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Corporate Social Responsibility in the MedTech Industry, the Emergence of Artificial Intelligence in the ERA of COVID-19

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Abstract: The medical technology industry has faced several unprecedented challenges due to COVID-19, including critical medical devices and supply chain shortages. We had to pivot rapidly to address the immediate need to provide lifesaving and sustaining devices, collaborate with competitors, and work collectively with regulators for emergency use authorization when the typical pathway was not viable. AI has provided an opportunity to use new technology in the MedTech space by offering ways to stay productive where human contact is not advisable. Artificial Intelligence has begun to be incorporated into all areas of our lives. The MedTech industry is responsible for improving the quality of a patient's life through technological advancements. Whether it be predictive or early diagnosis, streamlined workflows, and the utilization of electronic health records, the MedTech industry has the opportunity to be a leader in the responsible use of AI. This article examines the impact of COVID-19, the emergence of artificial intelligence (AI), what we did, how we do it, and our collective corporate social responsibility and ethics to our stakeholders, employees, customers, and the communities in which we operate. Finally, the article examines future innovations such as AI and how it can be used in a socially responsible way.

Keywords: COVID-19, Artificial Intelligence, Corporate Social Responsibility, Ethics, Sustainability

1. Introduction

There have been three major waves of technological innovation in the past one hundred and fifty years: a) the Industrial Revolution, b) the advent of computers, which opened the door to more automated production activities requiring higher skill sets, and c) information technology (IT) revolution, where devices are connected through a cloud, phones are now "smart," and most computer-based tasks done through a mobile app. These waves of technological evolution have benefitted many but have left many behind; those earning a living strictly through manual labor have seen their jobs go overseas for cheaper labor rates or replaced by robots and automation.

What is the purpose of our industry? What is our responsibility to those we employ and the communities we affect domestically and globally? Furthermore, what is our commitment to the environment based on our products? Is it an oxymoron that we develop medical devices only to discover that the same products we make are hurting our end users and the environment?

Profits are essential to a company if it effectively serves all its stakeholders over time – shareholders and employees, customers, and communities. Purpose drives focus and strategic discipline toward long-term profitability and unify management, employees, and communities. It also drives ethical behavior and creates checks and balances on the actions and interests of stakeholders. Our purpose should be an outcome of our culture, resulting in decision-making that provides long-term financial returns for the shareholders.

2. Stakeholders

The rise of connected devices has reached the MedTech industry vis-à-vis the Internet of Things, opening new opportunities for data-driven improvements in clinical outcomes. Companies are developing new business models, creating an ecosystem through digitalization, and seeing

increased demand for a more customer-centered healthcare experience. These drivers of change are at the forefront of challenges the MedTech industry faces.

Our stakeholders are investors, employees, customers, and suppliers. The corporate social responsibility drive has extended this to include communities, governments, and trade associations. Internal stakeholders are people whose interest in a company comes through a direct relationship, such as employment, ownership, or investment. External stakeholders do not directly work with a company but are somehow affected by the actions and outcomes of the business. Suppliers, creditors, and public groups are all considered external stakeholders and play a vital part in the company's success.

What we do and how we do it affect both internal and external stakeholders. For example, government entities use taxpayer dollars to prosecute reckless manufacturers that knowingly use cancer-causing substances in their implantable devices. Suppose we get inspected by a 3rd party auditor, which shut down our business in fines, penalties, seizures, or consent decrees. Regulatory compliance failure affects our shareholders, employees, suppliers, and the communities we support. Stakeholders are bound to a company by some vested interest, usually for a longer-term and for need reasons. A shareholder has a financial interest but can sell their company stock when they no longer have an interest. The goal of a successful company is to find the balance to meet all its stakeholders' expectations.

3. CSR

On the issue of corporate social responsibility and ethics, MedTech has a mandate to demonstrate responsible leadership and set the standard as role models for ethical behavior and professional integrity [1, 2]. This discipline will provide a framework for the requirements for employees to ensure that business activities are conducted ethically and responsibly. This industry, as well as others, recognizes that profits are a vital element of success. In this enlightenment era, the theories of Milton Friedman have hopefully faded for a new way of thinking and actions [2, 5].

Milton Friedman on corporate social responsibility selected quotes from his controversial article state: "There is one and only one social responsibility of business--to use its resources and engage in activities designed to increase its profits so long as it stays within the rules of the game, which is to say, engages in open and free competition without deception or fraud.", "Corporate social responsibility is pure and unadulterated socialism." [3]. "The manager is the agent of the individuals who own the corporation...and his primary responsibility is to them.", "To say that the corporate executive has a 'social responsibility...must mean that he is to act in some way that is not in the interest of his employers." [3]

4. Sustainability

Another area that has resulted from our "woke state" is the prioritization of sustainability coupled with ethics and quality are integral in how the company acts as a business and how it treats its employees, customers, and community. [4] A sustainable business model guides the company on creating long-term value, positively impacting society, and delivering value to all its stakeholders [5].

If a company does not become more environmentally responsible, it risks losing access to global markets. This global social agenda is gaining traction, and taking center stage is one of the day's issues. Reducing emissions and waste is now crucial to business strategy across several sectors, including pharmaceutical and medical device manufacturers. Compliance with new demands by regulators, hospital systems, governments, and consumers to address environmental issues may make or break your company.

Effective strategies include improving manufacturing processes, using clean, renewable sources, utilizing environmentally sustainable materials, and waste reduction. These strategies affect the entire product lifecycle development, reduce cost, and result in a shorter time to market.

The MedTech industry must acknowledge how its past efforts to develop medical devices were more focused on increasing profits at the expense of patients' quality of life. Now, we must ponder if we are good stewards in our development efforts to utilize advanced technologies and innovations to propel us to a new and unseen horizon. As we are in a globally regulated industry where the safety and effectiveness of our devices are most critical, how we design them and the materials we use in them are pivotal.

Our responsibility to sustainability and our impact on the climate is demonstrated through compliance with various industry standards. Some of these include removal of hazardous waste (ROHS), Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH), Waste Electrical and Electronic Equipment Directive (WEEE), Prop 65 (State of California's list of chemicals known to the state to cause cancer or reproductive toxicity). Through active regulation coupled with corporate drivers for sustainability, responsibility (to our stakeholders) for our actions will build collaborative long-term growth and innovation efforts.

5. Pandemic Effect

The COVID-19 pandemic has yielded an unexpectedly increased demand for medical devices, particularly those used for prevention, diagnosis, and respiratory therapy. The pandemic has also significantly disrupted medical device manufacturing and supply chain operations. It has led to new trends in medical device development and services that could not have been predicted before the pandemic and will likely have long-term implications.

As COVID-19 began to spread, healthcare providers leveraged remote care and telehealth to protect their patients and medical personnel [6]. The need for more protective, therapeutic, and diagnostic equipment such as ventilators, intensive care unit (ICU) beds, and personal protective

equipment (PPE) resulted in increased production from medical device companies, streamlined inventive contributions from the non-traditional medical device industries, and the repurposing of existing technology [7]. The medical device regulatory environment had to adapt to meet challenges by becoming more agile to reduce time to market, streamlining regulations while keeping quality and safety at the forefront.

The immediate impact of the pandemic on the medical industry was the slowdown of elective procedures and even procedures conventionally considered non-elective [6] COVID-19 increased the urgency for the MedTech industry to respond to these drivers and accelerate its transformation. The challenge of the pandemic has highlighted the need for improvement in MedTech business models, supply chain systems, regulatory relationships, and deployment of digital and data tools [6].

The COVID-19 crisis has disrupted societies worldwide and will have a lasting impact on our economies and technology development. Our new awareness of the threat of pandemic-level disease has altered the direction of healthcare for the long term. This experience is now driving new technology and digital disruption in many industries, healthcare being ground zero.

The pandemic has highlighted the limitations of the MedTech industry in ways we cannot ignore [8]. Strategies to avoid overwhelming demands for essential medical supplies and shortages and overwhelmed care centers will be crucial moving forward. The MedTech sector must continue collaborating to develop new technologies, including advanced artificial intelligence devices, telemedicine capabilities, and long-term sustainable materials with extended shelf lives that can be repurposed for such unprecedented times with a pandemic sense of urgency.

This new normal in the MedTech sector is here for the foreseeable future and serves as a future warning [7]. We must prepare for the potential of another pandemic-level health crisis, where business models that allow improved access to care while limiting risk by limiting exposure improve the care patients receive and create efficiencies in the health care system. Responsible and equitable consideration is also given to our stakeholders and communities directly impacting us.

6. Discussion

Diagnosing pathological conditions earlier than ever with artificial intelligence (AI) and machine learning (ML) is an integral part of healthcare ecosystems. AI-enabled medical technologies must comply with regulatory requirements applicable to all medical devices [8, 9] Yet, there are currently no harmonized standards that specifically address the unique performance aspects of AI technologies (but there are working committees addressing this very issue).

The European Union (EU) is governed by the EU's Medical Device Regulation (2017/745) which provides general requirements for medical device software and models [10]. The U. S. Food and Drug Administration (FDA) released in January 2021 an Action Plan outlining the agency's proposed framework for regulating and overseeing medical devices and software using AI technologies [11-13]. It will continue to issue guidance documents and regulations to advance the agency's management of AI/ML-based SaMD [11].

In China, that country's National Medical Products Administration (NMPA), formerly known as China's State Food and Drug Administration (CFDA) issued a Technical Guidance on AI-Aided Software in June 2019 [14]. The guidance reportedly addresses four critical considerations in registering AI-based medical technologies in China, including a) needs analysis, b) data collection, c) algorithm design, and d) verification and validation[4]. Establishing Partnerships will become important in attempting to establish a global regulation.

AI and related capabilities such as machine learning (ML) are becoming more prevalent in the healthcare industry. AI-enabled medical devices can quickly adapt to new information and be utilized in real-time. Improved patient outcomes through early detection can result in reduced costs and patient throughput, affecting the overall quality of healthcare everywhere. Some algorithms and data models are not "locked" but continuously learning and adapting their real-time functionality to optimize overall performance.

AI functionality is dependent on both the quality and the quantity of data. These factors directly impact how well AI algorithms and models perform. Data quality can include hidden biases in the selection and collection of data or errors in labeling data that has been collected. Data quality is also affected by overfitting or underfitting data, where data is aligned too closely or is not close enough to the data models' requirements.

7. Conclusion

Transparency and explainability remain difficult challenges to how the algorithm drives the functionality of medical technologies. AI models are generally based on a highly nested and non-linear structure, making determining which specific input data has determined device function difficult [14]. Given this lack of transparency, it is often difficult to validate the model's process's basis or appropriateness [14].

The Medtech industry is on the precipice of creating smarter technology, algorithms, and models that will redefine how healthcare is delivered [15]. This will enable us to deliver the insights for earlier diagnosis and treatments to patients at critical times in the healthcare ecosystem. This will lead to better-informed and more cost-effective care for providers and consumers [15].

Abbreviations

AI: Artificial Intelligence

COVID-19: Coronavirus (severe acute respiratory syndrome-related coronavirus 2, or SARS-CoV-2)

CFDA: China Food and Drug Administration

CSR: Corporate Social Responsibility

EU: European Union
FDA: Food and Drug Administration
ICU: Intensive Care Unit
IT: Information Technology
ML: Machine Learning
MedTech: Medical Technology
MDR: Medical Device Regulation
NMPA: National Medical Products Administration
PPE: Personal Protective Equipment
Prop 65: State of California's list of chemicals known to the state to cause cancer or reproductive toxicity.
ROHS: Removal of Hazardous Substances
REACH: Registration, Evaluation, Authorization, and Restriction of Chemicals
SaMD: Software as a Medical Device
WEEE: Waste Electrical and Electronic Equipment Directive

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Conflicts of Interest

The author declares no conflict of interest.

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