style led to tangible successes, including the delivery of Pfizer of the COVID-19 vaccines in record time, a 60% stock price increase and enhanced shareholder returns Biotech, 2018). The ELT significantly improved engagement scores across multiple categories, with strategic alignment improving by 27.1% from 2012 to 2018 (Ian, 2024).

However, the Chantix lawsuits highlight a significant scandal faced by Pfizer, which is mainly associated with an ***autocratic leadership style***. Chantix is a smoking cessation drug approved in over 100 countries and prescribed to 9 million US patients who faced allegations of causing severe mental and physical injuries, such as suicidal thoughts and anxiety (Kirkendall Dwyer LLP, 2022). In 2012, Pfizer had negotiated settlements for approximately 80 of the 2,700 lawsuits, incurring $273 million in costs with an additional $15 million set aside for remaining claims (Kirkendall Dwyer LLP, 2022). In this case, the approval of the leaders involved quick settlement and significant financial allocation to manage legal risks. It reflects a focus on unilateral decision-making rather than collaborative processes with stakeholders. This style can also influence earlier actions like pushing into widespread use without adequately addressing the risks (Kirkendall Dwyer LLP, 2022). This fallout of the case understood the limitations of autocratic leadership in crisis management, where a more inclusive approach could have addressed safety issues proactively and mitigated reputational damage.

***Management Style of* Pfizer Inc.**

The management style refers to the specific approach that managers use to achieve their goals. According to Mintzberg's Managerial Roles, there are mainly three management roles such as interpersonal, informational, and decisional roles (Bilić *et al.* 2023). In this case, the management style of Pfizer Pfizer maintains a ***monitoring role*** within the informational area that is focused on gathering, evaluating and analysing key information to guide decision-making.

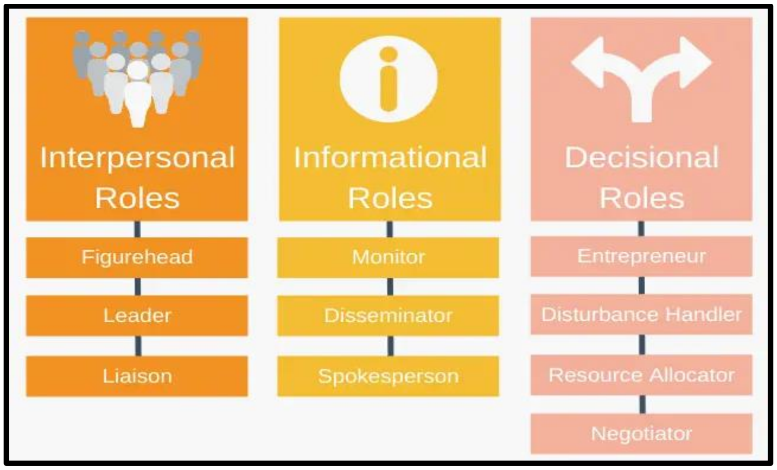

Figure 1: Mintzberg's Managerial Roles

(Source: Kirisci-Sarikaya *et al.* 2023)

Pfizer's Environment, Health & Safety (EHS) Management Systems (EHSMS) are central to the monitoring role of management. The EHS framework of the company is designed around risk-based management, which requires constant surveillance of environmental and health risks across its global operations (Pfizer, 2024a). The EHS program of Pfizer is structured similarly to ISO 14001 (Pfizer, 2024a). It mainly allows for ongoing monitoring and auditing of operations at all sites. This risk-based approach ensures that managers continuously gather and evaluate data on potential hazards, assess risks, and determine necessary controls to mitigate harm. The internal EHS audit program of Pfizer plays a significant role in this monitoring process (Bilić *et al.* 2023). It ensures that the company maintains high health, safety, and environmental protection standards.

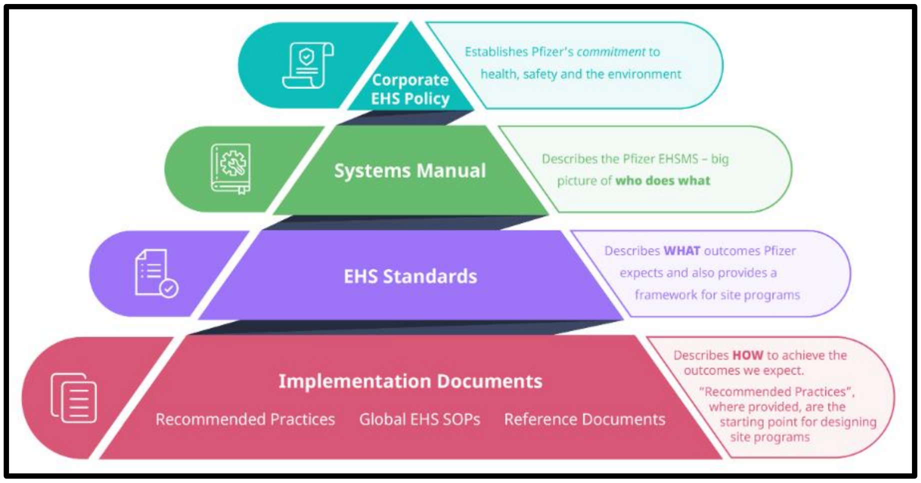

Figure 2: EHS Management Systems

(Source: Pfizer, 2024a)

Moreover, the management style of Pfizer places a strong emphasis on assessing and prioritising risks, setting goals to address the highest risks and adjusting processes as needed. This is in line with the monitor role of the theory as it requires constant evaluation of operational performance and the effectiveness of implementation strategies (Fitra *et al.* 2024). In this case, the Management Systems Standards (Series 100) follow the Plan-Do-Check-Act model, which includes steps for regular monitoring of progress, reassessing goals, and implementing necessary adjustments based on real-time feedback (Pfizer, 2024a). The leaders of the company monitor internal data related to safety incidents, environmental impacts and employee health. It ensures that the operations are continuously aligned with the EHS objectives of the company. The company also monitors external information related to regulatory changes and emerging industry trends (Moon, 2021). For example, the company monitors external standards such as ISO 14001 and ISO 45001 that evaluate their relevance and effectiveness in relation to the operations of Pfizer (Pfizer, 2024a). The company relies on its internal communication networks to share critical information about operational risks, performance, and regulations with EHS standards. The use of Global EHS SOPs helps management disseminate vital information across the organisation, ensuring that all teams are aligned and able to act on real-time data (Pfizer, 2024a).

However, the compensation of CEO Albert Bourla, near about 300 times the median employee pay, highlights a significant inequity that raises questions regarding the management's ability of management to monitor and respond to internal morale and employee engagement challenges. Inspite of the 35% reduction in pay, the disparity remains striking, especially the median employee pay of Pfizers is among the lowest in the biopharma sector (Manalac, 2024).

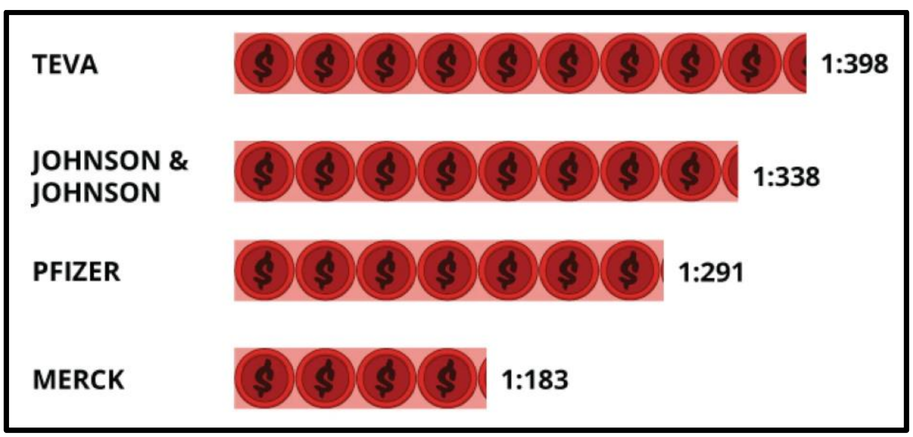

Figure 3: Pay gap of Pfizer

(Source: Manalac, 2024)

Apart from that, the monitoring of management in market trends appears insufficient, as evidenced by the company's reliance on COVID-19-related revenues and its failure to anticipate the post-pandemic decline. Pfizer reported a sharp 42% revenue drop from 2022 to 2023 and its first quarterly loss since 2019 (Manalac, 2024). These outcomes suggest that leadership did not adequately monitor and prepare for market shifts, which left the company vulnerable when demand for COVID-19 vaccines. The cost-cutting initiative launched in 2023 to save $3.5 billion through 2024 appears reactive rather than proactive (Manalac, 2024). This understood the inadequacy of real-time monitoring and care.

Task 2 - Corporate Governance and Regulation

Corporate Governance Structure

As specified by Kyere and Ausloos (2021), the corporate governance structure of a company is a set of rules as well as procedures that define how a company is run and controlled. This includes the distribution of rights as well as responsibilities of the stakeholders of the company such as employees, managers, shareholders and others. This governance structure established the decision-making process for the company which ensures that the environment of the company is more suitable and accountable for the workforce.

Internal Governance of Pfizer Inc.

Pfizer Inc.'s corporate governance structure and good governance are fundamental for the pharmaceutical business of the company. A cornerstone of governance at Pfizer is the shareholders, investors and the burgeoning issues that make the business policies and guidelines of the company (Pfizer CG, 2024). The board of directors is the ultimate decision-making body at Pfizer, as it is elected by shareholders to oversee the performance of the company and its strategic decisions. The board consists of independent directors, which enhances its ability to monitor senior management in an effective way (Pfizer CG, 2024).

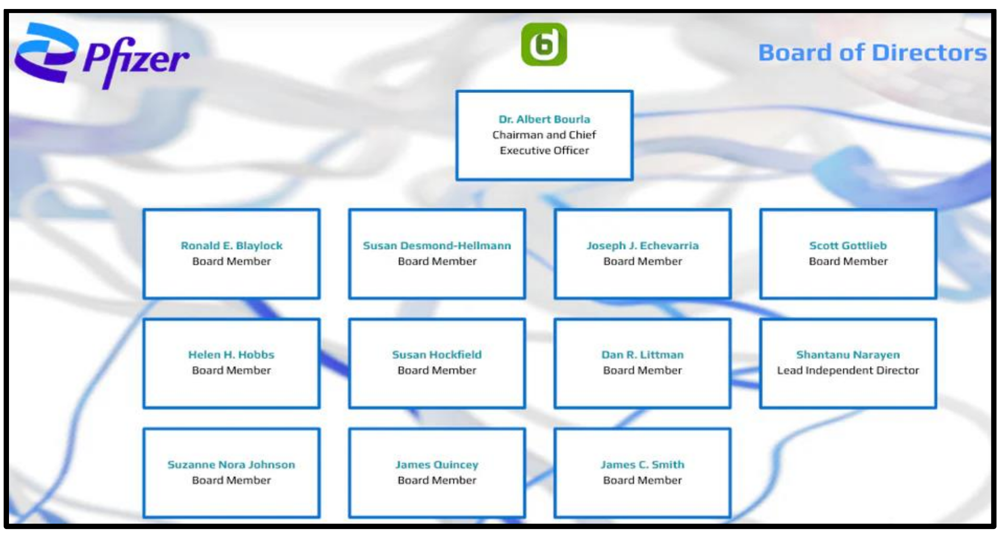

Figure 4: Executive Leadership Team of Pfizer Inc.

(Source: Databahn, 2024)

The board of Pfizer Inc. primarily consists of independent directors, which enhances its ability to monitor the aspect of management in an effective fashion. Here, the key responsibilities include section and evaluation of the management to ensure leadership guidance to meet the interests of the shareholders (Pfizer CGP, 2024). The CEO of Pfizer, Albert Bourla, is elected by the board of directors and where he takes on decisions to meet the interests of the shareholders. Albert Bourla and the head of vaccine research of the company, Kathrin Jansen, took in Artificial Intelligence, built and tested the vaccine for COVID-19, with a 95% efficacy (Reader, 2021). This is how the company met the interests of the shareholders by providing the vaccines in the market at the right time. This was done by the company by undertaking millions of data points regarding the vaccine in the study that Pfizer Inc. did with 44 thousand people (Reader, 2021). The company also created extra dose vials of the solutions to meet the expectations of the stakeholders to gain an advantageous market position.

One of the criticisms that Albert Bourla faced was the problem related to the underperformance of the values of the stocks under his leadership (Sonnenfeld and Tian, 2024). Other than that, Alber Bourla also faced allegations of overpaying several major acquisitions, where he squandered tens of billions of COVID-19 windfalls of the company (Sonnenfeld and Tian, 2024). These criticisms are linked with the internal governance of the company, as they highlight potential issues in the decision-making system of the company, oversight by the board and strategic direction of the company under Bourla's leadership. This suggests that the company needs better governance practices to ensure that the executive decisions align with the interests of the shareholders.

Strategies to meet the interests of the shareholders of Pfizer Inc.

External Governance of Pfizer Inc.

Pfizer Inc., a global pharmaceutical leader, operates in complex regulatory environments across different countries, which makes it governed by different laws and regulations (Grimm *et al.* 2023). However, like many multinational corporations, Pfizer Inc. has also faced different challenges in terms of adhering to these rules, which have raised ethical and legal concerns. This section provides a critical analysis of cases followed by examples of compliance to meet the shareholder interests of the company.

Violation of the 'Foreign Corrupt Practices Act 1977 (FCPA)'

In 2012, Pfizer Inc. was fined $60 million by the US Department of Justice as well as the SEC for the violation of FCPA (Liu, 2020). Pfizer Inc. has subsidiaries in 8 countries, including Russia, China, and Italy, as they were found to bribe foreign officials to boost drug sales as well as secure regulatory approvals (Liu, 2020). ***'The Foreign Corrupt Practices Act of 1977, as amended, 15 U.S.C. §§ 78dd-1, et seq. ("FCPA")'*** was enacted for the purpose of making payments to foreign government officials for obtaining and retaining business unlawful (Warczak Jr, 2021). Pfizer Inc. violated this act through bribery, which highlighted this incident as the company's failure to adhere to this rule. This incident highlights the lack of robust internal controls of the company as well as corporate governance mechanisms to monitor and prevent unethical practices in its global operations. This violation also damaged the confidence of the shareholders because of the reputational harm as well as financial penalties.

Violation of 'Federal Food, Drug, Cosmetic Act (FDCA)'

In 2020, Pfizer Inc., along with some other pharmaceutical companies, faced a case related to testosterone litigation that happened back in 2015 (Llamas and Miller, 2024). The depo-testosterone plaintiffs accused Pfizer Inc. of "disease mongering" as they showed the less negative side of the drugs and exaggerated the benefits (Llamas and Miller, 2024). The company negated the side effects of the drug, including serious health issues, heart attack, pushing the size of the heart larger and others. 'The ***Federal Food, Drug, and Cosmetic Act (FDCA)***' is a set of laws that gives the US Food and Drug Administration (FDA) to oversee the safety of food, medical devices and cosmetics, and it requires that food additives demonstrate no harm or side-effects (Lam and Patel, 2022). This lawsuit suggested that Pfizer Inc. did not sufficiently disclose the potential risks, which could be interpreted as a violation of FDCA requirements.

In 2013, Pfizer Inc. paid over $273 million, where it settled more than 2000 lawsuits as it surrounded the alleged links of Chantix as the drug led the users into having self-harming thoughts (Becker, 2024). The drug called Chantix propagated the users into having homicidal thoughts, which is related to suicide attempts as well as other psychiatric discrepancies (Becker, 2024). Because of this drug, a man named Timothy John died of suicide soon after he began to take the Chantix medication (McMillen, 2017). In this case, Pfizer Inc. also violated ***FDCA*** as it mandates drug labelling to provide accurate risks that are associated with the medication process.

Adherence to SEC and 'The Sarbanes Oxley Act of 2002'

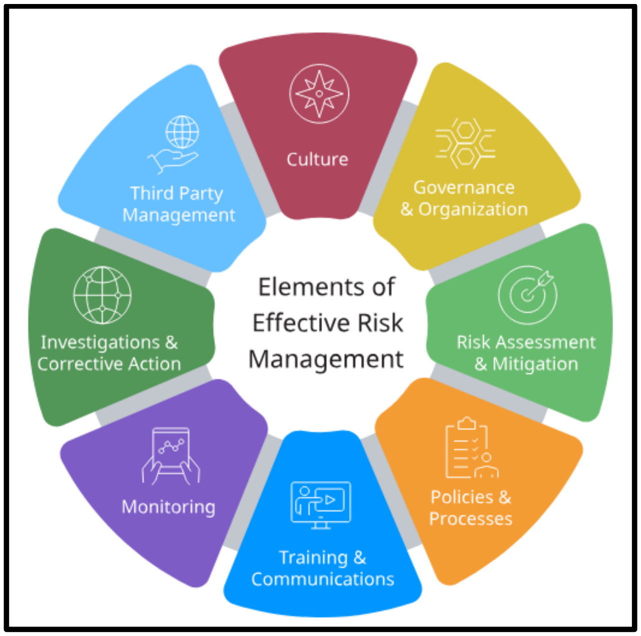

Figure 5: Pfizer Inc. Ethics and Compliance

(Source: Pfizer Ethics & Compliance, 2024)

Pfizer Inc. follows a Code of Conduct, the Blue Book, that is structured around the values of the company, which defines the company culture of courage, excellency, equity and joy (Pfizer Ethics & Compliance, 2024). The blue book of the company describes the guide to operate under ethical decisions to achieve the aims and goals of the company (Pfizer Ethics & Compliance, 2024). The company has a continuous monitoring system for compliance across all the global markets, which is strengthened by its auditing system. Pfizer has a standard operating quality control process across diverse markets that is designed to ensure product quality and its effectiveness and compliance (Pfizer Ethics & Compliance, 2024). The company also strengthened its internal auditing procedures coupled with financial controls to ensure accurate reporting and fraud prevention. The annual report of the company included a detailed disclosure of financial performance and governance practices as mandated by the SEC. As per Gorshunov *et al.* (2020), '***The Sarbanes-Oxley Act of 2002 (SOX)***' is a federal law that aims to provide investors by making corporate disclosures more reliable and accurate. The financial performance of the company is reflected in the annual reports of the company under the delegation of the SOX Act to rebuild the confidence of the investors.

Adherence to 'The General Data Protection Regulation (GDPR)' Compliance in Europe

Pfizer Inc. adheres to the GDPR regulations to ensure the prospect of data protection and transparency in its European operations. During COVID-19, Pfizer Inc. collaborated with the European regulators to make sure that the trials complied with the data protection laws and ethical guidelines. Because of this, Pfizer Inc. provided access to de-identified patient-level data to the regulators for the response of scientifically valid research proposals (Pfizer DAR, 2024). The company also considered the requests to access the clinical data from qualified researchers through their Vivli platform. This shows that Pfizer Inc. demonstrated adherence to GDPR laws in Europe.

Task 3 – Risk Management

Analyse three significant risks that the company faces and recommend appropriate responses to each of these risks.

Risk heat map

A risk heat map is a tool that is mainly used for visualising data that assists organisations in identifying and prioritising the risks that present the most significant threats (Lemmens *et al.* 2022). By using the risk heat map, three risks were identified that were faced by the organisations.

Risk ID	Risk Category	Description	Likelihood	Impact	Risk Level	Strategies
R1	Risk of regulatory delays and approval inconsistency	The company will face risks and challenges regarding scaling up vaccine production in Africa due to inconsistent regulatory standards and longer approval time (Jerving, 2021). Regulatory bodies in Africa often have inconsistent inspection histories and approval processes that are slower compared to regions such as the US, as outlined by Patrick van der Loo (Jerving, 2021). It will delay the dispersal of locally produced vaccines and impact the efficiency of manufacturing operations. It will create obstacles in Pfizer's ability to meet vaccine demand in low and middle income countries (Jerving, 2021). This can create higher operational costs and reduced market access.	Medium	High	High	The management should strengthen the partnership with regulatory bodies in Africa. They should implement training sessions for local compliance and allocate resources for expediting approvals.

R2	Risk of revenue decline and market volatility	The company will face the risk of inconsistent revenue growth and heightened markert volatility. The sales of the company peaked at $100.3 billion in 2022 due to high demand for COVID-19 products, driven to $58.5 billion in 2023, which shows a 42% decline in sales (Forbes, 2024). It will enhance high competition if the company fails to sustain growth through its initiatives, like expanding to achieve the projected $70 billion revenue by 2026 (Forbes, 2024). It will lose the confidence of investors and its ability to stabilise its stock value.	Low	Medium	High	The management should implement a diversified product portfolio. They should improve cost efficiency by implementing different cost-reduction programs.
R3	Risk of excessive pipeline dependency on research and development	Pfizer will face the risk of over-reliance on its R&D pipeline to offset upcoming patent expiration. Most of the drugs, such as Eliquis (2026), Prevnar 13 (2026), and Ibrance (2027), are nearing the end of exclusivity, which threatens significant revenue losses (Dilantha, 2024). While promising candidates like Elranatamab and Giroctocogene fitelparvovec show potential, the high uncertainty of clinical trial success supports risks. Despite of $43 billion acquisition of Seagen and strong cash reserves of $12 billion, failure to achieve FDA delays in the commercialisation of pipeline drugs will enhance financial pressure (Dilantha, 2024).	Medium	High	High	The company should accelerate drug development timelines. They should acquire complementary biotech firms and support AI in R&D to improve trial success rates.

Table 1: Risk Heat Map

(Source: Author)

R1: Risk of Regulatory Delays and Approval Inconsistency

Pfizer will face significant risk in scaling vaccine production in Africa due to inconsistent regulatory standards and prolonged approval timelines. African regulatory bodies often lack harmonised inspection histories and processes, creating bottlenecks that delay local vaccine production and distribution (Avila *et al.* 2023). This impacts of ability to meet vaccine demands in low-efficiency and middle-income countries. It increased operational costs and reduced market access (Prahalad *et al.* 2020). Addressing this risk requires strategic partnerships with African regulators, training for local compliance, and resource allocation for expedited approvals to ensure timely vaccine delivery and manufacturing efficiency.

R2: Risk of Revenue Decline and Market Volatility

Pfizer's revenue decline, exacerbated by falling COVID-19 product demand, mainly highlights a risk of inconsistent growth and market volatility. Revenues dropped dramatically from $100.3 billion in 2022 to $58.5 billion in 2023, a 42% decline (Forbes, 2024). Failure to sustain growth through strategic initiatives, such as achieving projected $70 billion revenues by 2026, could erode investor confidence and destabilize stock value (Forbes, 2024). Pfizer should diversify its product portfolio to mitigate this challenge. It mainly focused on non-COVID-related products and enhanced cost efficiency through programs and cost reduction plans to sustain competitiveness and stabilise revenue streams.

R3: Risk of Excessive Pipeline Dependency on Research and Development

With key patents for drugs such as Eliquis, Prevnar 13, and Ibrance expiring soon, Pfizer faces over-reliance on its R&D pipeline to compensate for potential revenue losses (Dilantha, 2024). Candidates like Elranatamab and Giroctocogene fitelparvovec face uncertainty due to lengthy FDA approvals and trial risks despite the $43 billion Seagen acquisition and $12 billion in cash reserves (Dilantha, 2024). In this case, Pfizer can accelerate development timelines, acquire complementary biotech firms, and support AI to enhance clinical trial success rates and pipeline efficiency to mitigate the risk.

Three horizon model

The three-horizon model helps organisations develop strategies by balancing immediate performance needs with long-term growth opportunities across three distinct phases (Su *et al.* 2023).

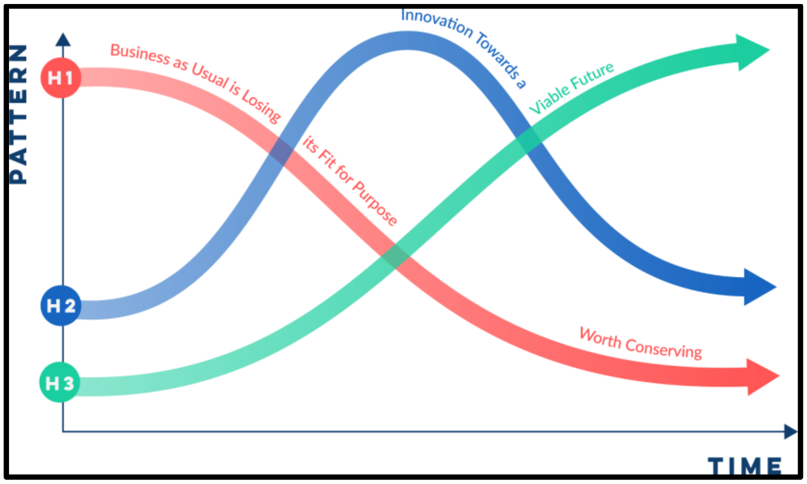

Figure 6: Three Horizon Model

(Source: Su *et al.* 2023)

According to the horizon model, the first horizon emphasises the risk of revenue decline and market volatility (Di *et al.* 2022). The immediate challenge of Pfizer is mitigating revenue decline due to reduced COVID-19 product sales and heightened market competition. The company can stabilise its revenue, which is projected to reach $70 billion by 2026, to address market volatility and investor confidence (Forbes, 2024). In this case, strategies like diversifying its product portfolio and implementing cost-reduction programs align with Horizon 1, focusing on sustaining existing operations and market stability.

In this case, the second horizon focuses on traditional growth and scaling opportunities. The efforts of Pfizer to expand vaccine production in Africa face obstacles with inconsistent regulatory frameworks and prolonged approval timelines (Aksenov *et al.* 2024). These issues delay local vaccine dispersal and impact operational efficiency.

Moreover, Horizon 3 prioritises future innovation and breakthroughs. The reliance of the company on R&D for pipeline success understood long-term risks (Shim *et al.* 2021). It was promising candidates like, Elranatamab and gene therapies represent opportunities for future growth. It focused on securing long-term innovation and sustainability.

Recommendations of appropriate responses to each of these risks

The 4T process is a risk management approach that mainly focuses on assessing risks and also determining appropriate control actions based on their potential impact (Palmer et al. 2024). This 4T process helps to mitigate the risks that are faced by the company.

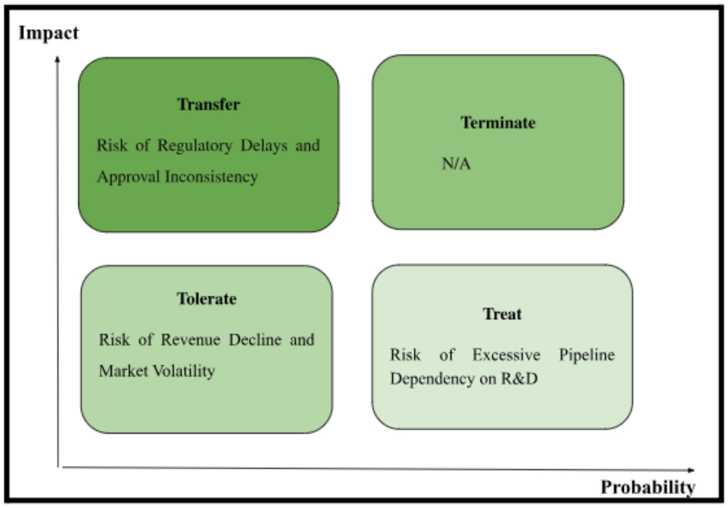

Figure 7: 4T Process

(Source: Author)

Transfer

Pfizer should transfer the risk by forming a strategic partnership with local regulatory authorities and third-party organisations in Africa (Avila *et al.* 2023). The company will collaborate with NGOs, health agencies, and local governments to help navigate regulatory complexities and expedite approvals of vaccines (Akhil *et al.* 2021). The company can mitigate delays and reduce operational costs by transferring operational responsibilities like inspections to trusted local partners.

Tolerate

The company should tolerate this risk in the short term while implementing strategies to stabilise revenue. The company should focus on maintaining investor confidence by improving transparency through proper communication with different stakeholders of the company (Prahalad *et al.* 2020). Apart from that, the company should diversify the product portfolio and also launch cost-reduction initiatives like the ***EffiCore Strategy*** that will reduce the long-term effects of volatility.

Treat

Pfizer should treat this risk by accelerating drug development timelines using advanced technologies such as data analytics and AI. This approach will help to mitigate dependency on a few drugs nearing patent expiry (Avila *et al.* 2023). The company should collaborate with other technical colleges, such as ***Imperial College and King's College,*** to hire technologically skilled employees in the R&D department (Akhil *et al.* 2021). The management should provide a diversified and innovative pipeline that will reduce financial pressures and support future growth.

Roles of Board Members

Board Member	Role	Risk Management Responsibilities to mitigate risks
Dr. Albert Bourla	Chairman and Chief Executive Officer	He can oversee overall corporate strategy, including risk management frameworks. He can ensure alignment of risk mitigation efforts with corporate goals, focusing on financial stability, regulatory challenges
Sally Susman	Chief Corporate Affairs Officer	She can lead communication and external relations. Manages risks related to public perception, regulatory challenges, and market volatility through strategic communication and stakeholder engagement.
Payal Sahni Becher	Chief People Experience Officer	She can manage risks related to talent retention and organisational culture, ensuring effective adaptation to external changes
Aamir Malik	Chief U.S. Commercial Officer, Executive Vice President	Focuses on commercial risks in the U.S. market, ensuring sustained revenue through market expansion while mitigating competition and market volatility.
Lidia Fonseca	Chief Digital and Technology Officer, Executive Vice President	Manages technological and data risks, ensuring the digital infrastructure of Pfizer supports efficient R&D and production processes, especially in the face of global regulatory variations.

Table 2: Responsibilities of Board Members

(Source: Pfizer, 2024b)

Task 4 – Ethical Leadership

Ethical Business Challenge

Pfizer has faced significant ethical challenges in relation to its involvement in testosterone replacement therapy (TRT) drugs, particularly in the context of lawsuits concerning its products like Depo-Testosterone (Llams, 2024). The company, along with other manufacturers, has been accused of marketing testosterone products for off-label uses, such as treating age-related fatigue and sexual dysfunction, despite the U.S. The Food and Drug Administration (FDA) only approved these drugs for hypogonadism (Llams, 2024). This practice raised ethical concerns regarding the potential risks of administering testosterone to healthy men, as these treatments were associated with different side effects, including heart attacks, strokes, and blood clots.

Pfizer and its counterparts were also criticised for failing to adequately warn patients about the dangers of these drugs, leaving men unaware of the cardiovascular risks associated with their use (Aksenov *et al.* 2022). The widespread promotion of testosterone for off-label uses further exacerbated these issues as it contributed to over-prescribing and unnecessary health risks (Llams, 2024). The lawsuits highlighted how pharmaceutical companies, in pursuit of profits, can prioritise marketing and sales over patient safety, an ethical issue that understood the necessity for transparency, accountability, and adherence to medical guidelines to protect consumer health (Llams, 2024). This ethical dilemma reflects the tension between corporate interests and public health responsibility in an organisation.

Impact on company and stakeholders

The main stakeholders of the company are mainly***. Patients, investors, regulatory bodies, NGOs, the public and advocacy groups***.

Therefore, the ethical challenges faced create a significant implication for its stakeholders. Firstly, patients are directly impacted by the failure to warn about potential health risks like heart attacks, strokes, and blood clots (Pfizer, 2015). This compromises patient safety and trust, which are core to the relationship between pharmaceutical companies and their consumers (Llams, 2024). Secondly, investors face reputational and financial risks due to the lawsuits and the potential long-term costs associated with legal settlements (Pfizer, 2015). The damage to the public image of Pfizer could affect investor confidence, stock prices, and profitability.

Regulatory bodies may impose stricter guidelines and penalties, further hindering the ability of Pfizer to market and distribute its products. The company's failure to adhere to FDA-approved uses for TRT creates regulatory risks and scrutiny from government agencies (Akhil *et al.*, 2021). NGOs and multilateral organisations which Pfizer collaborates with, can face challenges when working with the company on global health initiatives. Their partnerships may be questioned if the ethical practices of Pfizer are called into doubt, potentially obstacles to future collaborations (Pfizer, 2015). Finally, the public and advocacy groups could view actions of Pfizer as unethical, sparking demands for greater transparency, accountability, and stricter adherence to medical standards. In this case, the concerns about prioritising profits over patient safety could damage the company's reputation and erode trust in its commitment to public health (Llams, 2024). This scrutiny can lead to heightened regulatory information and an increased focus on ethical marketing practices (Akhil *et al.*, 2021). Advocacy groups could increase their calls for corporate responsibility, pressuring Pfizer to adopt more patient-centric strategies. These challenges could understand public confidence in and t in the broader pharmaceutical industry, affecting its credibility and societal impact.

Ethical leadership recommendations on how the company can address and manage this ethical challenge

Triple Bottom Line Theory

The triple bottom line theory is an accounting framework that measures the sustainability of the organisation (Shim *et al*. 2021).

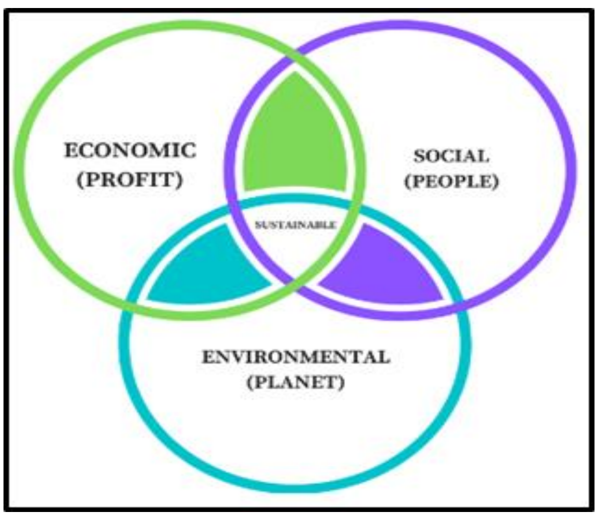

Figure 8: Triple Bottom Line Theory

(Source: Shim *et al*. 2021)

People

The leaders of Pfizer should prioritise patient safety by implementing strong safeguards against the off-label marketing of TRT drugs. Ethical leadership will require the company to review and revise its marketing practices that ensure compliance with FDA guidelines (Laosirihongthong *et al.* 2020). The company should commit to transparent patient communication through live campaigns like ***"Empower Your Health: Understand TRT***" about clear potential risks like cardiovascular issues. Moreover, the company should engage in ***collaborative partnerships*** with different medical professionals and regulators that will help to ensure informed decision-making and ethical treatment options (Kouaib *et al.* 2020). It will help to build trust and protect public health by addressing the necessities and concerns of patients and society at large.

Profit

Pfizer should adopt a more accountable financial model that does not prioritise sales at the expense of public health. The leaders of the company need to change marketing strategies for patient welfare (Shim *et al.* 2021). They should provide clear information about the drugs through their marketing. They should use real-world evidence and patient testimonials to showcase how a product impacts patient health in diverse settings (Palmer *et al.* 2022). The company should shift focus towards ***value-based healthcare*** where profits are linked to the health outcomes that are achieved rather than the volume of prescriptions (Laosirihongthong *et al.* 2020). A long-term commitment to this approach can support the reputation of Pfizer to mitigate legal risks and encourage a more sustainable ethical business model.

Planet

Planet is mainly related to sustainability or environmental factors. The challenge is not related to the planet or sustainability, so the company should not take any initiatives regarding the environment or sustainability to mitigate the risk.

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