



2020

WHOLESALE DISTRIBUTION TRENDS

IN LIFE SCIENCES

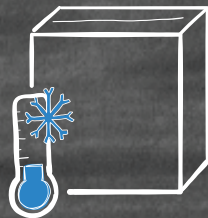
PERSONALIZED MEDICINES IMPACT ON WHOLESALE DISTRIBUTION

Personalized medicine is the next frontier in the prevention, treatment, and cure of many diseases. As these class of therapies continue to gain traction in the United States and abroad, the end-to-end supply chain needs to be radically altered from the traditional, validated model of commercialization where product and information is transferred from manufacturer to distributor to patient.

Personalized medicine, such as cell and gene therapies respectively, have many different characteristics than traditional medicines, specifically



shorter shelf lives



*the need for refrigerated
or freezer storage and
distribution (2-8C, -20C, -80C)*



*shorter cycle times
from manufacturing
to patient infusion*



*individualized
patient usage*

With these unique characteristics, all partners in the supply chain must be equipped with flexible, adaptable capital assets and resources to deliver the correct medicines to patients when it's required.

In 2019, personalized medicine's market value was \$13B but is expected to reach ~\$74B by 2027, **a CAGR of 24%**. This growth is driven by the rise in chronic diseases, genetic disorders, and government investments (Cures Act-2016).

With the emergence of personalized medicines and its predictive growth, wholesale distribution will need to be proactive in shifting its current business strategy and model from its core services. The ability of distributors to aggregate standard pharmaceutical orders for a broad population and ship these to pharmacies will become less valuable when more orders are individualized. This means the economies of scale that wholesale distributors bring to the life sciences industries potentially can be lessened and increase the cost of medicines to payers and patients respectively.

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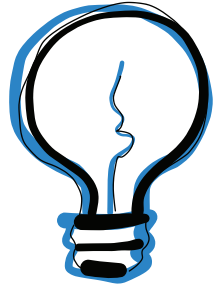
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With this potential scenario, other threats start to surface for these entities including:

1. Excess warehouse capacity since personalized medicines are not held in inventory for long period of time (standard cycle time from apheresis procedure to infusion is < 20 days)
2. Larger investments in technology and its ancillary components (i.e. hardware, resources, etc.) as the need to adhere to chain of custody and chain of identification requirements for personalized medicine will continue.

With every threat comes opportunities and wholesale distributors can start pivoting their business models to take advantage of them. A few of these opportunities include:



1. As the liaison between manufacturers and their patients, wholesale distributors have established, foundational infrastructure and partnerships that integrate these entities, allowing them to potentially further invest in value-added services such as data management solutions or white glove services.
2. Repurpose excess traditional warehouse capacity into capacity used for personalized medicines that require different handling and storage requirements
3. Evaluate opportunities to serve as 3rd party logistics providers to manufacturers
4. Assess potential to serve as third-party financiers (i.e. provide loans for capital intensive projects) to manufacturers.
5. Continue to invest significantly in track and trace interoperability that will afford patients the opportunity to view in real-time the order and delivery process of their personalized medicines.

DRUG PRICING PRESSURES ON WHOLESALE DISTRIBUTION

In 2019 and continuing into at least 2020, the debate on drug pricing within the United States will reach a fever pitch with both government and the private sector shifting the blame between each other for the rising cost of prescription drugs. As this debate continues, the public's tolerance on a solution being implemented will shorten and their negative perception of both the government and the pharmaceutical industry will continue to erode. The United States Congress' approval rating **sits at 23%** while the pharmaceutical industry is the most poorly viewed private industry in the United States with a **27% approval rating**.

With public scrutiny continuing indefinitely, this will eventually have an impact on the current model of drug pricing and in turn, an impact on the supply chain ecosystem. If legislation is passed that caps the amount of



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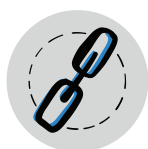
*The pharmaceutical industry is the most poorly viewed private industry in the U.S. with a **27%** approval rating*

money that a manufacturer can charge for prescription drugs and eliminates the rebates that manufacturers give to pharmacy benefit managers (PBMs), this will likely impact the existing list-price based wholesaler payment system and have a negative impact on the profits of wholesale distributors.

Under the current pricing model, wholesale distributors will always want drug prices to rise. At the start of 2020, drug prices rose **5.8% on average**. The distribution service agreements (DSA) that are implemented between a manufacturer and a wholesale distributor are generally calculated off of the drug's list price; therefore, whenever the list price of a drug increases, the wholesale distributor profits more.

The wholesale distributor has another avenue to profit when drug prices increase via residual inventory purchased at the initial wholesale acquisition cost (WAC). When the price of the listed drug increases, they will sell the inventory to the customer at a higher cost than planned, increasing their profit margins.

If the ideas generated from the US government come to fruition that cap the list price of drugs, wholesale distributors will need to find alternatives to make profits and sustain their important contribution to the healthcare sector. A few opportunities include:



Continue to invest in supply chain interoperability and financial services that will give these entities an edge over others in the life sciences industry



Develop creative pricing arrangements and agreements with manufacturers for all different classes of drugs that do not solely rely on a % fee based on WAC and subsidization

AMAZON'S EFFECT ON WHOLESALE DISTRIBUTION

In mid-2018, Amazon made a significant acquisition that made all entities in the drug supply chain ecosystem take notice. **Amazon's purchase of PillPack**, an online pharmacy that packages a patient's medication and delivers them directly to their homes, was a strategic investment with a potentially disruptive effect on the traditional wholesale distributors that serve as the liaisons between manufacturers and pharmacies. The critical aspect of the purchase was PillPack's existing licensing assets that awarded the company the legal right to distribute drugs in each state. With the extensive logistical and technological infrastructure that Amazon has created, sustained, and improved over the last 25 years, both manufacturers and pharmacies may opt to enter into arrangements and agreements with Amazon vs. the traditional wholesale distributors.

There are two main drivers as to why this may be so disruptive to the existing supply chain:



Customer Expectations:

As consumers continue to pivot away from traditional retail (i.e. brick and mortar) purchasing and substitute it for online ordering, their expectations for all types of purchases will become aligned, including drugs, whether OTC or prescription. This will place a heavy burden on traditional wholesalers as their logistical and technological platforms are not able to service customers at the same speed, cost, and experience as Amazon



Financial Transparency:

With Amazon's clout, PBMs, as third-party administrators of prescription drugs, could potentially be eliminated from the supply chain ecosystem. Amazon could negotiate directly with the drug manufacturers to lower prices. This could make the whole financial transaction process among manufacturers, insurers, and PBMs, which is currently very opaque, more transparent to give consumers an understanding of how final drug prices are set.

Both physicians and consumers believe that Amazon entering into wholesale distribution shows promise.



of physicians agree that Amazon could help healthcare professionals improve dosing adherence while

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of consumers say they are more likely to get prescriptions filled if they are delivered to the home.

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Even though these statistics show promise to a new supply chain ecosystem, consumers are still leery on a big-tech company filling and distributing prescriptions with



continuing to opt for a local pharmacy and

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fearful of how their personal health info could be used or managed by a technology company.

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GLOBAL COLD CHAIN LOGISTICS EXPANSION

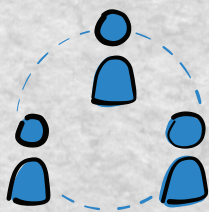
Cold chain logistics is a market consisting of transportation and packaging services for global biopharmaceuticals.

In 2018, global biopharmaceutical sales were \$1.1T with temperature-controlled supply chains representing **~30% or \$318B**. The utilization of this type of supply chain will continue to grow year-over-year by 8% while non temperature-controlled growth will be ~2%. In 2018, global spending for cold chain services was \$15B. It's projected to reach \$18.6B in 2022. With this continued growth, all stakeholders in the supply chain are seeing a tightening of capacity which is having an impact on costs and delivery times for medicines that patients expect a timely receipt on.

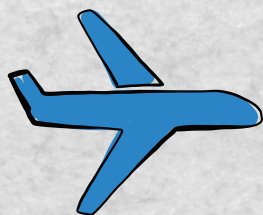
There are two main drivers to the continued growth of cold chain logistics:

1. **Regenerative Medicine Commercialization:** This type of drug requires either refrigerated or freezer storage and distribution (2-8C, -20C, -80C). The FDA is expecting 200+ Investigational New Drugs (IND) per year starting in 2020 with the majority of them being cell and gene therapies. And by 2025, the FDA is expected to approve 10-20 cell and gene therapy products a year with a large number of these approvals expected to be expedited via the FDA Expedited Approval Programs (e.g. Fast Track, Breakthrough Therapy, etc.).
2. **Clinical Research Trend:** In 2019, a little over 1000 clinical trials were being conducted globally on regenerative medicines, specifically gene and cell therapies. In 2019, this **market's value was \$13B** but is expected to reach ~\$74B by 2027, a CAGR of 24%. This growth is driven by the rise in chronic diseases, genetic disorders, and government investments (Cures Act-2016). As of 2019, **5,000 large molecule drugs** are in development.

With these facts alone, it's clear as to why the growth of this sector in both transportation and packaging continue to experience capacity shortages.



Manufacturers, 3rd party logistics providers, and wholesale distributors need to collaborate more frequently and share future demand projections and capacity plans to ensure services are available when required at the expected cost.



Other modes of transportation should be considered (ocean vs. truck; ocean vs. air) to alleviate constraints during peak times. By forming these important partnerships, each stakeholder can share in investment risks and commercialization rewards to ensure life-saving drugs are being delivered to patients on time and in a compliant fashion.

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TECHNOLOGICAL ADVANCEMENTS TO SECURE PHARMACEUTICAL WHOLESALE DISTRIBUTION

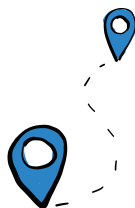
In 2013, the FDA took a monumental step in securing the United States' drug supply chain by introducing into law the Drug Supply Chain Security Act (DSCSA) with the purpose of building an electronic, interoperable system to identify and trace prescription drugs to eliminate the introduction of counterfeit drugs from manufacturer to the pharmacy. Even though the implementation of the interoperable system was a large investment for many stakeholders in the supply chain, specifically distributors, the benefits will be significant to ensure drug supply safety.

Advancement in technologies continue to show great promise in improving the safety, visibility, and customer experience of the drug supply chain and wholesale distributors will play a central part in their development, implementation, and adaption.

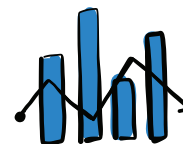
The most promising technology is that of blockchain which has multiple proof-of concept studies in progress with major pharmaceutical manufacturers and wholesale distributors. The technology will have many benefits including:



Allowing all distributors and customers to access the blockchain of a manufacturer so real-time verification of a drug package can take place once it's received into their facilities.



Providing a distributed chronology of custody from the beginning to the end of a drug's supply chain so drugs can be tracked in real time



Streamlining drug quality and compliance data collection and monitoring among multiple supply chain stakeholders to simply track the integrity of a drug

Other technologies that continue to advance in value and deployed widely into service are robotics and artificial intelligence respectively which eliminate human error in handling, storage, and transportation of drugs; and internet of things (IoT) providing real-time updates on specifics like drug product integrity, temperature conditions, and delivery schedules.



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For more information about how we can help your company with the challenges and opportunities in wholesale distribution, please contact us.

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