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"Economic and regulatory factors impacting the creation of medical device exporting enterprises in Mexico"

"Factores económicos y regulatorios que impactan en la creación de empresas exportadoras de dispositivos médicos en México"

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Abstract. The medical device (MD) industry plays a crucial role in global healthcare, driven by increasing demand, technological advancements, and evolving regulatory frameworks. Despite its rapid growth, the creation of new MD manufacturing companies faces significant economic and regulatory challenges. This study provides an exploratory and descriptive analysis of the key factors influencing MD business creation, focusing on market demand, investment costs, patent development, quality certification, and regulatory compliance. Through a review of statistical data, trade reports, and academic literature, the study examines the global MD market landscape and highlights the strategic role of North America, particularly Mexico and Canada, in supplying the U.S. market. Findings indicate that while the U.S. dominates the MD industry, Mexico and Canada remain underutilized markets, presenting opportunities for new businesses to enter the MD exportation sector. The study concludes that fostering innovation, regulatory compliance, and leveraging nearshoring strategies could enhance MD business creation in emerging markets. Future research should incorporate empirical studies to validate these findings and assess policy interventions that facilitate industry growth.

Keywords. Medical devices, business creation, enterprise creation, economic factors, regulatory compliance, export industry.

Resumen. La industria de dispositivos médicos (DM) desempeña un papel crucial en la atención médica global, impulsada por la creciente demanda, los avances tecnológicos y los marcos regulatorios en evolución. A pesar de su rápido crecimiento, la creación de nuevas empresas manufactureras de DM enfrenta desafíos económicos y regulatorios significativos. Este estudio proporciona un análisis exploratorio y descriptivo de los factores clave que influyen en la creación de negocios de DM, con un enfoque en la demanda del mercado, los costos de inversión, el desarrollo de patentes, la certificación de calidad y el cumplimiento normativo. A través de una revisión de datos estadísticos, informes comerciales y literatura académica, el estudio examina el panorama global del mercado de DM y resalta el papel estratégico de América del Norte, particularmente México y Canadá, en el suministro del mercado estadounidense. Los hallazgos indican que, si bien Estados Unidos domina la industria de DM, México y Canadá siguen siendo mercados infrautilizados, lo que presenta oportunidades para que nuevas empresas ingresen al sector de exportación de DM. El estudio concluye que fomentar la innovación, el cumplimiento normativo y aprovechar las estrategias de nearshoring podría mejorar la creación de negocios de DM en mercados emergentes. Las

investigaciones futuras deberían incorporar estudios empíricos para validar estos hallazgos y evaluar intervenciones políticas que faciliten el crecimiento de la industria.

Palabras Claves. Dispositivos médicos, creación de negocios, creación de empresas, factores económicos, cumplimiento regulatorio, industria de exportación.

1. Introduction

The MD industry plays a crucial role in improving healthcare and quality of life worldwide. A MD is defined as an instrument, apparatus, machine, implant, or in vitro reagent that includes components, parts, accessories, which diagnoses, cures, treats, or prevents disease or condition. Unlike pharmaceutical products, MD acts on the structure or function of the body without chemical intervention (Food and Drug Administration [FDA], 2022). Given their importance in medical care, the global MD market was valued at approximately $500 billion USD in 2023, with an estimated compound annual growth rate (CAGR) of 3% (Market.Us, 2023). The Americas region leads this industry, with the United States as the world's largest exporter (Pan American Health Organization [PAHO], 2024).

Mexico has established itself as a key player in the MD industry, particularly in manufacturing. Since the implementation of North American Free Trade Agreement (NAFTA) in 1994, the Mexican MD market has shown remarkable growth, positioning the country as an important global manufacturing hub. Between 2003 and 2020, Mexican MD exports grew at an average annual rate of 8.6%, reaching a total export value of approximately $10.668 billion USD, with the United States as the primary destination (Pineda, 2022). However, despite the sector's expansion, the national industry remains highly dependent on imports, with only one-fifth of the total production coming from domestic manufacturers (González, 2022).

The creation of MD manufacturing companies in Mexico faces multiple challenges influenced by economic and regulatory factors. Key determinants such as market demand, initial investment costs, patent development, quality certifications, and compliance with health regulations impact the feasibility and sustainability of these enterprises (Marešová et al., 2020). Additionally, Mexico's reliance on imported MDs, primarily from the United States and China, underscores the need to strengthen domestic production to enhance economic growth and reduce external dependence (INEGI, 2022).

This article analyzes the economic and regulatory factors influencing the creation of MD exporting companies in Mexico. By examining these elements, this research seeks to provide insights into the opportunities and barriers faced by entrepreneurs in this sector. Understanding these dynamics is essential for developing strategies that promote business growth, enhance Mexico's role in the global MD industry, and support the expansion of national manufacturing companies.

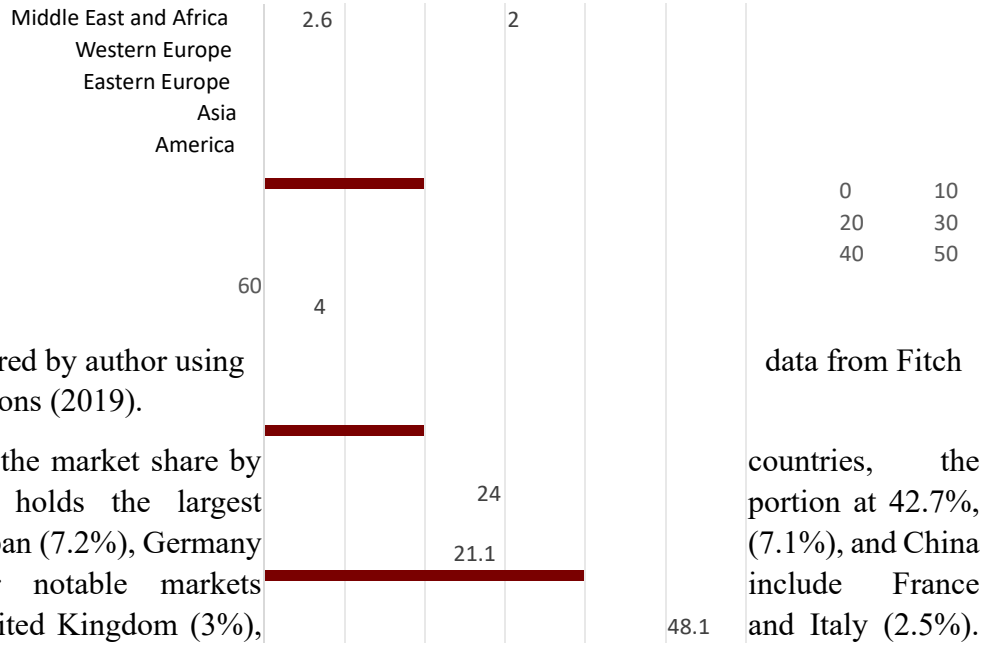
2. Literature review

The creation of new businesses in the MD industry is influenced by a variety of factors, many of which are directly influenced by economic and regulatory elements. These factors not only play a critical role in promoting the establishment of new MD manufacturing companies worldwide but also in determining market entry feasibility and long-term sustainability. This section reviews key theoretical perspectives and empirical studies that provide insight into the factors shaping the development of MD manufacturing firms.

2.1. Market Overview of the Medical Devices Industry

The global market for MD was valued at $404.5 billion in 2019, with the Americas representing the largest share at 48.1%, followed by Western Europe at 24.2%, Asia at 21.1%, Eastern Europe at 4%, and the Middle East and Africa at 2.6% (Fitch Solutions, 2019). This distribution is illustrated in Figure 1.

Figure 1. Percentage by Region of the Global Medical Device Market Value in 2019.



Source: Prepared by author using data from Fitch Solutions (2019).

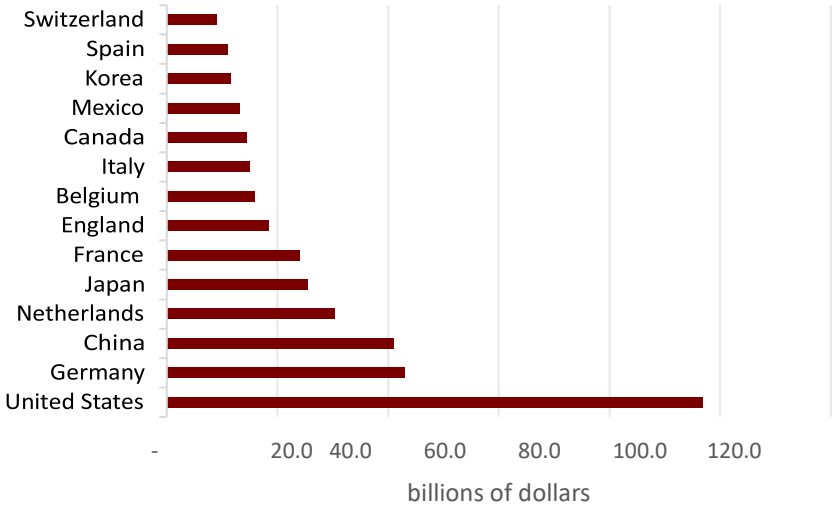
Looking at the market share by countries, the United States holds the largest portion at 42.7%, followed by Japan (7.2%), Germany (7.1%), and China (6.8%). Other notable markets include France (3.8%), the United Kingdom (3%), and Italy (2.5%). Mexico, with a 1.4% share, ranks among the emerging markets in the global MD landscape, as shown in Figure 2.

Figure 2. Percentage by Country of the Global Medical Device Market Value in 2019.

Source: Prepared by author using data from Fitch Solutions (2019).

The MD import market in 2019 was primarily dominated by the United States, Germany, China, the Netherlands, and Japan (Drevinskas et al., 2023), as seen in Figure 3. This underscores the significant role of these countries in global trade in MD.

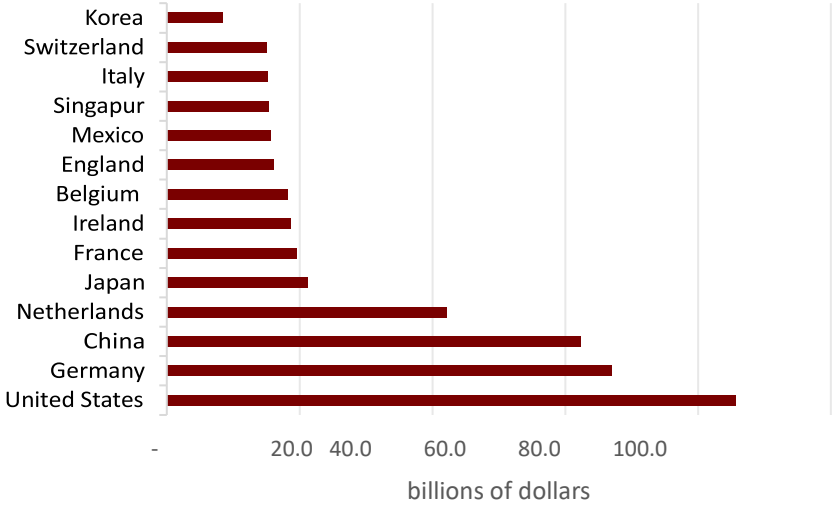
Figure 3. Value of Medical Device Imports by Country in 2019.



Source: Prepared by author using data from Drevinskas (2023).

Simultaneously, the export market for MD mirrors this distribution, highlighting the influence of the same leading countries in driving global exports, as shown in Figure 4.

Figure 4. Value of Medical Device Exports by Country in 2019.



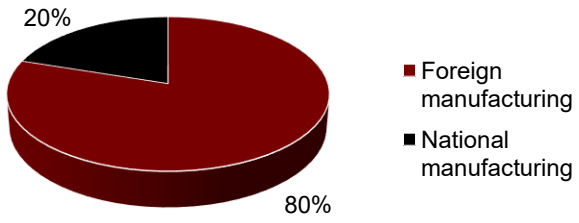
Source: Prepared by author using data from Drevinskas (2023).

In Mexico, the MD market reached approximately $5.86 billion in 2019. The country's export volume significantly outpaces domestic production, with exports reaching $10.67 billion in 2020, compared to $5.42 billion in imports (INEGI, 2022).

A relevant fact is that the Mexican market is covered with more than 80% of imports, which indicates that the national supply is less than 20% as shown in Figure 5, while the volume of exports is almost double the size of the national market, which means that international companies, a large part of which are American, decided to strategically move their industrial and manufacturing operations to the Mexican territory with the aim of

reducing production costs, taking advantage of geographical proximity, high quality standards and staff training in science and technology (BasqueTrade, 2023).

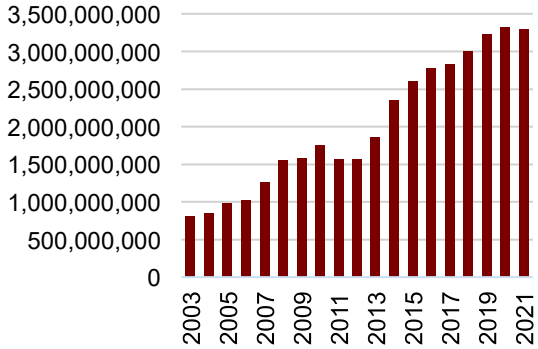
Figure 5. Percentage of Domestic vs. Foreign Manufacturing of Medical Devices in Mexico.



Source: Prepared by author using data from BasqueTrade (2023).

Notably, the growth trend in Mexico's MD export market, particularly within the tariff fraction 9018.90.99 (other medical instruments), shows a positive trajectory, as shown in Figure 6 (SIAVI, 2024).

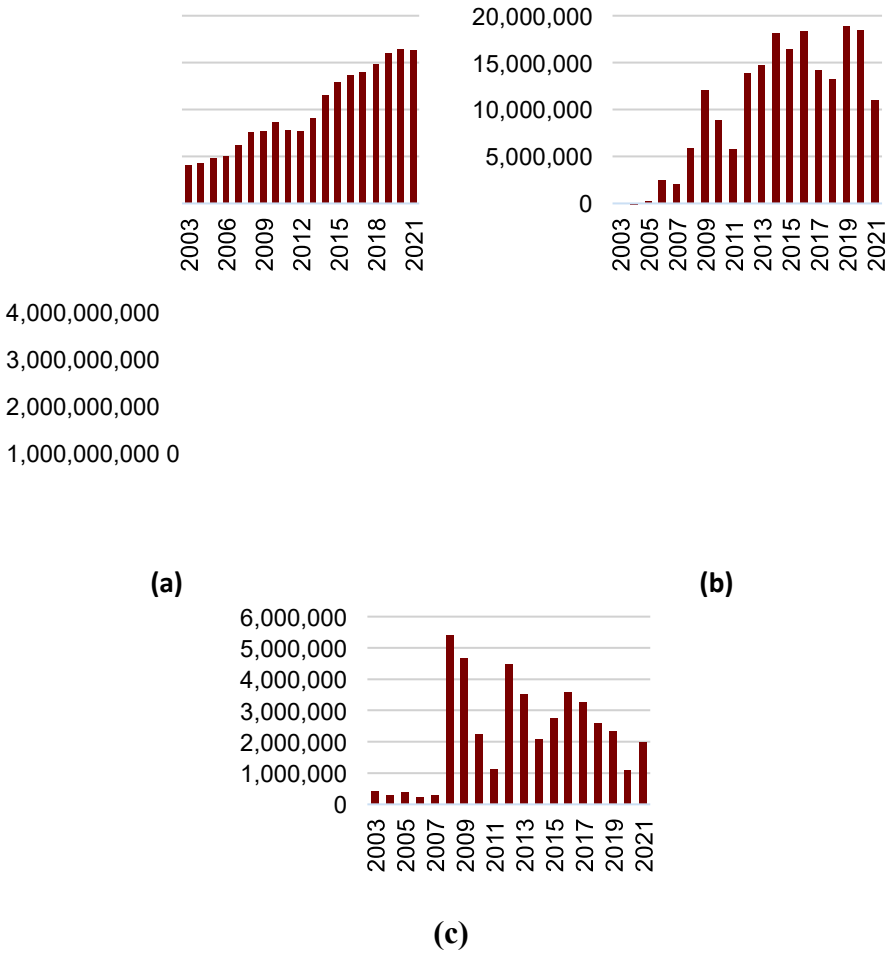
Figure 6. Evolution of Exports of the Tariff Fraction 9018.90.99.



Source: Prepared by author using data from SIAVI (2024).

The United States remains the primary destination for Mexican exports in this category, followed by the Netherlands and Germany. These trends are visually represented in Figure 7, which indicates a growth trend for exports to the U.S. and the Netherlands, while exports to Germany have seen a slight decline.

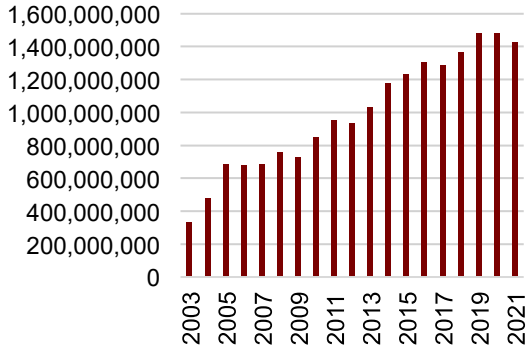
Figure 7. (a) United States, (b) Netherlands, and (c) Germany as the Main Export Destinations for Tariff Fraction 9018.90.99 from Mexico.



Source: Prepared by author using data from SIAVI (2024).

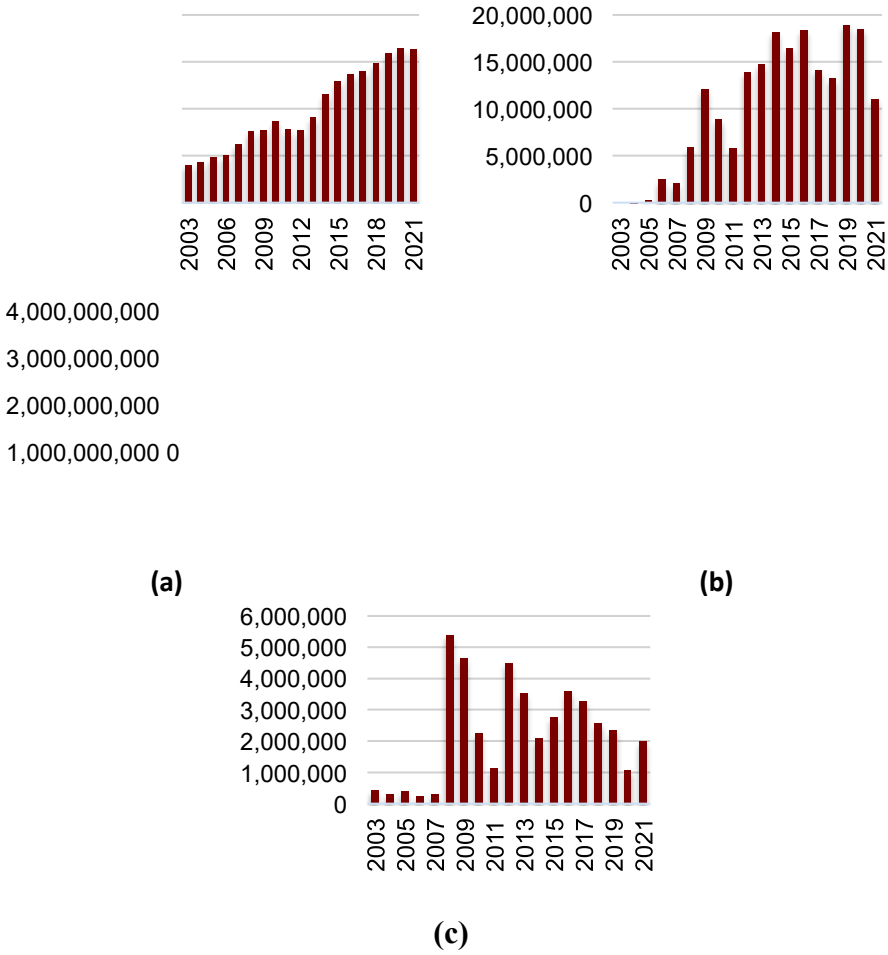
On the import side, the same tariff fraction also exhibits growth, as shown in Figure 8. Countries such as United States, China, and Germany contribute the leading suppliers to Mexico's MD imports, as detailed in Figure 9.

Figure 8. Evolution of Imports of the Tariff Fraction 9018.90.99.



Source: Prepared by author using data from SIAVI (2024).

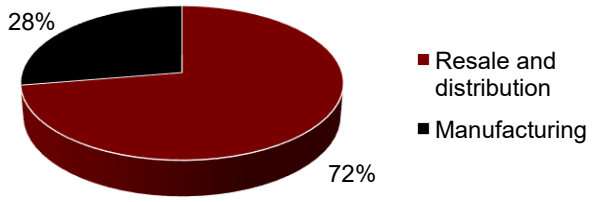
Figure 9. (a) United States, (b) China, and (c) Germany as the Main Import Sources for Tariff Fraction 9018.90.99 to Mexico.



Source: Prepared by author using data from SIAVI (2024).

In Mexico, there are 368 companies dedicated to the commercialization of MD, and 140 companies engaged in the manufacturing of these devices, as shown in Figure 10 (SIEM, 2024). However, only 20% of these manufacturers are national producers, a crucial factor when considering the challenges and opportunities in the domestic market.

Figure 10. Percentage of Medical Device Commercializing vs. Manufacturing Companies in Mexico.



Source: Prepared by author using data from SIEM (2024).

The global MD market, post-COVID-19, has shown a promising growth trajectory, with a market value of $518.46 billion in 2023 and an estimated projection to reach $886.8 billion by 2032 (Fortune Business Insights, 2024). In Mexico, the compound annual growth rate (CAGR) is estimated at 6.2%, while the United States is seeing a similar growth trend of 6.1% (BasqueTrade, 2023; Fortune Business Insights, 2024).

The trade dynamics, including the growing reliance on nearshoring due to the shifting economic and political landscape, underscore Mexico's strategic position as a hub for manufacturing MD for the U.S. market (Barry et al., 2023). This shift is largely driven by the proximity, favorable labor costs, and robust regulatory standards that make Mexico an attractive destination for U.S. companies.

The MD industry has seen remarkable growth driven by key factors which have played a significant role in the establishment of new businesses in this sector. The increasing demand for MD worldwide has created a robust market for companies to capitalize on. As the global healthcare sector expands, there is a rising need for innovative solutions and high-quality products, encouraging new players to enter the market and meet these needs (Arango, 2017).

One of the key factors behind the growth of the MD industry is the lower production costs and attractive infrastructure in some regions. As highlighted by Gómez (2018), the possibility of reducing initial investments and operating more efficiently in countries with favorable economic conditions incentivizes the establishment of new companies. This is especially relevant in markets where production costs are a key consideration for companies seeking to remain competitive in a rapidly evolving industry.

Technological advancements and the continuous development of patents are also essential for fostering new enterprises. Löfsten (2015) emphasizes how research and development in medical technologies have allowed companies to stay competitive by creating cutting-edge solutions. As a result, startups and new companies are encouraged to innovate and bring fresh ideas to the market, increasing the overall value of the sector.

Furthermore, international certifications and compliance with quality standards have opened doors for companies to expand their market reach globally. Wu and Wu (2019) explain that businesses meeting international quality standards have better opportunities for

exporting their products. The ability to access foreign markets significantly boosts the potential for new businesses, especially those looking to expand beyond domestic boundaries.

The regulatory environment, including the requirement for sanitary registration, also plays a critical role in facilitating the creation of companies. As noted by Huusko et al. (2023), the clarity and accessibility of the regulatory process help new businesses enter the market and participate in global trade. By ensuring that MD meets necessary standards, companies can increase their credibility and attract more investment.

In summary, factors such as market demand, investment costs, patents development, quality compliance and the ability to meet regulatory requirements all contribute to the growth of the MD industry. As these factors continue to evolve, they present further opportunities for the creation of new businesses in this sector, ultimately shaping the future of global healthcare.

2.2. Theoretical Framework for Business Creation

The history of business creation dates to ancient civilizations like Greece, China, and Rome, where entrepreneurial activities through trade and usury began to lay the foundations for today's business landscape (Góral et al., 2022; Kolesnik et al., 2013). Today, business creation is considered a vital driver of economic growth, and it involves various stages, from identifying opportunities to securing financial resources and successfully entering the market (Sánchez, 2015). Drucker's Business Theory (2017) offers a framework to understand how entrepreneurs define their mission, adapt to environmental changes, and create organizations that can thrive in a competitive market. According to Villar et al. (2014), business creation encompasses the entire journey, from the conception of an idea to its realization. Key motivations for entrepreneurial ventures are varied, ranging from continuing a family legacy to creating wealth (BBVA, 2023).

Factors influencing business creation are complex, and previous studies highlight both external and internal obstacles that entrepreneurs face. For instance, Genesca and Veciana (1984) identified barriers such as lack of capital and political instability, which can hinder new ventures. Meanwhile, Gómez et al. (2018) emphasized the importance of market demand as a key driver for business creation. The empirical analysis conducted by these authors underscores the significance of understanding market dynamics to validate business opportunities.

2.3. Theoretical Framework for Economic and Regulatory Factors

a. Market Demand as a Reason for Business Creation

Market demand is a foundational concept in economics and directly affects the establishment of new businesses. It is influenced by consumer preferences, purchasing power, and overall market conditions (Aruka, 2015). The theory of supply and demand, developed by economists like Werner Hildenbrand (1994), explains how market demand is shaped by the

interactions between consumers' needs and producers' supply. According to Peiro (2024), market demand represents the willingness of consumers to acquire products at various price points, while Moya (2015) highlights its direct relationship to market size and potential sales volume. However, high demand does not automatically translate into business growth. Barriers such as industry consolidation, intellectual property restrictions, and supply chain dependencies can limit new entrants despite strong market opportunities.

In Mexico, for example, over 80% of the domestic MD market is supplied by imports (BasqueTrade, 2023), which suggests that local companies struggle to compete with established international manufacturers. This heavy reliance on foreign suppliers presents both a challenge and an opportunity, while it reflects barriers to local business creation, it also indicates a market gap that could be filled by domestic firms if investment and regulatory conditions improve.

Several empirical studies demonstrate the critical role of market demand in the creation of businesses. For instance, Arango (2017) found through a study in Colombia that market demand is a primary driver for entrepreneurs, as it signals opportunities for business growth. Additionally, Kirkley (2016) explored how customer demand and market opportunities influence entrepreneurial decisions. His research, conducted with entrepreneurs in New Zealand, reveals that understanding customer needs and market conditions is essential for business success.

b. Investment Costs and Competitive Advantages

Investment costs are another crucial determinant in the process of business creation. The historical development of economic theories, such as the "supply function" and "adjustment costs," provide valuable insights into how investment decisions are made (Mussa, 1977). These theories indicate that investment decisions are influenced by the expected returns and the costs associated with entering a new market (Casson & Casson, 2014).

The costs associated with setting up a new business include expenses related to machinery, technology, product development, and labor (Kuri, 2021). Investment in these areas is essential for the business's ability to function and compete in the marketplace. According to MytripleA (2024), initial capital investments can be substantial, requiring financial resources for technology, licenses, and administrative expenses.

Research highlights the direct relationship between investment costs and business creation. Blazenko and Pavlov (2009) argue that businesses are established when expected returns exceed financial opportunity costs. Furthermore, studies by Eka and Rahman (2022) and Saraiva et al. (2020) emphasize the importance of continuous investment and financial management in sustaining and expanding new ventures.

Countries with favorable production and investment costs, skilled labor, and welldeveloped industrial infrastructure tend to attract more MD companies. Mexico and Canada, for example, have become key manufacturing hubs for U.S. firms looking to reduce

production costs through nearshoring strategies (Barry et al., 2023). Despite Mexico's 1.4% market share, compared to the U.S. at 42.7%, its strategic advantages such as lower labor costs, geographic proximity, and trade agreements like the United States-Mexico-Canada Agreement (USMCA) position it as a viable alternative to Asia for MD production. However, the fact that most MD companies operating in Mexico are foreign-owned means that profits often leave the country rather than fueling local industry expansion.

c. The Role of Innovation and Patent Development

Patent development is a key component in fostering innovation and encouraging new business creation. The U.S. patent system, which grants inventors exclusive rights to their creations, has long been recognized to stimulate technological advancements and enable entrepreneurs to commercialize their inventions (Lamoreaux & Kenneth, 2001). The protection provided by patents serves as an incentive for innovation, granting a competitive edge to businesses by preventing imitation (Wadhwani & Lubinski, 2018).

Fisher (2001) suggests that intellectual property protections, such as patents, play a significant role in business creation by safeguarding valuable assets and encouraging new ideas. Löfsten (2015) further explores this by examining 131 startups in Sweden, showing that a robust patent strategy contributes to business success. Similarly, Giudici et al. (2017) found that patent development is an essential factor influencing the creation of tech startups, highlighting its positive impact on business growth.

In Mexico, patent development remains limited compared to major MD exporters like the U.S. and Germany, highlighting the need for policies that encourage local R&D investment and technology transfer initiatives.

d. The Strategic Importance of Certification and Market Access

Beyond regulatory approvals, international quality certifications play a crucial role in determining market entry success. The importance of quality certifications has grown as consumer demands for high-quality products and services have increased. Certifications, which ensure compliance with recognized standards, serve as a signal of reliability and safety for consumers and businesses alike (Viadiu et al., 2002; Wimmer & Chezum, 2007). The theory of Total Quality Management (TQM) underscores the significance of customer satisfaction, continuous improvement, and employee involvement in ensuring product quality (Aichouni et al., 2023).

Companies that obtain certifications such as ISO 13485 or FDA 510(k) clearance gain a significant competitive advantage in global trade (Wu & Wu, 2019). Without these certifications, even companies with high-quality products may struggle to secure distribution agreements and access foreign markets, also, their study, involving 878 manufacturing firms in China, found that obtaining certifications boosts product performance and market competitiveness. Utami et al. (2021) also found that TQM practices significantly improve startup performance, providing new companies with a competitive edge.

In Mexico, where many MD companies are foreign-owned, local manufacturers must compete at an international level to remain viable. This requires not only compliance with domestic regulations but also alignment with global quality standards, reinforcing the need for stronger support mechanisms for certification processes.

e. Regulatory Compliance as a Market Barrier

Health regulations are fundamental to ensuring the safety and efficacy of MD, especially in sectors like medical technology. The concept of regulatory compliance is rooted in the U.S. market economy of the 19th century and has evolved into a global necessity to protect public health while enabling the smooth flow of trade (Jacobson, 2001). Health regulations, such as the International Health Regulations, aim to minimize risks associated with public health threats and ensure that products meet established standards (Nuttall, 2014).

Maci and Marešová (2022) highlight the importance of compliance with health regulations, noting that adherence to these regulations not only ensures consumer safety but also fosters fair competition and innovation. Compliance with standards such as ISO 13485, FDA approvals, and CE marking is often a time-consuming and costly process, requiring companies to invest heavily in quality assurance and regulatory expertise. Studies, such as those by Huusko et al. (2023), demonstrate the critical role that compliance with health regulations plays in the success of MD companies. Their study in Finland found that health regulatory compliance directly influences the establishment and success of new companies in the MD sector.

3. Methodology

This article adopts an exploratory and descriptive approach to examine the economic and regulatory factors influencing the creation of MD manufacturing companies in Mexico. The study synthesizes historical trends, statistical data, and theoretical frameworks to provide a structured understanding of industry dynamics. By relying on secondary data, this research serves as a foundation for future empirical studies, offering insights into market conditions, investment trends, and regulatory environments.

3.1. Research design

A documentary research design was adopted to analyze quantitative and qualitative secondary sources. This approach allows for a systematic review of statistical trends and theoretical information, ensuring a comprehensive assessment of the MD industry. The study integrates market intelligence reports, trade databases, and academic literature to contextualize how economic and regulatory variables influence business creation.

3.2. Data collection

The study relies on secondary data from official sources, including:

a. Market and Trade Data

SIAVI (2024), BasqueTrade (2023), and INEGI (2022), provide insights into Mexico's MD trade flows, import dependency, and export growth.

Fitch Solutions (2019) and Fortune Business Insights (2024), offer global market valuations and regional growth trends, contextualizing Mexico's role in the global MD landscape.

b. Regulatory and Business Environment Data

Huusko et al. (2023) and Wu & Wu (2019), discuss how regulatory compliance affects business entry and international market access.

SIEM (2024) and SCIAN databases, identify the number and type of MD manufacturers in Mexico, highlighting gaps in domestic production capacity.

c. Academic Literature

Arango (2017), Gómez (2020), and Löfsten (2015), explore economic factors influencing MD business creation, including market demand, investment costs, and patent development.

Barry et al. (2023), Provide insights on nearshoring trends, a key factor shaping investment decisions in North America's MD sector.

3.3. Dana Analysis

A comparative and interpretative approach was used to analyze how Mexico's MD industry aligns with global market conditions. The study identifies: 1. Key economic and regulatory trends shaping MD business creation.

2. Comparative insights on Mexico's position relative to leading MD markets (U.S., Germany, China, etc.).
3. Strategic implications for business creation, emphasizing Mexico's potential for nearshoring and domestic industry expansion.

3.4. Scope and Limitations

This study does not involve primary data collection, instead, it offers a theoretical and statistical foundation for future research. Given their reliance on secondary sources, real-time market dynamics and recent regulatory developments may not be fully captured. Future studies should incorporate surveys, case studies, or firm-level analyses to validate and expand upon these findings.

4. Conclusions

The MD industry plays a vital role in global healthcare, with market expansion driven by economic and regulatory factors that influence business creation. This study highlights how market demand, investment costs, patent development, quality certification, and regulatory compliance shape the emergence of MD manufacturing companies. These factors not only determine entry conditions for new firms but also define their long-term competitiveness in an increasingly regulated and technology-intensive industry.

A key finding is that market demand alone is not sufficient to drive business creation, the ability to overcome regulatory barriers, manage investment costs, and obtain international certifications is equally critical. Despite a growing global market, high entry costs and complex regulatory environments remain major obstacles for new companies, particularly in emerging economies.

The study identifies a major gap in North America's MD industry structure. While the United States dominates the global market with a 42.7% share, Mexico and Canada account for only 1.4% and 1.8%, respectively. This discrepancy presents an opportunity for new companies to enter the sector with a focus on exporting to the U.S., where demand continues to grow.

Furthermore, Mexico's 80% import dependency indicates a significant reliance on foreign manufacturers, meaning that most profits generated in the country are redirected to overseas companies. While foreign firms benefit from Mexico's skilled workforce, competitive labor costs, and trade advantages, the lack of domestic players limits local industry development.

To strengthen domestic MD manufacturing and reduce import dependency, the following strategic actions could be considered:

1. Enhancing local innovation and patent development. Policies that promote research funding, technology transfer programs, and industry-academia collaborations can help increase Mexico's intellectual property output and reduce reliance on foreign technologies.
2. Facilitating market entry for new manufacturers. Streamlining regulatory processes, reducing approval delays, and expanding support for ISO 13485 and FDA certification would enable local companies to access international markets more efficiently.
3. Leveraging nearshoring for industry expansion. Given U.S.-China trade tensions, Mexico is strategically positioned to attract investment from American MD firms. Developing industrial clusters, improving supply chain resilience, and strengthening cross-border logistics could further enhance its role in the North American market.

4. Strengthening incentives for domestic production. Government incentives such as tax benefits, export financing, and investment in high-tech manufacturing infrastructure could help increase local business participation in the MD sector.

This study serves as a theoretical and statistical foundation for future empirical research. Future studies could:

1. Conduct surveys and case studies with MD manufacturers to validate the economic and regulatory factors identified.
2. Perform comparative analyses between Mexico and other emerging MD markets (e.g., Brazil, India) to assess competitive positioning.
3. Investigate the long-term impact of nearshoring on MD industry growth in North America.

By studying these gaps, future research can provide data-driven recommendations for policymakers, industry leaders, and investors seeking to strengthen the global MD manufacturing landscape.

5. Conflict of Interest Statement

By submitting this paper, I acknowledge that I am the author of the submission and that I have the permission of all co-authors to include this paper/summary note/abstract in the 29th Annual Western Hemispheric Trade Conference Proceedings. I also acknowledge that I have the rights to include any third-party materials in the submission.

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