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Adam received an MBA from Northwestern University Kellogg and a bachelor's in accounting from the University of Illinois at Chicago. He is a Certified Public Accountant with extensive experience evaluating, transforming, and leading financial, accounting, operations, and IT organizations in manufacturing, advisory, and military environments.

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The Influence of Economic Factors on Biopharmaceutical Manufacturing

The biopharmaceutical industry is a fast-growing sector of the US economy, contributing “1.53% of all U.S. GDP in 2021, and 9.94% of Manufacturing’s contribution to GDP in the same year.”¹ However, its stability and growth are intricately linked to the broader economic environment, including inflation, recession, and legislative changes. These economic elements not only influence the operational dynamics of biopharmaceutical companies but also have far-reaching implications on healthcare accessibility and innovation. The focus here is to unravel and comprehend the complex effects these economic factors exert on the biopharmaceutical manufacturing sector.



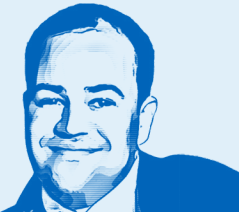
INFLATION

Inflation, characterized by the general rise in prices, significantly impacts the biopharmaceutical manufacturing sector, particularly in 2023, when an increase in prices is challenged only by new healthcare reimbursement constraints. “40% of healthcare industry professionals (surveyed) viewed inflation as having the biggest negative impact on the biopharmaceutical industry in 2023, followed by pricing and reimbursement constraints (31%).”² As raw material costs, equipment expenses, and labor wages increase, companies face elevated operational costs. This escalation often compels firms to adjust their pricing strategies, sometimes leading to higher drug prices, which raises concerns about healthcare affordability and access. Moreover, inflation can dampen investments in research and development (R&D), which is the lifeblood of innovation in this industry. The delicate balance between managing increased costs and sustaining investment in R&D becomes a crucial challenge during inflationary periods.

To counter these challenges, several strategies can be implemented. First, the manufacturers could increase their investment in automation and technology to streamline operations and reduce labor costs. This approach not only addresses the issue of labor redundancy but also enhances efficiency. Second, diversifying supply chains can be a crucial step. By sourcing materials from a broader range of suppliers and locations, companies can reduce the risk of disruptions and delays. Lastly, a focus on lean management practices can help control operational expenses. Implementing cost-control measures and optimizing resource usage can play a pivotal role in maintaining profitability in an inflationary environment. Together, these strategies can help the biopharmaceutical industry navigate through economic challenges and sustain its growth momentum.

¹ <https://ei.com/wp-content/uploads/2023/05/BioPharma-Economic-Impact-on-the-US-Economy.pdf>.

² <https://www.globaldata.com/media/pharma/inflation-drug-pricing-reimbursement-constraints-will-biggest-negative-impact-biopharmaceutical-industry-2023-finds-globaldata/>.



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RECESSION

Recessions, marked by a decline in economic activity, can slow down biopharmaceutical innovation. The demand for certain pharmaceutical products may fluctuate as financial constraints influence healthcare spending. For instance, elective and non-urgent treatments might see reduced demand, affecting associated pharmaceutical products. Additionally, funding for new ventures and research initiatives often becomes scarcer during recessions. Companies might resort to operational streamlining, delaying expansion plans, or even downsizing to maintain financial stability. Although these measures are crucial for immediate survival, they can have a detrimental effect on the industry's growth and innovation over time.

Furthermore, during recessions, biopharmaceutical manufacturers might face challenges in securing loans and other forms of credit, which are essential for funding ongoing research and development projects. The tightening of credit markets can lead to reduced liquidity, forcing companies to prioritize short-term financial commitments over long-term research investments. This shift can delay the introduction of new treatments and slow the pace of medical advancements.



Recessions pose a multifaceted challenge to biopharmaceutical manufacturers, affecting everything from funding and credit availability to supply chains and regulatory landscapes. The cumulative effect of these challenges can significantly hinder the industry's ability to innovate, grow, and deliver new treatments to patients.

Several tactics can be employed to navigate through these challenges. First, the manufacturers could increase their investment in automation and technology to streamline operations and reduce overall costs. This approach addresses the expensive issue of labor redundancy and enhances efficiency. Secondly, diversifying supply chains can be a crucial step. By sourcing materials from a broader range of suppliers and locations, companies can reduce the risk of disruptions and delays. Lastly, focusing on lean management practices can help control operational expenses. Implementing cost-control measures and optimizing resource usage can be pivotal in maintaining profitability in an inflationary environment. Together, these strategies can help the biopharmaceutical manufacturer develop a long-term plan that navigates economic challenges and sustains its growth momentum despite economic conditions.



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LEGAL AND REGULATORY LANDSCAPE

The economy plays a crucial role in shaping the legal and regulatory landscape governing biopharmaceutical manufacturing. Economic policies and legislative changes can lead to new regulations, affecting everything from manufacturing standards to drug approval processes and market accessibility. Compliance with these evolving regulations incurs additional costs, further straining company budgets. Furthermore, international trade laws and tariffs, influenced by economic agreements and conflicts, critically impact global supply chains. These changes can disrupt established networks, affecting raw materials and finished products' availability and cost.



The most recent and impactful change is arguably the Inflation Reduction Act (US). This act helps to ensure that drug prices do not over-inflate. The main change was to “introduce drug price negotiations and caps on annual price rises. This affects the industry by potentially reducing revenue from high-cost drugs, particularly those covered by Medicare.”³ The impact will remain to be seen as the implementation was in 2023. This may shape decisions related to drug development and regulatory submissions, potentially shifting focus toward specific drug types over others.

National economic policies, healthcare spending, and insurance coverage changes can also directly impact the biopharmaceutical industry. Policies that affect healthcare funding, drug reimbursement rates, or the inclusion of drugs in national healthcare systems can alter market dynamics. Biopharmaceutical companies must stay attuned to these policy changes, adjusting their market strategies and pricing models accordingly to remain competitive and ensure access to their products.

³ [https://www.giejournal.org/article/S0016-5107\(20\)34466-7/fulltext](https://www.giejournal.org/article/S0016-5107(20)34466-7/fulltext).



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The future of the biopharmaceutical industry, therefore, lies in its agility and resilience in the face of economic challenges, ensuring continued advancement in healthcare and treatment for all.

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To mitigate the potentially restrictive and negative business impacts of these policies, several risk-averse measures can be adopted. Emphasizing agile business models and flexible production systems can help companies adapt quickly to changing regulatory landscapes. Investing in robust risk management and scenario planning can prepare businesses to navigate financial uncertainties more effectively. Furthermore, fostering strong relationships with investors, stakeholders, and research partners can secure a stable flow of resources and support collaborative efforts towards innovation even during tough economic times. Maintaining a strong focus on core competencies while exploring diversification in product lines or therapeutic areas can also mitigate risks associated with a narrow market focus. These approaches, combined, can equip biopharmaceutical manufacturers to withstand the adverse impacts of government regulations, ensuring resilience and sustained growth



While resilient and innovative, the biopharmaceutical manufacturing industry is not impervious to the fluctuations and shifts of the economic environment. Inflation, recession, and changing laws each present unique challenges, from escalating operational costs to reshaped demand and complex regulatory compliance. As the industry navigates these turbulent economic waters, its ability to adapt and innovate remains crucial. Companies that can effectively manage these economic impacts, while continuing to invest in R&D and maintain regulatory compliance will not only survive but thrive. The future of the biopharmaceutical industry, therefore, lies in its agility and resilience in the face of economic challenges, ensuring continued advancement in healthcare and treatment for all.

Questions?

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