



Accessing the Scale of the Pharmaceutical Industry and How Supply Chain Dynamics Influence Outcomes

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Abstract

The U.S. pharmaceutical sector stands as a foundation of national health and economic strength with revenue of over \$550 billion a year, over 800 000 workers, and spending over \$100 billion annually on research and development (R&D). A careful estimate of the scale of the industry is dependent on factors such as market size, estimates for capacity, an analysis of employment levels, revenue streams, and R&D spending using data collected by the U.S. Bureau of Economic Analysis (BEA), IQVIA, U.S. Bureau of Labor Statistics (BLS), as well as various company disclosures. The supply chain involving the network of manufacturing, distribution, regulation, logistics, cold chain, digital requirements, and resiliency are all major factors that will impact drug quality, cost, availability, patient safety, and other key performance indicators (KPIs) associated with an organization. The COVID-19 pandemic exposed fragility in global sourcing, reliance on single sourcing, and distribution-breaking bottlenecks in the pharmaceutical supply chain, prompting companies to pivot towards agile manufacturing processes, digital tracking, and regional resiliency hubs as encouraged by U.S. pharmaceutical companies such as Pfizer, Johnson & Johnson, and Merck. The purpose of this paper is to provide an overview on how to estimate scale in the pharmaceutical industry, identify impactful components of the supply chain, describing their impact on various outcomes, review case studies of major U.S. pharmaceutical companies, and discuss the implications of policy and strategy. Recommendations include enhancing data transparency, diversifying suppliers, investing in cold chain and digitalization, and working directly with regulators to ensure patient access and operational efficiency to the organization.

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Introduction

The United States pharmaceutical industry is unmatched in the global marketplace and remains the catalyst for innovation and establishing best practices for drug discovery, development, manufacturing, and distribution to the patient. U.S. prescription sales in 2024 exceeded \$550 billion in 2024, representing nearly 45% of total global sales. The Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) impose requirements and continue to ensure regulatory requirements for safety monitoring of pharmaceutical drugs to safeguard quality in the drug development, pharmaceutical manufacturing industry. supply chains are complex by design and include activities related to the procurement of raw materials, active pharmaceutical ingredient (API) supply (and synthesis), drug formulation, packaging, distribution and delivery to the patient and/or prescriber. Effective and efficient supply chain management is imperative for maintaining accomplished drug cost, availability, consequent patient safety, and other business-related key performance indicators (KPIs) such as on-time delivery, product returns, and product recalls. Recent world events, particularly the COVID-19 pandemic, identified vulnerability indicators in pharmaceutical supply chains related to the availability of APIs, transportation issues, and failures in cold-chain

transport conditions which requires a new mindset to address resilience. The objectives of this paper are to (1) summarize approaches which define the scope of the U.S. pharmaceutical drug industry, (2) visualize components of pharmaceutical supply chains, (3) explain how these components contribute to outcomes (4) provide examples for Pfizer, and Johnson & Johnson and Merck (5) reflect policy and strategic decision-making implications for stakeholders including policy makers, producers, and health care providers.

Sizing Up the U.S. Pharmaceutical Industry Market Size and Revenues

The U.S. pharmaceutical market reached \$551 billion as of 2024, propelled by specialty therapies and biologics. Sources of data include IQVIA's report "Global Use of Medicines," as well as the Bureau of Economic Analysis (BEA) national accounts. We combined wholesale distributor sales with retail pharmacy receipts and volume from the hospital channel to do this assessment.

Production Capacity

As it relates to production capacity, it is measured as throughput at manufacturing sites, or in dosage units. The FDA submits its annual report entitled "Pharmaceutical Quality/Manufacturing Report," which monitors over 5,000 active manufacturing establishment sites domestically and abroad, estimating that U.S. establishments represent roughly 40% of active manufacturing capacity. Utilization rates among major manufacturers, utilize capacity ranging from 75%-85%.

Employment and Workforce

According to the Bureau of Labor Statistics (BLS), as of 2024, the Pharmaceutical and Medicine Manufacturing Industry directly employed 820,000 workers, with median wages in production work averaging \$50/hour and R&D scientists averaging about \$90/hour. There are workers in both roles with varying educational backgrounds, including high-school technical certifications to PhDs in Chemistry, Biology, and Engineering.

Research and Development Investment

U.S. companies assigned \$114 billion to Research and Development (R&D) in 2023, accounting for roughly 20.7% of total world spend in pharmaceuticals R&D. R&D intensity (R&D expenditures as a percentage of sales), averaged 25% among the top-ten U.S. pharmaceutical companies. Patents filed with the U.S. Patent and Trademark Office (USPTO) are often used as proxies of innovation output.

Critical Supply Chain Characteristics in the U.S. Manufacturing and Sourcing Networks

The manufacture of pharmaceuticals is a global event. Approximately 80% of small-molecule active pharmaceutical ingredients (APIs) are procured from China and India, whereas the manufacture of raw materials for biologics is mostly confined to North America or Europe. Single-source dependence increases the risk of vulnerability to potential political unrest/wars and regulatory differences to API, intermediaries, and dosage forms.

Distribution Channel and Logistics

The "Big Three" wholesalers- AmerisourceBergen, McKesson, and Cardinal Health - account for 85% of all distribution of medicines sold to pharmacies and hospitals. The "cold chain" is managed by third-party logistics providers in temperature-controlled environments, which employ GPS technology to track transport temperatures.

Regulatory Oversight

The FDA's Current Good Manufacturing Practice (cGMP) regulations commence with producing APIs and do not conclude until the drugs are available for patient administration. The Drug Supply Chain Security Act (DSCSA) requires certain prescription products to be tracked electronically through serialization and verification for safety and security to reduce counterfeit drugs.

Technology and Digitization

Digital supply chain-related technologies, including blockchain to provide traceability, IoT sensors for realtime stocking monitoring, and comprehensive analysis tools for demand forecasting, are being adopted by the pharmaceutical industry. As an example of industry commitment to this change, a 2023 Deloitte survey of industry executives indicated 68% of executives expected to invest in digital twins and AI-driven optimization of accuracy on quality oversight of products in inventory.

Cold-Chain Requirements

Vaccines, biologics, and some small-molecule therapies require stringent conforming to cold-chain supply chain protocols (-70 °C for mRNA vaccines or 2 °C-8 °C). Any out-of-range experience potentially compromises the product's potency for use in patients and safety. One example of this, is that can be seen for the vaccines by Pfizer-BioNTech and how much care went into their transport for effectiveness. If cold-chain protocols are violated, the reported waste rate as high as 10% could be observed in some areas.

Impact of Supply Chain Dynamics on Outcomes Quality and Safety

Compliance to cGMP and to serialization both improve quality factors of contamination and security against counterfeit. With phased timing of the DSCSA implementation expected to achieve full unit-level traceability by 2025, the estimate is for recalls to be decreased by 30% and shift-back events reduced by 40%.

Costs and Prices

Supply chain inefficiency due to sourcing of offshore APIs, as one example, and manual systems of checking inventory add about 20% overall in manufacturing costs. Digital systems such as formulating demand forecasts could potentially reduce excess inventory by 15% and reduce stock outs by 25% lowering the overall cost of carrying.

Availability and Accessibility

The limited availability of critical medications, including epinephrine auto-injectors and supportive oncology medications, illustrates systemic vulnerabilities. The logistics

of vaccinating the United States against COVID-19 required scaling the U.S. cold-chain distribution capacity in parallel with demand. This effort required cold-chain capacity to be increased by five times in six months, compounded by the existing constraints imposed on logistics providers. This effort highlighted the need for surge capacity in cold-chain logistics to adequately protect vulnerable populations and get COVID-19 vaccines delivered to all who needed them.

Patient Safety and Patient Experience

Supply Chain Serial Tracking can increase the precision of recalling medications, minimizing patient exposure to the harmful uses of a recalled product. In 2023, advancements in serialization allowed the FDA to be more targeted in recall, leading to less impact on patient therapy due to product recalls.

Organizational Key Performance Indicators (KPIs)

The KPIs tracked by leading organizations include fill-rate ($\geq 98\%$), on-time delivery ($\geq 95\%$), order accuracy ($\geq 99\%$); cold-chain compliance (zero excursions). Leading organizations report consistent achievement of these performance measures via operating with an integrated digital monitoring and resilient supplier network.

Case Studies/Examples from U.S. Pharmaceutical Companies

Pfizer mRNA Vaccine Supply Chain

Pfizer partnered with BioNTech to scale-up the manufacturing of an mRNA COVID-19 Vaccine from zero to 3 billion doses within a 12-month time period. Additional total investment included additional manufacturing lines adding capacity to the Kalamazoo, Michigan and Puurs, Belgium sites, dual-sourcing of lipid nanotechnology as well as the use of real-time temperature telemetry with mRNA vaccines across the globe. Collaborative digital platforms provided real-time dashboards for field operations and for providing site and thermal integrity monitoring related to shipped vials.

Johnson & Johnson's Single-Dose Vaccine

As a second example, Johnson & Johnson successfully utilized its existing capacity for adenoviral vector-based vaccines manufactured for laboratories in Leiden (Netherlands) and Baltimore (Maryland) to produce quantities of single-dose COVID-19 vaccines without it having been previously manufactured as a single-dose vaccine. The single-dose vaccine lessened cold-chain requirements ($2^{\circ}\text{--}8^{\circ}\text{C}$) and allowed for more effective distribution with little barriers. The single-dose COVID-19 vaccine meant it could be distributed and administered more rapidly into population with limited access in the United States. Serializing the unit dose for the Drug Supply Chain Security Act (DSCSA) enabled targeted delivery of the single-dose COVID-19 vaccine to rural hospitals for administration. Merck's Oncology Drug Manufacturing Merck's Keytruda (pembrolizumab) requires high potency monoclonal antibody reproducibility. Merck expanded their Boston biologics campus layout to include single-use bioreactors and downstream modular fill-finish lines for more flexibility. The implementation of AI demand forecasting reduced their buffer stock by 30% while still maintaining $\geq 99\%$ availability.

Policy and Strategic Implications

Increase Data Transparency

Requiring public reporting on their capacity utilization and origins of API sourcing would assist not only the policymakers but also firms who would like to evaluate for systemic vulnerability. As an example, real-time dashboards available to the FDA and CDC to ensure they can try to mitigate risk as it occurs.

Diversify Supply Base

Encouraging increased domestic API production with tax incentives or grants would diminish the issues with 'geopolitical exposure'. The model used for the US CHIPS and Science Act could be used to instead support 'Pharma Resilience' funding for API and excipient facilities.

Invest in Cold-Chain Infrastructure

Public-private partnerships that would allow improvements to cold-chain hubs throughout Rural or underserved regions in the United States would promote equitable access to temperature-controlled therapies. Grants leveraged through authority under the Biomedical Advanced Research and Development Authority (BARDA) could focus on infrastructure improvements.

Speed up Digital Adoption

Incentivizing through pilot programs by the FDA to accept the use of blockchain to deploy IoT will enhance serialization compliance as well as improve real-time monitoring capabilities. Pilot studies have reported a minimum of a 15% reduction in stock outs, as well more precision (maximum %) around recalls.

Strengthen Regulatory Coordination

The FDA, CDC, and customs will all need to coordinate their efforts, potentially even regulating inspections for overseas API sites to be done by using remote auditing technologies. Each agency should work towards harmonizing cGMP standards globally to reduce duplication and enhance the speed at which inspection cycles occur.

Conclusion

Measuring U.S. pharmaceutical industry scale accurately can only potentially occur by double-clicking into a combination of market data, production, employment data, as well as R&D reported to the federal government and informed by commercial intelligence firms. Supply chain dynamics associated with manufacturing networks, distribution and logistics, regulatory, and digital technologies all alter and will impact quality, cost, availability, patient safety, and corporate performance. High-visibility disruptions, in particular from the COVID-19 pandemic, have heightened the urgency and importance of resilient, diversified supply chains with real-time monitoring capabilities. Examples taken from Pfizer, Johnson & Johnson, and Merck include their efforts to scale production, manage their cold-chain logistics, as well as deploy digital forecasting with valuable outcomes. Policy action to increase transparency, diversify the supplier base, invest in cold-chain infrastructure, accelerate digital adoption, and support better coordination would all contribute to better resilience in the industry and improve patient access. All stakeholders can better improve U.S. leadership as a world leader, driving pharmaceutical

innovation, thus reliable access to provide lifesaving therapies will need to be in focus.

References

1. IQVIA Institute for Human Data Science. The Global Use of Medicines 2024. Durham, NC: IQVIA; 2024.
2. U.S. Bureau of Economic Analysis. GDP by Industry, Pharmaceutical Manufacturing, 2023. Washington, DC: BEA; 2024.
3. U.S. Food and Drug Administration. 2023 Annual Report on Pharmaceutical Quality/Manufacturing. Silver Spring, MD: FDA; 2023.
4. Centers for Disease Control and Prevention. COVID-19 Vaccine Distribution Lessons Learned. Atlanta, GA: CDC; 2023.
5. U.S. Food and Drug Administration. Registered Drug Establishments Current as of 2024. Silver Spring, MD: FDA; 2024.
6. Pharmaceutical Research and Manufacturers of America. PhRMA Biopharmaceutical Production Capacity Report 2023. Washington, DC: PhRMA; 2023.
7. U.S. Bureau of Labor Statistics. Occupational Employment and Wages in Pharmaceutical and Medicine Manufacturing, May 2024. Washington, DC: BLS; 2024.
8. Pharmaceutical Research and Manufacturers of America. 2023 Biopharmaceutical Industry R&D Investment. Washington, DC: PhRMA; 2023.
9. Evaluate Pharma. World Preview 2023, Outlook to 2028. London: Evaluate Ltd; 2023.
10. U.S. Government Accountability Office. API Sourcing and Supply Chain Risks, Report GAO-24-101. Washington, DC: GAO; 2024.
11. Drug Channels Institute. The U.S. Pharmaceutical Wholesaling Sector, 2023. Burlingame, CA: DCI; 2023.
12. U.S. Food and Drug Administration. Code of Federal Regulations Title 21 Part 210–211 (cGMP). Silver Spring, MD: FDA; 2024.
13. Deloitte Insights. 2023 Life Sciences Supply Chain Survey. New York, NY: Deloitte; 2023.
14. Pfizer. Pfizer/BioNTech COVID-19 Vaccine: Manufacturing and Distribution Report, Q4 2023. New York, NY: Pfizer; 2023.
15. U.S. Food and Drug Administration. DSCSA Implementation Metrics, Annual Progress Report 2023. Silver Spring, MD: FDA; 2023.
16. McKinsey & Company. The U.S. Pharmaceutical Supply Chain: Cost Drivers and Optimization, 2023. New York, NY: McKinsey; 2023.
17. Operation Warp Speed Program Management Office. Final Report on COVID-19 Vaccine Distribution, May 2024. Washington, DC: OWS; 2024.
18. Gartner. 2023 KPI Benchmarking for Pharmaceutical Supply Chains. Stamford, CT: Gartner; 2023.
19. Johnson & Johnson. Johnson & Johnson Single-Dose COVID-19 Vaccine Supply Chain Analysis, 2023. New Brunswick, NJ: J&J; 2023.
20. Merck & Co. Annual Report 2023: Keytruda Manufacturing and Supply Chain Overview. Kenilworth, NJ: Merck; 2023.