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Global Supply Chain Effects on Medical Devices

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ABSTRACT

Global supply chain plays a vital role in developing and distributing medical devices essential for diagnosing, treating, and monitoring various health conditions. The complexity of the global supply chain can significantly influence the availability, quality, and pricing of medical devices. This paper examines the effects of global supply chains on the medical device industry and analyzes the geographic distribution of the medical device supply chain. It specifically focuses on key production centers and the global transportation of medical devices. Our paper will emphasize the contribution of supply chain disruptions, caused by factors such as trade law changes, transportation difficulties, and geopolitical tensions, to the shortages or delays in accessing essential medical devices.

Furthermore, the paper will conduct a comprehensive analysis of the financial impacts and costs associated with medical devices. It will focus on identifying the variables that influence the overall cost structure, including raw material prices, labor costs, currency exchange rates, and trade agreements. Additionally, the paper will examine the effects of supply chain consolidation and market concentration on pricing and competition policies.

Finally, the paper will discuss potential strategic solutions that mitigate the risks and challenges that global supply chain poses to the medical device sector. This section will conclude by reviewing how concepts like localized production, supply chain diversity, and digitization can improve resilience.

Keywords: Trade network; Medical devices; Supply chain disruptions

INTRODUCTION

Manufacturers who create devices and tools for the prognosis, prevention, or treatment of illness make up the medical technology sector. The global supply chain for essential medical equipment changed after World War II to improve accessibility, quality, and price. However, balancing these objectives has become increasingly challenging due to the high costs of technological advancements and the limited resources available from taxpayer-funded patients [1]. Therefore, medical technology is crucial in diagnosing, treating, and managing various medical disorders.

Also, chronic diseases, technological breakthroughs, regulatory actions, natural disasters, demand increases, economic factors, and the growth of the world's population all contribute to a rising need for medical equipment. As a result, there is a significant shift in the sector's structure. The difficulties that medical device suppliers must overcome evolve with supply and demand dynamics. Manufacturers must be flexible to fulfill client expectations while negotiating a challenging regulatory environment that is constantly changing.

However, the intricate and global supply chain supporting the production and distribution of medical devices carries various risks and disruptions that greatly affect their availability, quality, and cost-effectiveness. With multiple stakeholders involved across continents, including producers, suppliers, distributors, and healthcare professionals, the supply chain enables efficient production, global distribution, and cost reduction. However, it also exposes vulnerabilities that can disrupt the flow of medical devices and pose challenges to patient care. By gaining a comprehensive understanding of these complexities, stakeholders can collaborate to implement practical strategies and policies, ensuring a resilient and sustainable supply chain that meets the evolving needs of patients and healthcare systems in our interconnected global landscape.

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GEOGRAPHIC DISTRIBUTION OF THE MEDICAL DEVICE SUPPLY CHAIN

Key Manufacturing Regions

The growth of the healthcare industry is closely linked to the expansion of the medical device market, which is a crucial component of the global supply chain. In fact, medical devices are among the most traded goods, with international trade in this sector reaching $ 150 billion as of 2021. According to Wolters Kluwer (2019), the global medical devices market was valued at $ 489 billion in 2021, $ 512.29 billion in 2022, and it is expected to grow to $ 719 billion by 2029, with an annualized growth rate of 5.5% from 2022 to 2029 [2]. The price sensitivity of medical device makers allows them to raise prices as the demand for medical device production increases globally [3].

While the globe's market for medical technologies is centered mainly in the United States, Europe, and Japan, trade in medical equipment only accounts for 0.71% of all global trade [4]. However, China is an emerging market that is expanding quickly, with the prediction that by 2030, its market share might reach 25% [5]. In 2018, the United States dominated the global medical equipment supply chain, holding approximately 40% of the market value. Europe followed with 30%, while China accounted for 10%.

Last five years, the wholesale sales of medical supplies in the United States have increased significantly, with a CAGR of 3.9%. The U.S. market growth will be 2.3% by 2023 [6]. Healthcare providers are investing more substantially in medical supplies to address patient needs because of rising healthcare consumption in recent years, increasing the demand for medical supplies. Big firms, including Cardinal Health, Inc., Henry Schein, Inc., Mckesson, Healthline, and GEMCO Medical, drive the industry [7].

On the other hand, the European Union is a major global producer and exporter of medical products [7,8], with Germany, France, and the United Kingdom leading the medical equipment market. Italy also holds a significant position as a fourth-place leader in the European market [9]. In 2022, the European medical devices market reached a value of $ 140.7 billion and an expected CAGR of 4.09%, reaching $ 171.19 billion by 2027 [10]. Factors such as the increasing number of healthcare institutions, a rapidly aging population, and the adoption of technological advancements contribute to this growth [11]. Despite this growth, there are stringent regulations, high costs of medical device purchases, reimbursement issues, and an increasing rate of product recalls that pose challenges to the market's expansion. The key market players in Europe are Medtronic Stryker, Fresenius SE & Co., KGaA, Koninklijke Philips N.V, F. Hoffmann-La Roche Ltd., General Electric Company, Siemens Healthineers AG, BD, Boston Scientific Corporation, and Johnson& Johnson Services Inc [11].

According to Market Data Forecast (2023), the medical device market in the Asia-Pacific region (APAC) has an anticipated CAGR of 4.4% from 2022 to over $ 225 billion in 2030 [12], $ 96.7 billion expected in yearly sales and a 43% market share of the medical device business. Hospital supplies will remain the leading device category in 2023. Also, the endoscopic device segment was identified as the fastest-growing category, with sales estimated to reach $ 8.3 billion in 20230, or 10.5% annual market growth between 2022 and 2030 [13].

China's role in the APAC medical device region is significant, accounting for approximately 10% of the global market for medical technology, which is valued at USD 53.6 billion. While China has traditionally focused on low-cost production, it is now making strides in the global medical technology market by embracing advancements in high-end medical device technology [3]. Notable companies in the APAC region, particularly in the fields of hospital supplies, *in-vitro* diagnostics (IVD), cardiology, and orthopedics, include Roche, Abbott, Medtronic, Becton Dickinson, and Cardinal Health [13].

Global Distribution of Medical Devices

The global transportation of medical device raw materials and finished goods plays a crucial role in ensuring availability and accessibility of medical equipment worldwide. Advancements in global logistics and supply chain management have facilitated expanded market reach, as noted by Mangan and Lalwani (2016) [14]. Europe, Asia, and North America have emerged as prominent production regions for medical equipment, as highlighted by the International Trade Administration (2022) and Cinde Invest in Costa Rica (2022) [9,15]. Countries like Costa Rica have also entered the global value chain, with approximately 96 companies involved in the export of medical devices [16]. The global medical devices market, valued at around $ 450 billion in 2021, is projected to grow to $ 700 billion within the next 5 years to 6years, demonstrating significant industry growth [17].

Compliance with import and export regulations and adherence to product specifications are crucial for maintaining an efficient medical device supply chain. The complex legal landscape, which prioritizes patient safety and device effectiveness, poses significant challenges that need to be navigated [18,19]. Developed countries, such as the United States and the European Union, enforce rigorous regulatory requirements to ensure the safety, performance, and efficacy of medical devices. Meeting these standards is essential for maintaining the reliability and reputation of medical devices throughout the supply chain. The regulatory frameworks of the United States and the European Union are highly regarded internationally in this area [19]. The World Trade Organization (WTO) plays a vital role in facilitating international trade of medical goods by negotiating binding tariffs, reducing trade costs, and addressing uncertainties [20]. The WTO through its Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement strikes a balance between promoting innovation in drug development and allowing governments to address public health concerns [21].

Additionally, the 2015 Information Technology Agreement Expansion removed tariffs on cutting-edge medical equipment. The Agreement on Pharmaceutical Products also removed tariffs and fees from various drugs and their inputs [20], which impacts distribution during exports. Major medical device distributors have established more comprehensive policies covering their products' marketing, promotion, and sale. Similarly, the Federal Food, Drug, and Cosmetic Act (FD&CA), supervised by the Food and Drug Administration (FDA) governs

the import and export of medical equipment in the United States [22]. Only compliant shipments are accepted. However, the FDA may use discretion and permit importers to correct nonconforming shipments. Shipments not compliant with requirements are destroyed or exported again [22]. On the other hand, the European Union has standardized policies established by the Medical Device Regulation (MDR [2017/745]) and the *in-vitro* Diagnostic (IVD) Medical Devices Regulation (E.U.) 2017/746 [23]. These regulations impose new responsibilities on organizations importing medical equipment from outside the E.U., such as guaranteeing that the devices adhere to relevant requirements [24].

Sub-Saharan African nations rely on imported medical products to meet their healthcare needs, creating a $ 3.2 billion import-dependent medical supply and equipment market [25]. While this is a growing market, some of the challenges include a lack of well-defined medical device regulatory systems in many African nations, which frequently force manufacturers to rely on approval from the U.S. Food and Drug Administration or the European Medicines Agency [26,27]. Additionally, the regulatory procedures of significant countries in the industry need to address Africa's unique requirements and security challenges sufficiently. Obtaining regulatory approval or clearance in multiple African countries can be challenging due to process variations [28]. Consequently, Africa needs help to become a significant contributor to the global manufacturing and export of medical equipment.

Despite the above, trade laws which govern import and export continue to raise difficulties in the global supply chain of medical items, notwithstanding WTO efforts and nation-specific laws. While net importers have removed tariffs to encourage imports, major exporters have imposed export restrictions to meet domestic demand, hindering efficient global transportation of medical tools. As a result, this highlights the need to ensure a steady supply of medical materials and introduces concerns about the reliance on domestic vs. international production [29].

The Impact of Disruption in Transportation and Trade Policies on the Distribution of Medical Devices

Disruptions in transportation and trade policies make distributing medical equipment challenging [30]. Access to healthcare and addressing medical needs depend on the timely and effective distribution of medical apparatus [31]. However, hurdles to the efficient flow of medical devices include more than delays in shipping, limitations, and changes in trade policy [32]. Additionally, logistics disruptions arising from natural disasters, global pandemics, or infrastructure issues have led to delays in the delivery of medical devices. Furthermore, the outbreak of Ebola virus disease in West Africa also led to logistical difficulties resulting from restrictions on U.S. military air deployments, among other issues [33,34]. In healthcare facilities, particularly in distant or underserved areas, access to essential medical devices poses a severe barrier that might jeopardize patient treatment and outcomes. Similarly, regulated medical products in fields like radiology, which rely on advanced diagnostic and therapeutic tools, often face marketing delays and hinder innovation due to the complex regulatory system of the U.S. Food and Drug Administration (FDA) [35]. The FDA has changed regulations to increase system efficiency while preserving safety and quality requirements because it is aware of the complexities and effects of delaying commercialization of these devices for the medical profession and society at large.

Government-imposed trade restrictions on essential medical supplies and medications have created significant disruptions in international trade, impacting countries like Iran. The trade, financial, and banking restrictions imposed on Iran hindered the importation of pharmaceuticals and medical equipment, leading to prolonged import timelines and limited access to affordable healthcare supplies. Challenges with money transfers further compounded the difficulties, causing frequent shifts in suppliers and compromising the quality and continuity of healthcare provisions. As a result, approximately 6 million Iranian patients faced restricted access to medical care for various illnesses, forcing the country to import substandard drugs and raw materials [36,37].

Similarly, the Japanese tsunami significantly damage to healthcare facilities, which led to 52% of hospitals refusing treatment for new patients and 14% being unable to admit patients due to resource shortages [38]. Additionally, the destruction of transportation infrastructure had a profound impact, causing numerous healthcare facilities to suffer substantial losses [39].

Furthermore, measures such as movement limitations and strengthened border controls have also contributed to this disruption [40]. Based on the research of Beleche et al. (2022), they found that from 2010 to 2019, there were five significant medical device shortages on average per year in the US [41]. The pandemic produced an upsurge in shortages in 2020; however, before COVID-19, product quality and manufacturing-related regulations and enforcement activities were the leading causes of shortages, contributing to 70% of triggering events in the U.S. The escalating global demand, like in the case of the pandemic and the market for medical technologies driven by rising healthcare needs, highlights the importance of reducing dependency on imports and avoiding the risks associated with deglobalization [40]. Regulatory actions such as product recalls, and government seizures have complicated the importation of medical raw materials and finished products, including medical devices [36]. These actions have created challenges and disruptions in the import process, affecting the availability and accessibility of essential healthcare supplies. According to Schumacher, governments must exercise social responsibility by putting in place solid procedures for handling risks associated with product recalls that endanger consumer safety [42]. Using the Cambridge University Hospital case study, they suggest implementing a downstream quality inspection system as a workable strategy to reduce product quality and safety concerns in dire circumstances like the COVID-19 pandemic, where recalls may not be practical.

Potential strategies for addressing medical device supply chain limitations include adopting secure and accessible cross-border policies, ensuring consistent procurement and distribution of essential supplies, fostering advantageous trade agreements, and implementing effective economic and regulatory measures. One practical approach involves developing and enforc-

ing regulatory policies to prevent the circulation of counterfeit medical devices from prominent biotechnology companies. Incorporating technologies such as barcoding, holograms, and radio frequency identification (RFID) can facilitate the capture and verification of product authenticity throughout the supply chain [43]. A resilient and dependable distribution network for medical devices must address difficulties brought on by trade and transportation regulations changes. For a safe and effective delivery of medications and medical supplies, governments should also prioritize maintaining open borders, a distribution network that is dependable and easily accessible, and a healthcare system that successfully satisfies the population's healthcare demands. Furthermore, it is imperative to reduce potential risks associated with excessive reliance on foreign manufacturers of medical products [44].

It is significant to emphasize that to ensure a seamless and effective flow of medical devices, all parties engaged in their distribution, including manufacturers, regulatory agencies, logistical service providers, and governments, must cooperate. Healthcare systems can assure the availability and accessibility of crucial medical equipment by proactively controlling and minimizing these interruptions, eventually improving patient care and public health outcomes.

Geopolitical Tensions and their Impact on the Supply Chain: The U.S.-China Trade War Case Study

Geopolitical conflicts significantly disrupt the supply chain for medical products, leading to shortages and impacting patient care, such as natural disasters like hurricanes, communication failures can hinder the delivery of emergency supplies [45]. Strategies such as expanding local manufacturing, diversifying suppliers, and fostering international cooperation are crucial to mitigate these challenges. Additionally, implementing open and transparent trade policies, strengthening diplomatic relations, and employing effective risk management techniques are essential for safeguarding the medical equipment supply chain from geopolitical uncertainties. The U.S. China trade war emerged since China entered the World Trade Organization (F.P. Analytics, 2021) because of U.S. concerns over China's significant trade surplus, alleged illegal acquisition of U.S. technology, potential risks to U.S. national security, and perceived undervaluation of the Chinese yuan [46-48]. The U.S. contends that China designed its trade and exchange rate policies to favor Chinese exports and impede imports [49]. As a response, the U.S. imposed trade restrictions, including tariffs, to pressure China into addressing these concerns and complying with U.S. demands across various issues [47,48]. The U.S. and China trade war has significantly impacted the global supply chain of medical products, affecting the availability of critical medical supplies in the U.S. market [50]. China, being a major global supplier of Personal Protective Equipment, medical devices, antibiotics, and active pharmaceutical ingredients, experienced terrible trade restrictions, and these restrictions have caused medical equipment shortages in the U.S. since then [51].

Despite attempts at trade talks, both the U.S. and China have implemented measures to alleviate the impact of tariffs on healthcare costs. Notably, they have refrained from imposing tariffs on vital medical supplies not quickly produced domestically or by third parties [52]. China has exempted medications and eliminated tariffs on most imported drugs, while the U.S. has granted exemptions for pharmaceutical preparations, affordable medical devices, and crude drugs [52]. However, the U.S. implemented a 25% tariff on high-value Chinese medical goods, including imaging equipment, diagnostic reagents for X-ray examinations, dental drills, and metal alloys like aluminum and steel in medical device manufacturing Similarly, China has imposed a 5%-25% tariff on expensive U.S. medical devices and specific consumables. These tariffs significantly affect the cost and availability of medical products in both countries, which may hinder healthcare services accessibility for individuals with limited incomes. Using replacement medical equipment and consumables to bypass tariffs raised concerns about their quality, potentially resulting in misdiagnosis and ineffective treatment [52,53]. To limit China's advanced manufacturing sector, U.S. President Joe Biden implemented strict export controls on computer chips [54]. Device manufacturers with supply chains spanning the U.S. and China have faced considerable difficulties because of the trade war and are required to pay hefty taxes at various points along their logistics network [55].

The resurgence of China and the weaknesses shown by the COVID-19 pandemic have caused the United States to refocus on industrial policy [44]. There is significant financing for scientific research and domestic production of high-tech products, particularly semiconductors, through programs like the CHIPS and Science Act and the Inflation Reduction Act [56]. Additionally, President Biden's October 2022 export curbs and other policies are geared at slowing the expansion of rival Chinese sectors, which may influence the semiconductor industry in China [54]. Until the trade duel between these world powers ceases, the numerous problems it has created will continue to exacerbate and impact the medical appliance supply chain and industry. Specifically, it has presented the fragile and dire obstacles in the globally intertwined reliance on chip production in all sectors, including healthcare [57].

ECONOMIC IMPLICATIONS OF GLOBAL SUPPLY CHAIN ON MEDICAL DEVICES

Raw Material Costs

The increasing costs of raw materials significantly impact global supply chains for medical devices. Metal, plastic, and electronic component price increases can result in more significant production costs and impact how affordable medical devices are [58,59]. The development and distribution of medical devices are only possible if manufacturers can locate and secure an appropriate supply of raw materials. Global producers of medical products face various challenges that disrupt their business operations. Natural disasters like pandemics, such as the COVID-19 outbreak, geopolitical tensions, economic crises, manufacturing difficulties, and strict government regulations can all harm production and distribution. These disruptions result in shortages of raw materials, affecting the supply of medical products [60-63]. Manufacturers heavily reliant on specific raw materials face challenges securing a stable supply at reasonable prices.

To address these, organizations employ strategies for alternative sourcing options [64], negotiate price agreements, and invest in research and development to find cost-effective substitutes and optimize material utilization. However, raw material disruptions affected production schedules and resulted in inventory issues [65], adversely impacting the timely delivery of medical devices to healthcare facilities. Furthermore, GlobalData (2022) noted that escalated costs and shortage of raw materials for medical devices are expected to persist in 2023 such as higher production costs result from the rising price of medical device raw materials-metals, polymers, and chemicals. Data from the U.S. Bureau of Labor Statistics, demonstrating notable recent rises in producer price indexes for medical equipment and supplies manufacturing, corroborate this. The average growth rate in 2022 was 3.4%, compared to 1.2% in 2021.

Compared to the prior year, the price index as of November 2022 hit a record high of 4.2%. Moreover, the COVID-19 pandemic has led to a worldwide scarcity of hospital equipment, causing a sustained rise in export costs throughout 2020 [66,67]. Similarly, the ongoing trade war between China and the United States has negatively affected the healthcare sector, imposing tariff cost hikes that further strain healthcare manufacturers, providers, and patients [68,69].

Critical for clinics and hospitals, sterilization and medical imaging equipment are included in the 25% duty on Chinese goods. China also supplies the components for hip replacement procedures, frequently performed on the aging baby boomer population in the United States. These tariffs could significantly increase the price of this medical procedure.

In response to inventory shortages and potential disruptions, medical device manufacturers have emphasized the importance of strengthening supplier relationships [70]. They have pursued strategies such as nationalizing medical supply chains, diversifying sourcing approaches, and increasing safety stocks. By negotiating pricing contracts and implementing long-term supply agreements, healthcare device makers aim to enhance the resilience of the medical device supply chain during challenging times [71,72].

Currency Exchange Rates

The value of currencies significantly impacts the global economy, affecting trade, investment, finance, migration, and travel. The current exchange rate system has shaped the international economic order [73], and worldwide supply chain of medical devices raising costs for producers and distributors alike and make medical equipment unaffordable and inaccessible in various nations. Currency volatility impacts the supply chain's sourcing, planning, and financial management [74]. These factors affect the profit margins of MedTech companies operating in international markets, thus eroding business profitability, which introduces uncertainty and risks into supply chain planning.

Manufacturers and distributors need to consider exchange rate risks when sourcing components, setting inventory levels, and managing contracts because of the numerous challenges it brings, including adverse effects on competitiveness.

A classic example of the negative impact of currency exchange rate risks on the medical device supply chain is the significant appreciation of the U.S. dollar against the euro in 2015, which posed challenges for European medical instrument manufacturers, resulting in lower sales and complex export negotiations [75]. The average exchange rate between the U.S. dollar and the euro ranged from 0.8271 to 0.9146. Such exchange fluctuations prompted certain businesses to review their pricing and marketing strategies. In contrast, companies manufacturing outside Europe and the U.S. benefited from the stronger U.S. dollar and were unaffected during that period. This highlights MedTech companies' global challenges due to macroeconomic factors such as inflation and supply chain disruptions. According to studies conducted by the Organization for Economic Cooperation and Development (OECD), the annual growth rate of the producer price index has varied between 1% and 2% over the past decade.

Additionally, in 2022, medical equipment prices experienced a substantial year-on-year increase of -20%. Significant foreign exchange rate fluctuations contributed to price volatility for both materials [76]. They finished goods in specific global markets, driven by the 20% rise in the U.S. Dollar Index during that period. Trachtenberg et al. indicate that healthcare equipment manufacturers are consolidating production sites and optimizing supply chains to minimize negative impacts on their balance sheets [76]. However, this approach leaves the global supply chain vulnerable operationally and financially. According to their research, the base cost of healthcare decreased by -8% between 2021 and 2022, with an expected decrease of -6% through 2023. The survey conducted by LEK Consulting suggests that the most significant cost increases will likely come from raw materials and personnel.

Medical device manufacturers must manage currency exchange rates effectively to preserve a competitive edge, ensure supply chain stability, and meet healthcare demands. Implementing currency hedging strategies helps minimize the impact of exchange rate fluctuations by using financial instruments such as forward contracts, options, or futures. Diversifying into multiple markets reduces reliance on a single currency and mitigates the effects of currency fluctuations. Flexible pricing strategies maintain profitability and competitiveness across different markets. Negotiating contracts with suppliers and customers that consider currency risks allows for adjustments in pricing or payment terms to address exchange rate fluctuations. These measures contribute to a resilient, competitive, and stable supply chain in the face of currency exchange rate fluctuations.

Trade Agreements and Tariffs

After World War II, the international community changed its emphasis from protectionist trade policies to an open trading system based on rules, which positively impacted the economy regarding increased trade activity, economic output, and income growth [77]. Trade, therefore, plays a vital role in human interactions, encompassing the exchange of goods and services between transacting entities for monetary value.

Contracting parties formalized these transactions through binding agreements. Countries establish trade relationships through bilateral or multilateral trade agreements, which outline terms and conditions for trade between two or more

nations. These agreements govern the movement of goods, services, and investments, including shaping the global supply chain of medical devices.

As discussed in Chapter 1, medical instruments are the most traded goods. In 2021, the global trade value of medical goods reached nearly $ 150 billion, according to the Organization for Economic Cooperation and Development. The World Trade Organization (WTO) recorded a steady increase in the value of medical goods imports and exports, with $ 2,028 billion in 2019, $ 2,343 billion in 2020, and $ 2,654 billion in 2021 [78]. Recent market projections indicate a strong growth trajectory for the medical device industry. Fortune Business Insights (2023) reported a global market value of $ 519.29 billion for medical devices, in line with the anticipated increase predicted by Wolters Kluwer (2019) [2]. Furthermore, Fortune Business Insights projects growth to $ 536.12 billion in 2023, reaching $ 799.67 billion by 2030, while Wolters Kluwer predicts a further increase of $ 719 billion by 2029.

These trade statistics have provided valuable insights into global health-related product market trends. These notable figures were possible because of efforts by international organizations such as the WTO to ensure fair transactions. For example, the WTO established a multilateral agreement called TRIPS on intellectual property rights. Trade agreements such as these establish rules and regulations governing international trade, including the movement of medical devices across borders. The WTO's TRIPS Agreement ensures fair and stable conditions for international trade, including intellectual property protection for medicines.

The United States has made efforts to recognize higher levels of intellectual property protection in bilateral and regional trade agreements [79]. This agreement modified the General Agreement on Tariffs and Trade (GATT), the multilateral trade agreement established in 1947 [80]. They simplify trade procedures, reduce barriers, and promote market access.

The United States and South Korea also established a trade agreement to promote fair and competitive trading for American medicine and medical device manufacturers in South Korea. This agreement included gradually eliminating tariffs on pharmaceuticals and medical equipment within specific timeframes. It also addressed other aspects, such as the pricing and payment of medical devices within the South Korean National Health Insurance System [81].

Similarly, in November 2019, the EU-Singapore Free Trade Agreement (EUSFTA) was established to facilitate trade in pharmaceutical products and medical devices between the E.U. and Singapore [82]. This agreement promotes competitiveness, innovation, and cooperation between health authorities while eliminating non-tariff barriers to bilateral trade. It includes provisions for zero tariffs on these products, ensuring favorable market conditions [83]. Before the pandemic, the WTO recorded those 89 countries-imposed tariffs on imported medical equipment.

Since the beginning of 2020, 105 jurisdictions have implemented 228 import policy reforms, indicating efforts to enhance trade facilitation [84]. To fight the COVID-19 pandemic, Algeria, despite not being a WTO member, exempted medical equipment from customs duties and value-added taxes (VAT) in May 2020. The World Bank (2022) noted the positive impact of open trade and the immediate support from the government in the production of vaccines during the pandemic, which increased trade in medical goods [85]. Governments leverage trade and trade-related policies to boost the domestic availability of critical medical goods, accounting for measures to liberalize imports and exports of medical products.

On the other hand, the World Bank (2022) noted that "import reforms and export curbs during the pandemic increased average trade costs of medical goods by 60%". The United Nations Conference on Trade and Development observed the weaknesses of the trading system for medical products during the pandemic [86]. It emphasized the importance of establishing a responsive and efficient international trade environment by implementing regional trade agreements (RTAs). It also facilitated regulatory cooperation by streamlining technical regulations and reducing unnecessary burdens, enabling countries to respond to medical emergencies effectively. By implementing internationally recognized trade agreements and harmonizing regulatory standards, countries can liberalize trade; reduce barriers such as tariffs, and increase market entry and expansion, enabling manufacturers to access a broader customer base. According to the World Bank (2022), implementing low medical product tariffs and lowering import costs for ICT and health-related business services would increase global income by over $ 6 billion annually, with more than half of this benefit going to low-income countries. In contrast, imposing tariffs may raise the price of imported raw materials or completed goods, impede economic expansion, diminish affordability, restrict market access, and result in lower incomes and employment rates. It is essential to recognize that production and exchange create wealth and that open trade and investment have benefited nations like the United States [77,87].

Understanding and monitoring the implications of tariffs is essential to navigating the global supply chain effectively. Medical equipment manufacturers must remain informed about trade negotiations, assess the potential impact on costs and market access, and proactively adjust sourcing, production, and distribution strategies to maintain a competitive edge in the dynamic global market.

Labor and Market Concentration and Pricing Strategies in the MedTech Industry

The MedTech industry encompasses medical technology and devices used in healthcare, and various factors that affect its global supply chain include labor and market concentration and pricing strategies. Labor plays a significant role in the medical device industry's global supply chain. The availability of skilled labor, particularly in manufacturing and research and development (R&D), is crucial for the production and innovation of medical devices. The medical technology industry supports a significant number of jobs worldwide. In the United States, it accounts for approximately 519,000 jobs, while in Europe; it supports over 800,000 jobs (MedTech Europe 2022). From 2010 to 2014, the projected number of jobs in the U.S. medical device industry ranged from about 87,280 to 89,571 [88-90]. The industry employs approximately 116,915 people

in China, and in Canada, the figure stands at 25,962 [91,92]. In Europe, the Medical and Dental Instrument manufacturing industry employs 527,428 individuals, and in the U.S., approximately 58,871 people in medical equipment repairs and maintenance services.

The medical device industry relies on skilled labor and faces challenges due to labor shortages and rising costs. The outbreak of the COVID-19 pandemic caused significant disruptions in the MedTech industry because of the vast demands for equipment and supplies such as diagnostic tests, personal protective equipment (PPE), ventilators, and other critical equipment [92,93]. As a result, there was a shortage of labor resources in the post-pandemic labor market, affecting various product categories and leading to backorders [94,95]. The categories of highly skilled workers in lack are technicians, including master machinists, floor leads, programmers, and manufacturing engineers, who are required to meet the growing demand [96]. Trade conflicts, like those between the U.S. and China, further caused distributional impacts on the labor market. These impacts gave rise to a decrease in international trade activities and led to a shortage of resources and a rise in labor costs.

Automation and outsourcing jobs have also raised concerns among workers in the medical device industry. Manufacturers have embraced automation to enhance the resilience of the medical equipment supply chain, primarily because of the impact of the pandemic [97]. Since the pandemic, medical device manufacturers have increasingly embraced open innovation models to tap into a large and geographically diverse talent pool, ensuring business continuity [98]. The shift towards data-driven systems and automation has led to elimination of certain jobs and the diminished value of specific skills. Additionally, some businesses have relocated to countries with lower labor and manufacturing costs as part of the expanding global supply chains. Labor costs and workforce capabilities in different regions have affected sourcing decisions and manufacturing locations within the supply chain. Countries with a highly skilled labor force and favorable labor costs may attract more investment and production activities. As a result, some workers have relocated overseas, reducing their job security in certain countries. Workers who are inexperienced in using digital work tools would then require additional assistance or resources that are not always accessible as they struggle to navigate and adjust to new digital technologies. Fenske (2023) highlights the struggle to find skilled labor and the subsequent reliance on automation, noting that it should not replace human resources but enhance workforce engagement and flexibility [99].

MedTech manufacturers must actively attract and retain workers to meet market demand and create a robust global supply chain. To achieve this, employers should provide training and development opportunities to reskill and upskill their workforce. They can also recruit talent from related industries. Competitive salaries, benefits, and fulfilling job opportunities should empower employees to make a meaningful impact [96].

Similarly, market concentration influences pricing, distribution, and medical device availability. Market concentration refers to the dominance of a few large companies in a particular industry. In the MedTech industry, market concentration impacts the global supply chain in several ways. Firstly, dominant companies may control the supply chain significantly, influencing medical device pricing, distribution, and availability. It led to a concentration of power, potentially limiting competition, innovation, and consumer choice. Pricing strategies employed by medical equipment companies can also impact the global supply chain. MedTech products often involve high research and development costs, regulatory compliance expenses, and ongoing investments in innovation. These factors determine manufacturing locations, R&D investments, device access, and competition levels. The global supply chain for medical devices has become more complicated, making it harder to forecast demand and set prices. Companies today must deal with both the addition of new items and the quick changes in client requirements brought on by the development of digital technology. To correctly estimate demand, businesses must understand client needs and have more robust forecasting capabilities [100].

Furthermore, pricing has become more challenging for companies due to the supply chain's increased complexity, including components from many sources. Businesses must account for the cost of manufacturing and delivering specific features and the varied expenses related to different markets to determine competitive pricing [101]. As such, companies must have more knowledge and resources to forecast demand and establish pricing effectively. Pricing decisions must consider these factors, along with market demand and competition. Pricing strategies such as value-based pricing, volume-based discounts, or differential pricing for different markets influence the allocation of products across the global supply chain. Monitoring and addressing potential anticompetitive behavior are essential for a fair and efficient medical device manufacturers' supply chain. The combined impact of labor, market concentration, and pricing strategies on the global supply chain of the medical device industry can result in various outcomes. These may include the following:

a. Geographical distribution of manufacturing facilities: Companies may choose to locate manufacturing facilities in regions with favorable labor costs and expertise. Market concentration also leads to the clustering of production activities around dominant players.

b. Innovation and R&D investments: Availability of skilled labor and concentration of market power impact the allocation of resources towards innovation, and R&D. Dominant companies may have more resources to invest in research, leading to the development of advanced medical technologies [89].

c. Access to medical devices and pricing disparities: Market concentration and pricing strategies affect medical device availability and affordability in different regions. Higher concentration and pricing strategies limit access to specific devices or lead to market pricing disparities.

d. Competition and market dynamics: Market concentration can affect competition levels within the MedTech industry. A highly concentrated market may limit the entry of new players and potentially stifle competition, innovation, and product diversity.

STRATEGIES TO MITIGATE RISKS AND CHALLENGES IN THE MEDICAL DEVICES SUPPLY CHAIN

Medical device manufacturers take proactive measures to address challenges in the global supply chain and maintain a consistent supply of their products. They adopt various strategies, including diversifying the supplier base, localizing manufacturing, investing in technology and digitization, fostering strong supplier relationships, enhancing supply chain visibility, implementing risk assessment and mitigation strategies, developing contingency plans, collaborating with regulatory authorities, fostering talent development and retention, and monitoring geopolitical and economic factors. By implementing these strategies, medical device companies can strengthen the resilience of their supply chains and minimize disruptions. In the following sections, we will explore some of these strategies in detail and discuss how medical equipment manufacturing companies can effectively utilize them to mitigate risks and ensure the smooth operation of the entire supply value chain.

Supply Chain Diversification

The medical device supply chain transports devices from manufacturers to end-users but faces disruptions and cost issues. Its complexity leads to inefficiencies and delays, necessitating visibility and transparency throughout the system [102]. Supply chain diversification is one of the risk-mitigating strategies to resolve these issues. It is a proactive approach that involves expanding and distributing sourcing and manufacturing activities across multiple suppliers, regions, and markets to minimize risk and increase agility. It includes multi-sourcing and multi-shoring strategies. The risk of supply chain disruption has been receiving massive attention, especially since the pandemic, as countries strive to prioritize scarce resources to meet domestic needs [103]. The MedTech industry actively diversified its supply chain during the pandemic in response to increased demand and declining revenue to mitigate the adverse impact of these disruptions on the supply value chain [104]. Through diversification, manufacturers reduce reliance on a single source or location and increase the supply base, enabling companies to better adapt to disruptions, improve sales performance, provide flexibility, and enhance supply chain resilience [105]. Robinson (2021) emphasizes that a diversified supply chain provides a competitive advantage, drives innovation, opens new markets, and has a positive socioeconomic impact [106]. Agca et al. (2022) support this viewpoint, highlighting the significance of global sourcing in improving operational efficiency and enhancing global competition [103]. Over the past decade, China has served as the global manufacturing and supply hub, with numerous companies' worldwide sourcing raw materials. However, manufacturing outsourcing to China presents certain risks, such as transportation risks and increased shipping costs. Additionally, global trade tensions, such as the China-US trade war, have highlighted the necessity of addressing vulnerabilities in the global supply chain that are crucial for national security and economic competitiveness.

Furthermore, companies must assess vulnerabilities in their supply chain nodes and prioritize critical suppliers, manufacturing plants, and distribution centers for enhanced supply chain resilience in the medical technology (MedTech) industry. This assessment enables the development of effective mitigation plans for comprehensive resilience. Key actions include reviewing financial performance, addressing regulatory risks, managing reputation, strengthening organizational maturity, and addressing structural challenges like trade tensions, climate change, and pandemics [107]. By implementing these actions, medical device manufacturers gain valuable insights into their operations and identify areas for improvement, ultimately enhancing supply chain resilience and minimizing disruptions.

Medical equipment companies adopt proactive measures such as dual-sourcing or multi-sourcing to ensure business continuity and timely delivery. This strategy involves incorporating pre-approved backup suppliers for product components. However, certifying multiple suppliers to meet specifications requires time and resources, underscoring the importance of early consideration during the design process [108,109].

The COVID-19 pandemic has underscored the significance of manufacturers seeking alternative sources of raw materials to meet the increased demand for medical devices. While seeking new sources during stockouts or shortages may address short-term demand, it can result in additional expenses for expedited shipping unless local backup suppliers are available. Collaborating with on-shore or nearby partners can ensure the successful delivery of critical components on-time and within budget [108].

Ensuring high-quality products and services from suppliers is also crucial. Supplier quality management systems, mandated by regulatory bodies like the FDA, require manufacturers to qualify suppliers of raw materials, subcontractors, and consultants. This process ensures that vendors meet the manufacturer's quality and compliance standards, reducing the risk of receiving defective materials or services that could impact product quality and customer [110].

According to research by Lee et al. (2022), MedTech manufacturers with lower market status tend to expand their supply bases more extensively than manufacturers with higher market status [105]. Although further research is ongoing in this area, diversifying the supply chain in the medical device industry would help ensure a prompt, reliable, and flexible supply of products. This diversification would also reduce the potential impact of disruptions on patient care and business operation.

Localized Manufacturing

Localized manufacturing is vital for diversifying medical device supply chains. It entails establishing manufacturing facilities near end-users, reducing reliance on distant sources, and minimizing risks from global disruptions. By adopting this approach, companies can enhance supply chain resilience, ensure prompt delivery of medical devices, and respond effectively to market demands. Moreover, localized manufacturing promotes job creation, economic growth, and improved access to healthcare resources in the localized regions.

Durach et al. (2017) define distributed manufacturing as integrating technology, systems, and strategies to transform manufacturing economics and organization, focusing on location

and scale [111]. Distributed manufacturing involves producing components in different physical locations and managing the supply chain for final product assembly, as discussed by Srai et al. (2016) [112]. Dithurbide (2022) observes companies employing a multi-domestic strategy in distribution, customizing product offerings, and marketing strategies to match specific national conditions.

Location and geography are pivotal in driving innovation and technological advancements, particularly in three-dimensional printing (3DP) for medical device manufacturing. Gebler et al. (2014) emphasize the effectiveness of 3DP in reducing inputs and outputs in markets with low-volume, customized and high-value production chains like aerospace and medical components, leading to lower energy consumption, decreased resource demands, and reduced CO2 emissions throughout the product life cycle [113]. Furthermore, it changes labor structures and facilitates the transition to digital and localized supply chains. Anderson (2012) describes 3DP as a "new industrial revolution," underscoring its potential to democratize manufacturing through online-distributed blueprints and localized production [114].

By establishing manufacturing facilities closer to customers, companies can reduce dependence on distant suppliers, mitigate the risk of disruptions, and enhance supply chain resilience. The localized manufacturing strategy enables a faster, more reliable, and more flexible supply of medical devices, ultimately minimizing the impact on patient care and corporate operations. In recent years, Europe has witnessed a growing trend towards localized manufacturing and supply of medical devices. Various factors drive this shift, including the need for enhanced supply chain resilience, shorter lead times, and improved responsiveness to market demands, and compliance with regional regulations. Several European countries, such as Germany, France, and Switzerland, have established themselves as critical hubs for medical device manufacturing. These countries boast advanced healthcare systems, a skilled workforce, and robust infrastructure, making them attractive destinations for localized production.

Regarding technological advancements, European countries have been at the forefront of innovation in the medical device industry by applying cutting-edge technologies such as additive manufacturing (3D printing) and digitalization. These technologies enable rapid prototyping, on-demand manufacturing, and increased customization of medical devices, all of which are well-aligned with the goals of localized production.

As a recommendation, medical device manufacturers should consider integrating localized manufacturing into their international supply chain strategy. These companies can achieve this by assessing the feasibility of establishing manufacturing facilities in strategic locations, partnering with local companies, and leveraging advanced technologies such as 3D printing. Strong collaboration with regulatory agencies, healthcare providers, and other stakeholders is crucial to ensure compliance, quality assurance, and smooth integration of localized production into the global supply chain. By adopting localized manufacturing, medical device firms can enhance supply chain resilience, ensure timely delivery, and effectively respond to changing market demands. This approach fosters a more reliable and efficient supply chain, benefiting patients and the healthcare industry.

Digitization and Technology Adoption

Technology has been a fad for more than over the past decade with the advent of the Internet of Things (IoT); companies learn and leverage the advancements and advantages it brings to automate their business processes for ease and efficiency. These advancements through digitization and automation extend beyond healthcare delivery to medical equipment manufacturing and the entire supply chain value. Digital technologies are being quickly embraced by the healthcare and medical industries, resulting in creative upgrades to production techniques. Despite the industry's slower adoption of these innovations in the healthcare industry, there have been tremendous improvements in recent years. The production of medical equipment has seen a considerable transformation because of digitization and technology adoption, which has also revolutionized patient outcomes and healthcare delivery [115].

Likewise, supply chain processes are changing because of technology, and old ways of doing things could be more effective. Due to recent technological breakthroughs, decision-makers are becoming more and more aware of the significance of digitization because of its positive impacts. Improved inventory management and supply chain efficiency are one of its advantages. With electronic records and supply chain management software, makers of medical tools can track and monitor inventory levels, shipments, and logistics processes. To increase demand forecasting accuracy, these businesses, according to Khan Kinza (2023), transform their operations by analyzing historical data, market trends, and consumer behavior using advanced analytics and AI-powered algorithms [116]. Cole, Stevenson, and Aitken (2019) highlighted the benefits of digitization to medical device businesses, including enhancing customer satisfaction, reducing inventory costs, eliminating intermediaries, optimizing production schedules, minimizing overstocking, and influencing new product design and development [117]. For instance, producers can track the movement of supplies, monitor inventory levels, and track expiration dates by utilizing radio-frequency identification (RFID) technology. Manufacturers can gather information using RFID readers and the associated tags on items to increase the effectiveness of the supply chain and decrease waste. According to Saghbini (2017), high-value medical devices or physician-preference items contribute to a significant waste of $ 5 billion annually (up to 30% of total waste). To enhance inventory management and visibility for these items, Saghbini proposed using RFID technology [118].

On the other hand, this kind of software combats counterfeiting, ensures product authenticity and improves patient safety by tracking the journey of each device throughout the supply chain. Furthermore, analyzing supply chain data, implementing mitigation strategies, and utilizing predictive analytics and machine learning algorithms allow for proactive management of supply chain risks in business process management [119]. This approach helps identify vulnerabilities and detect potential disruptions, enabling timely risk response to minimize impact.

DISCUSSION

Manufacturing companies play a crucial role in the after-sales service value chain, which involves a network of parts suppliers, manufacturers, repairers, recyclers, remanufacturers, and other service providers. These entities collaborate to co-create value through activities such as maintenance, repair, parts supply during product usage, and recycling and remanufacturing during product disposal [120]. MedTech companies leverage technology to assess supplier capabilities, ensure compliance with regulations, and maintain effective communication throughout the supply chain. Digital platforms and tools facilitate better supplier management, including supplier qualification, performance tracking, and relationship management. Technological platforms and cloud-based solutions facilitate collaboration and information sharing among stakeholders within the supply chain. Such platforms include sharing product specifications, documentation, and regulatory information and fostering better communication and coordination between manufacturers, suppliers, and distributors [121-125].

As the industry adopts technology to optimize business processes, enhance the supply chain of medical devices, and provide value through devices and digital data, it will fuel the global medical devices market. This trend would encourage the development of new business models and holistic care delivery approaches, leading to market growth. Maria Celeste Bailo projected that by the end of 2022, the market would reach $ 464.54 billion, surpassing the $ 425.21 billion in 2021 [126-129].

CONCLUSION AND RECOMMENDATIONS

There are substantial ramifications for the medical device business from supply chain consequences. Manufacturers and other stakeholders confront difficulties, including rising prices, manufacturing setbacks, stockouts, and delivery delays to healthcare facilities. Player interdependence and the global structure of the supply chain amplify these effects. Supplier diversity, stakeholder collaboration, technology adoption, regulatory compliance, market intelligence, and risk management methods would improve resilience and reduce disruptions. By putting these procedures in place, the supply chain will be better able to provide healthcare facilities with high-quality medical devices, which will benefit both patients and healthcare professionals, particularly those in developing nations.

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CONFLICT OF INTEREST

The authors declare that there are no conflicts of interest regarding the publication of this study.

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