EBOOK FROM THE EDITORS OF Pharmaceutical Executive

Securing the Global Supply Chain:

STRATEGIES FOR OPERATIONAL EXCELLENCE

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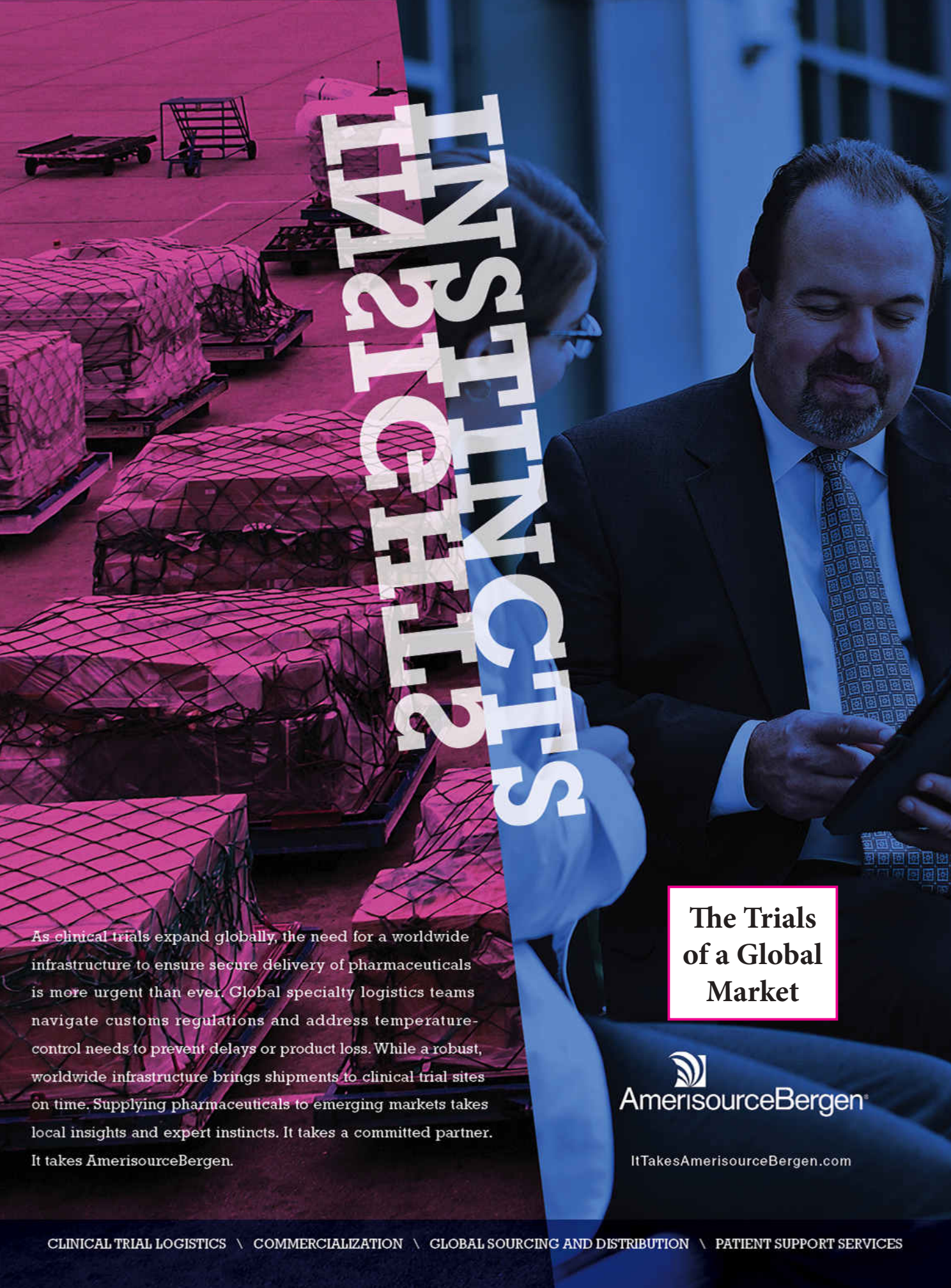
TOC | GLOBAL SUPPLY CHAIN



As clinical trials expand globally, the need for a worldwide infrastructure to ensure secure delivery of pharmaceuticals is more urgent than ever. Global specialty logistics teams navigate customs regulations and address temperature-control needs to prevent delays or product loss. While a robust, worldwide infrastructure brings shipments to clinical trial sites on time. Supplying pharmaceuticals to emerging markets takes local insights and expert instincts. It takes a committed partner. It takes AmerisourceBergen.

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STRATEGY

FINDING STRATEGIC LEVERS IN THE SUPPLY CHAIN

BY TOM REYNOLDS

Admit it. When most pharmaceutical executives think about the pharmaceutical supply chain, their eyes start to glaze over. Traditionally, the supply chain has been considered, at best, a back-room function that reports in to operations and is responsible for delivering a reliable supply of product to meet forecasted demand.

In fact, the supply chain is a deep and widely underutilized strategic resource for companies seeking to focus their organizations on the changing healthcare environment. New customers with different needs are emerging in every sector of the healthcare market—from tech-savvy consumers that expect instant informational gratification, to newly integrated healthcare delivery systems with access to vast stores of information about how and by whom pharmaceutical products are being used. And pharmaceutical supply-chain executives are seeking new ways to understand the central question of how they can deliver greater value to their organization by helping to improve the customer experience.

Traditionally, pharmaceutical supply-chain management has been defined as managing the network of suppliers, resources, and manufacturing capabilities that are needed to supply product demand or sales targets. This role is, by nature, somewhat static and reactive rather than proactive, and its ability to be responsive is further limited by the highly regulated nature of the pharmaceutical industry. In general, pharmaceutical supply-chain capabilities lag behind those of the technology and consumer packaged goods (CPG) sectors.

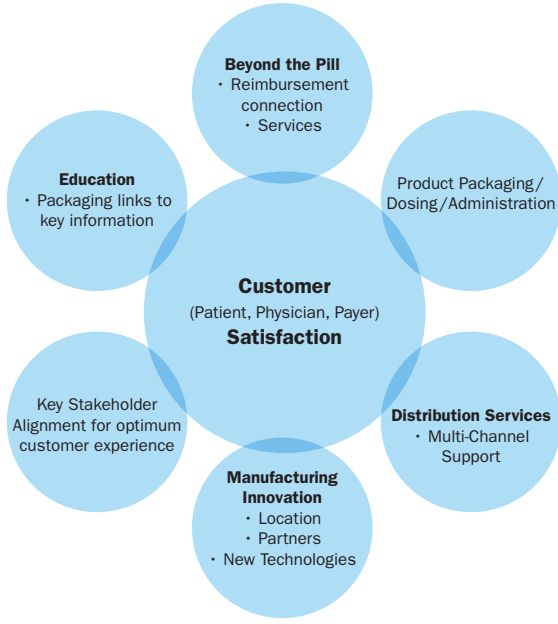

Figure 1: Customer value levers.

> "THE SUPPLY CHAIN IS A DEEP AND WIDELY UNDERUTILIZED STRATEGIC RESOURCE FOR COMPANIES SEEKING TO FOCUS THEIR ORGANIZATIONS ON THE CHANGING HEALTHCARE ENVIRONMENT."

In the technology sector, for example, Dell has built a global reputation for its ability to deliver custom-configured products of high quality and reliability, and has built a nimble and flexible supply chain that lets them consistently meet their customer needs and wants. Consider what it would take for a pharmaceutical company to deliver custom-configured products to its millions of customers worldwide. Yet this type of customer need is becoming increasingly possible as science continues to unveil the possibilities of personalized medicine and individualized therapies.

Although the challenges of personalized medicine are likely a few years out, there are ways in which the pharmaceutical supply chain can be more effectively engaged to address current customer unmet needs. Customers in emerging countries, for example, may have substantially different wants and preferences in terms of pharmaceutical product taste, texture, package size, unit dosing, or services. All of these aspects of the product can be addressed through the supply chain, and could have a large impact on local acceptance and usage.

Decisions about how to build or engage local manufacturing are another area where strategic supply-chain decision-making can come into play. Traditionally, many pharmaceutical companies have invested in regional manufacturing, building large facilities to meet demand during products' extended lifecycles. Today, however, companies are exploring partnerships with local manufacturers that have underutilized capacity, and are teaching these local resources the skills needed to manufacture and distribute more complex specialty products, such as biologics or other large molecules. Such arrangements may save capital, but perhaps more importantly, prevent the company from having to navigate complex local tax and investment regulations.

Twenty first century supply chain

Today's healthcare customer is more complex than ever before. The new healthcare ecosystem encompasses payers and healthcare organizations as well as their preferred service providers,

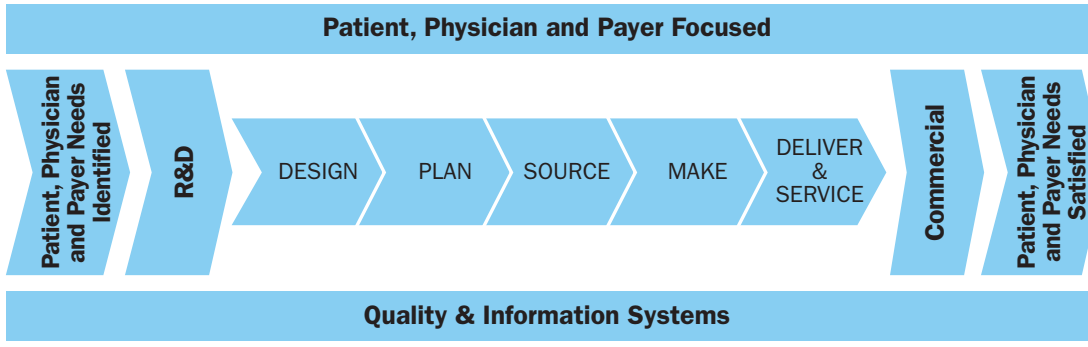

Figure 2: The customer-focused approach to identifying supply chain solutions.

physicians, and a large number and variety of other healthcare providers that interact with patients, either directly or indirectly, during the course of a healthcare transaction. Creating a customer-centric pharmaceutical supply chain requires that information about customer needs, wants, and even desires be communicated throughout the organization.

Executives responsible for supply-chain management should have opportunities to engage one-on-one with their customers in the locations where products actually are stored or used. For example, a recent conversation with an infusion nurse uncovered that the packaging for an IV product was stiff and hard to handle, and that nurses were getting paper-cuts. The supply-chain team collaborated with marketing and key customers to change the packaging to recycled paperboard and to improve ease of opening for nurses—a simple, low-cost modification that made the product more customer-oriented and eco-friendly.

The key to successfully harnessing pharmaceutical supply-chain innovation is a re-imagining of how product and supply-chain attributes can become customer value levers (Figure 1). This 360-degree view of value drivers that can be impacted by the supply chain illustrates the various supply-chain touch-points that can make an enormous difference in addressing customer needs.

Consider the following scenarios:

- The manufacturer of an oral solution for treatment of infections in immuno-compromised patients received customer feedback that the product was extremely irritating for patients with oral mucositis, a frequent complication of some cancer therapies. This information led to reformulation of the product into two additional formulations that will address the needs of the full complement of patient types.

- Responding to requests from a large national managed care organization (MCO) for ways to increase member adherence with chronic-care medications, a manufacturer challenges its supply-chain management team to devise low-cost adherence packaging solutions for several of its best-selling chronic medications. The plan is to test packaging alternatives within the MCO's current population to determine which approach delivers the desired outcomes.

- A supply-chain manager visiting rural pharmacies in an emerging Latin American market learns that access to refrigeration is not commonplace, leading to a re-assessment of the formulation for a new pediatric product.

Focus on the Customer

The key to creating a customer-focused supply chain is providing supply-chain managers direct access to customers and integrating key customer information in operations. For example, the supply-chain team could "follow the product" from the time it leaves the company until it reaches and is administered to a patient. Experiencing every aspect of the product flow and customer experience provides significant insights to unmet customer needs. This learning experience should be a part of a multi-layer approach to learning about customers, including the extensive prelaunch research with prescribers and end-users that is done in partnership with commercial teams, or the wealth of customer qualitative or focus-group research that is done to support product configuration and distribution channels.

Once supply-chain management is engaged in and focused on identification and resolution of customer needs and desires, their focus will shift to the identification of supply-chain solutions: how to design, plan for, source, produce, and deliver and service the product that satisfies customer needs and desires (Figure 2). By shifting the focus from internal customers, including R&D or commercial operations, to the larger customer ecosystem, pharmaceutical supply-chain management can become a dynamic contributor to 21st century healthcare delivery.

Strategic management of the supply chain is vital to winning with customers. Cost and quality are important, but they are not the only things customers care about: new services, flexibility in relationships, reliability of supply, and ability to creatively overcome obstacles in delivery of product are also core values. Pharmaceutical product portfolios and customers are becoming more complex. In order to stay ahead of this trend, customer-focused supply-chain capabilities will become a more important part of a company's competitive advantage.

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LOGISTICS

INDUSTRY SEEKS CLEARER TRACK-AND-TRACE STANDARDS

BY JILL WECHSLER

Beginning Jan. 1, 2015, manufacturers and distributors needed to have in place systems able to transmit information on prescription drug movement in the United States from plant, to packagers and various wholesalers and distributors, and ultimately to dispensers. FDA is charged by the Drug Supply Chain Security Act (DSCSA), a key component of the Drug Quality and Security Act (DQSA) of 2013, to issue guidance and rules for establishing such a process and is consulting with all stakeholders on viable approaches and policies (1).

FDA held a public workshop in May 2014 (2) to gain input from manufacturers and other supply-chain parties on developing standards for what eventually will be an interoperable tracking system for prescription drugs. FDA officials and industry leaders further reviewed DSCSA requirements, along with broader supply-chain security issues, at a June conference in Washington, D.C. sponsored by the Parenteral Drug Association (PDA).

The larger aim of drug tracking is to prevent drug diversion and to keep counterfeit and substandard products out of the US supply chain, observed Janet Woodcock, director of the Center for Drug Evaluation and Research (CDER), in opening the FDA workshop (2). Woodcock cited

the recent discovery in the US of counterfeit drugs to treat cancer, hypoglycemia, and hormone replacement, and noted the dangers of stolen or diverted products entering the distribution system. Electronic tracking, Woodcock noted, also would help manage product recalls, prevent shortages, and deter criminal elements from introducing substandard drugs into the US market.

Seeking guidance

FDA is working with supply-chain parties to tackle its multiple assignments under DSCSA, starting with guidance on how manufacturers and distributors should identify suspect products and then notify other parties that such products are not legitimate. More challenging is a November 2014 deadline for draft guidance that sets standards for interoperable exchange of required information. That includes transaction information (TI), transaction history (TH), and transaction statements (TS)–the "3Ts"–every time a product changes hands. Initially, data will apply to drug lots, as opposed to individual packages, and can be provided via paper or electronic systems. Supply-chain participants have to maintain data records for six years, and they have to be able to provide drug transaction information fairly quickly when requested by FDA or other agencies or is needed to notify trading partners when illegitimate products are detected. By 2017, manufacturers will need unique identifiers on drug packages and electronic data transmission. A fully electronic package-level tracing system is set for 2023, most likely based on the Electronic Product Code Information Services standard.

There is broad agreement among supply-chain parties that clear standards are crucial to success, but considerable debate about crafting the specifics. Woodcock noted at the FDA workshop that it's difficult to reach agreement on standards, formats, and practices because that usually requires some parties to change what they're doing. Workshop participants indicated a need for clearer definitions of basic concepts, such as "efficient interoperability" and "electronic data interchange." There was discussion about use of packing slips to identify the contents in shipments, which is common practice for manufacturers, but raised objections from wholesalers that reliance on packing slip information would slow down the distribution process.

There also was debate over using email to send transaction information, an approach that seems simple and direct to some parties, but raises concerns about security and data control for others. Similarly, participants considered whether transmission of a PDF document constitutes dissemination of an electronic or paper document. Electronic transactions that disclose product prices are a concern for manufacturers, who fear that such information could encourage pilferage or theft and undermine rate negotiations.

Some stakeholders questioned the viability of the envisioned step-wise data transmission system called for by the legislation. An alternative suggestion was for all parties to submit information to a centralized data hub, which could provide records to determine if the product is legitimate when a problem arises, instead of each supply-chain partner passing and accepting thousands of product transaction reports. There also was a proposal that FDA limit its standards to what information has to be transmitted, and leave it to trading partners to figure out how to send data and messages. FDA officials agreed on the need for flexibility but also noted that the legislation requires the agency to issue standards for the program. Overall, stakeholders expressed

strong interested in seeing FDA's policy earlier than November to help them meet the January 2015 implementation deadline.

Costs and benefits

While FDA crafts further guidance, manufacturers are preparing for both short-term and long-term changes, which are laid out in a DSCSA implementation timeline prepared by The Pew Charitable Trusts (3). Manufacturers already have spent millions of dollars on technology to implement drug serialization systems and anticipate that it will be costly and challenging to integrate new technologies with existing operations, according to stakeholder perspectives on drug serialization and traceability, prepared for the Pew by Booz Allen Hamilton (4).

Pharmaceutical companies report that off-the-shelf software often is suitable to support databases and communication systems, although customization is needed to meet individual business needs. Most pharma companies plan to outsource systems development and implementation, and a host of IT consultants and vendors have emerged to tackle such projects.

Despite notable costs associated with serialization and tracking, there is optimism that such initiatives will translate into important gains for the industry.

Not only will improved supply-chain visibility help block distribution of counterfeit or compromised pharmaceuticals, there is the potential for added business benefits, according to respondents to the Pew/Booz Allen study (3). In addition to facilitating drug recalls and enhancing cargo security, manufacturers anticipate gaining more timely and accurate production and shipping information. This information could help reduce production lead times, enhance inventory control, process returns more efficiently, prevent distribution of expired goods, help manage supplies for clinical trials, and improve tracking of drug samples.

More detailed information on product movement through the supply chain, moreover, could help manufacturers ensure the accuracy of sales and chargebacks and support drug rebate reconciliation. Future gains might extend to improved accuracy in drug-reimbursement systems, better medication adherence by patients, and support for FDA reporting requirements for high-risk products. All together, these developments could support efforts to prevent drug shortages.

As standards emerge for a drug-tracking system in the US, policy makers are looking to facilitate policy harmonization with the European Union, China, and other nations. A broad goal is to agree on barcodes on pharmaceuticals that are acceptable in all markets. European governments are establishing unit-level tracking policies, with requirements for anti-tampering features on packages and guidelines for serialization and authentication. Most countries are adopting two-dimensional barcodes, although China may opt for a linear barcode requirement. Different requirements and implementation timelines in other regions, unfortunately, would add to the complexity of establishing pharmaceutical traceability systems that gain international acceptance.

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DATA

Supply Chain Analytics:

PHARMA'S NEXT BIG BET

BY JACOB SNAPP, SRIHARI RANGARAJAN

Pharmaceutical and Life Sciences (PLS) companies are under tremendous pressure to improve their supply chains and operations efficiency. Market headwinds include a staggering number of mergers and acquisitions; additionally, big Pharma continues to face an increase of drug patent expirations and downward pressure on profit margins. Aggressive competition from generic pharmaceutical manufacturers, as well as increasing costs to develop and launch new products also factor in—mandating improvements in supply chain and operations. Supply chain analytics is the strategic differentiator for PLS companies to excel in the face of adversity, and will ultimately help these companies become world-class drug or medical device suppliers.

Supply chain analytics are used to measure, monitor, and improve individual business processes as well as the overall performance and health of the supply chain. PLS companies struggle with suboptimized Sales & Operations Planning (S&OP) processes due to a variety of factors, including lack of effective governance, fragmented decision-making, misaligned key performance indicators (KPIs), and a general distrust in sales forecast accuracy. Historically, drugmakers have not been as focused as other industries on working capital. However, the topic has received greater attention in recent years due to expiry of patents, and the squeeze the pricing pressures have put on profit margins. Today, pharma supply chains hold massive buckets of data; this makes it a rich place to look for and establish analytical advantages and for PLS companies to develop a comprehensive, analytical approach to optimize their supply chain and operational efficiencies.

Why supply chain analytics?

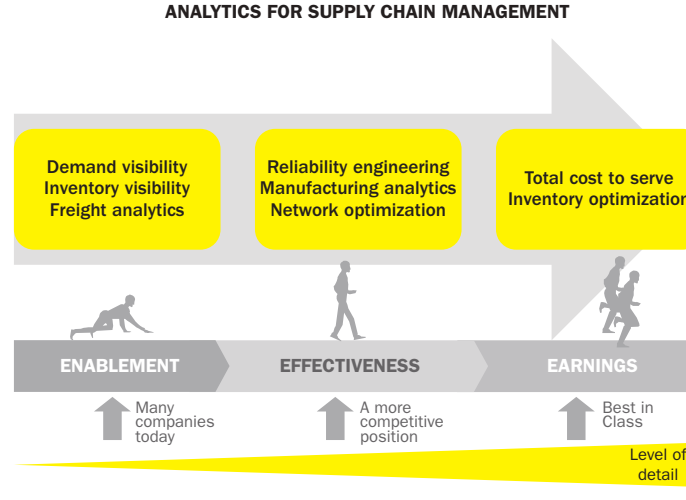
For years, conventional wisdom in the pharma industry had it that research and development was the strategic business driver while mainline manufacturing and supply chain strategies were overlooked. Cost of goods sold as a percentage of sales was low and blockbuster drugs commanded premium pricing and market exclusivity. Pharma executives had settled into a mantra of "do no harm" to other strategies. However, in recent years, the dynamics of the drug industry have begun to change. FDA approvals have been slow, and, consequently, revenue growth has lagged. Sales have declined and government involvement in the healthcare industry has put downward pressure on drug prices. Adding to this volatile environment is the fact that many of the market-making drugs are going off patent protection. In light of this, governments have encouraged direct competition by enabling generics. In conjunction, there have been several changes in the regulatory approach that has put a huge emphasis on quality.

So where does this leave big Pharma? The industry has responded in bits and pieces, but executives are beginning to realize that the complex web of supply chain holds the key to competitive advantage and potential innovation. According to a research article by HFS in 2011 (1), a majority of organizations were planning to increase investments targeted toward supply chain analytics. Insights from such initiatives will help PLS companies optimize their supply chain functions and enable them to manage market pressure, while robustly managing financial performance.

To meet the current industry challenges and increasing supply chain complexity, supply chain analytics must evolve in a rapid way around three areas—enablement, effectiveness, and earnings.

Enablement

Rapid globalization for drug companies has resulted in an outburst of various types of world-class suppliers, near-shore and outsourced manufacturing plants, far-flung distribution centers, and increased number of drug retailers. Rapid growth in emerging markets has spawned a rising trend to introduce a wide variety of established drug products. The upshot has been the creation of many complex and extended global supply chains that need to be carefully managed.



Before pharma companies can analyze how effective their supply chain really is, they will need to have clear, end-to-end visibility of their global supply chains. At a simple glance, this begins with basic metrics and reporting, as these tools provide the backbone of data for performance measurements. However, in the current state, there is no single source

of truth for supply chain visibility. The industry lacks a unified physical and financial view of the supply chain domains that links supply chain strategy, performance management, and risk. To achieve maximum effect, an advanced analytic "control tower" can enable real-time decisions and KPI's through the cloud.

Enablement in pharma supply chain analytics can be broadly classified into three areas:

- Demand visibility
- Inventory visibility
- Freight analytics

"THE INDUSTRY LACKS A UNIFIED PHYSICAL AND FINANCIAL VIEW OF THE SUPPLY CHAIN DOMAINS THAT LINKS SUPPLY CHAIN STRATEGY, PERFORMANCE MANAGEMENT, AND RISK"

Demand visibility — Poor forecast accuracy and demand volatility continue to challenge drug companies due to sub-optimized sales and operations planning (S&OP) processes. The S&OP process is fragmented due to a lack of effective governance and disconnected decision-making, with misaligned KPIs leading to a lack of confidence in sales forecasts. In addition, the pharma industry faces important quality and health implications due to the fact that the product not only needs to be in the right place at the right time but also with the right quality.

Counterfeit drugs are on the rise. Product authenticity will need to be monitored through increased visibility, especially during a time where there is a intense regulatory scrutiny. There is need to have basic forecasting metrics more visible to enable replenishment; KPIs such as forecast accuracy, forecast bias, and On Time-In-Full can be very quickly deployed and will help measure the pulse in the supply chain planning domain.

Inventory visibility — Pharma company inventory metrics have been used for a while; however, there has been a lack of focus on inventory accountability within big Pharma due to business process and information disconnects and commercial vs. supply chain inventory responsibility. Pharma lags in inventory KPIs primarily due to no stock-out policies and complexity created by market specific product expiration requirements. The result includes increasing product discards year over year due to lack of coordination, thereby leading to inventory shortages and overages worldwide.

A KPI dashboard with trend analysis for inventory at a market level and with a multi-dimensional drilldown will be a welcome solution for pharma companies to increase visibility and insight. With incremental detailed data, further analytics can enable near real-time inventory tracking and tracing for controlled drugs. Enabling such metrics will ensure that commercial opportunities are realized for at-risk inventory. Once inventory becomes visible, all other supply chain parties such as vendors and customers, both internal and external, can share information and be in a better position to manage inventory. In the research world, this inventory visibility will form the backbone in managing high-dollar laboratory materials, track supplies in real time and reduce the negative impact it can have on research productivity. Analytics in this space include inventory variance analysis, inventory revaluation, slow-moving inventory reporting, tolled inventory reports, gross-to-net inventory bridge,

days on hand, as well as inventory usability for obsolescence purposes.

Freight analytics — According to a Seabury trade database (2), over the past decade, pharmaceutical tonnage has grown in both air and ocean modes to the tune of four million tons per year. More valuable drugs travel by air, with air freight accounting for the majority of the total value shipped. Out of a total value of $269 billion, air freight cost a whopping $213 billion in 2012 alone. Fluctuating demand and global logistics have driven drug companies to continuously reflect on their distribution network design and strategy. Drug companies can realize immense performance improvement opportunities through analytics driven activities such as improved visibility to in-transit goods, freight lane reporting, fleet sizing, load planning, and freight cost consolidation. A quick win here would be to target freight lanes that create imbalances over time and identifying which route supports the business and which ones do not.

Another basic analysis would be to use the Pareto principle; determining the percentage of the network that constitutes 80% of the cost and refining those to maximize yield. An agile approach here would be healthy in monitoring and continually fine-tuning network designs for efficient logistics management. With the recent wave of consolidations in the pharma domain, there is a huge advantage in determining network synergies to drive considerable reduction in overall transportation costs.

Effectiveness

An effective supply chain is characterized by the appropriate, consistent movement of data up and down the supply chain. Decisions can only be as good as the data coming through. In the previous section, we discussed how supply chain visibility can be enabled to empower drug companies to make insightful decisions. In this section, we take a look at two advanced analytic capabilities that can power pharma to remain competitive for the future.

Reliability engineering / manufacturing analytics — Big Pharma's main challenge is that its information is spread across multiple data systems, maintained by different organizations across the globe. Bringing data under a single umbrella becomes a powerhouse for driving process improvement in the manufacturing space in conjunction with compliance to the ever-changing regulatory guidelines. The industry has taken various routes to ensure manufacturing reliability. Genentech and Baxter, for example have embraced lean while Novartis has developed its own six sigma internal tool kit. However, none of these have been entirely successful in maintaining a predictable operational performance. An integrated manufacturing, holistic system that embraces process methods, toolsets, along with analytical models could help pharma with anemic product launches and manufacturing performance.

Real-time measurements of process parameters allow drug manufacturers to leverage advanced statistical analytical methods to monitor and correct process conditions before a potential quality failure occurs. Meaningful, metrics such as overall equipment effectiveness and asset utilization can be used to measure performance trends over time. Loss-tracking analytics can then be activated to ensure that variations to target can be evaluated. Another area of analytics would be to do with critical process constraints. Regulatory initiatives such as design to quality require drug companies to identify critical to quality (CTQ) parameters to ensure that their end products are safe.

When batch data, process, and product quality data come together, then analysis can be done to identify these CTQ parameters and their acceptable range.

Network optimization — With industry acquisitions and consolidation, it is widely understood that network design is the most fundamental decision that will impact customer service levels. This will be the key profitability driver because networks directly affect both supply chain costs and customer satisfaction. The huge investment cost of buying assets and building facilities makes it essential to design a supply chain network which performs well over a long period of time. Because drug and medicine are globally considered a strategic commodity, achieving a stable yet flexible design while optimizing cost becomes the end goal.

Increasingly, supply chain networks have become disparate. As pharma companies seek tax efficiency in European countries, a variety of factors ranging from cost structure, tax laws, materials, and new product launches have driven drug companies to reconsider their supply chain networks. Network design is a powerful analytic driven, modeling approach proven to deliver significant reduction in supply costs and customer-service-level improvements.

A targeted multi-stage network optimization approach will immediately help the pharma landscape. Most PLS companies are constantly evaluating a multitude of product launches, emerging markets, process and real estate investment, as well as divestitures to drive their future state. At this juncture, it is vital to do a quick cost-based analytics exercise focused on KPI's such as investment cost; return on investment; sunk costs; stock costs; transportation costs; etc. Once these KPIs are established, they can then be leveraged to choose between a centralized and a decentralized network design model. Once the right model has been established to optimize the network, a series of "what-if" analyses can be performed. These scenarios would be based on demand and supply fluctuations, cost inflation, currency exchange risk, fiscal and economic policies, market volatility, tax and tariffs, social sentiments, and so on. The simulation structure would then enable a new, rationalized network with significantly less operating expenses and no impact to customer service levels.

> "AN INTERGRATED MANUFACTURING, HOLISTIC SYSTEM THAT EMBRACES PROCESS METHODS AND TOOLSETS, ALONG WITH ANALYTICAL MODELS, COULD HELP PHARMA WITH ANEMIC PRODUCT LAUNCES AND MANUFACTURING PERFORMANCE"

Earnings

Drug companies have long been the envy of other industries, with their strong balance sheets, attractive operating margins, and hordes of cash—not to mention single-product lines that generate billion-dollar annual revenues. The consequence was that little attention was paid to working capital, which is typically defined as the difference between a company's current assets and liabilities. A positive working capital ratio is essential for a firm to be able to operate profitably, service its debt and fund upcoming operational expenses.

A recent EY report (3) on the performance of large pharma companies, has found that there is an aggregate total of $20 billion to $43 billion in cash unnecessarily tied up in working capital, equivalent to between 3.6% and 7.7% of sales. The analysis also showed that the cash opportunity is distributed across each working capital component—40% coming from inventories, 35% from payables, and 25% from receivables. This is where supply chain analytics can play a huge role in the active management of working capital. The focus on achieving a high-quality balance sheet requires granular level cost information at every point in the supply chain—by product, by distribution channel, and by customer. Quantifying these cost differences can help a company discontinue an unprofitable product, alter a distribution network to increase profitability, and then redeploy the freed up capital towards new drug research or towards other innovations.

Once the basic ERP and other legacy system data have been enabled on a common platform, a "total delivered cost" analytic approach can be used to illuminate the granularity of cost variation across the supply chain. This approach works by overlapping additional logic to the data from the company's various information technology domains. Then, the analytical approach will connect the dots between what the company is selling and to which customers, while highlighting the various levels of costing across the supply chain. Specifically, the first step in this would be to engage in a cost-to-serve as is analytics exercise. This baseline analysis will identify actual costs in comparison to theoretical costs; in addition, this will also build visibility of historical cost to serve at a product and customer level. The second phase in this analytical approach will be based on trade terms efficiency. A trade model can be developed that addresses incentives and discounts based on true cost. This will then be integrated into the commercial and supply chain functions to deliver changes with the trade terms and ultimately, their successful adoption. A third and a complex step to complete the exercise would be to simulate cost-to-serve scenarios across both the internal and the customer network that can help promote joint value creation.

Inventory management

Another key area of working capital that analytics can address is inventory optimization. An end-to-end methodology uses several analytical steps to optimize inventory. The leading step is to develop a supply chain network map that captures the product flow across the network. This is crucial as this will identify the involved sites, the relative volume, and the value of product flows, inventory holding points, the supplier base, and the key markets for the network products. Simultaneously, the lead times across the network are also established and, then, segmented into release, production, quality, and logistics buckets. Once all the information is enabled, statistical analytical models can be built to determine inventory target levels based on observed demand and supply variability and the desired service levels.

The supply chain is globalized in a typical pharmaceutical company. The pharma supply chain is also complex, so inventory optimization should be carefully managed using a two-step approach.

Step 1: Highly strategic inventory locations are analyzed and optimized individually at single stages. This will secure quick wins and allow inventory to be released within a few weeks to months without decreasing customer service levels. The output of this model should be target

cycle and safety stock quantities calculated at each node, including factors such as minimum order quantities, production costs, and vendor managed inventory among others.

Step 2: The second phase will be to optimize inventory at a multi-echelon level, which is typically done with the help of an advanced optimization tool. A true multi-echelon approach should take into account the following factors:

- Elimination of demand signals from the next node in the supply chain.
- Account for all the lead-time variations from suppliers, both internal and external.
- Harmonize order cycles throughout the distribution network.
- Segmented customer service levels based on product demand and supply.

The end game: Maintaining supply chain efficiency

Integration of global supply chains and establishing end-to-end supply chain visibility in the pharmaceutical industry have spawned a variety of challenges; this includes growth in emerging markets, competitive generic equivalents, and volatile customer demand—all of which add to pharmaceutical supply chain complexity. Supply chain analytics represent a systematic approach to ease the brunt of these challenges. Enablement of basic supply chain metrics and standardized operational reporting are important stepping stones, as these capabilities will pave the way to increasing supply chain effectiveness. Advanced analytics, inventory optimization engines, and network design models will support supply chain executives with the necessary tools to meet the ever-changing needs of the pharma supply chain landscape and enable them to maintain a competitive advantage.

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INNOVATION

Vaccines: FIRE IN THE COLD CHAIN

BY *PHARMACEUTICAL EXECUTIVE* EDITORS

Vaccines are a proven and cost-effective preventative therapy for numerous disabling and fatal diseases, producing significant public health gains that generate tens of billions of dollars in health system savings each year. Only recently, however, have vaccine producers experienced the commercial returns commensurate with this long record of positive public health performance. Vaccines are now the industry standout in delivering high rates of revenue growth, with double-digit increases of 10% to 15% annually, which are expected to continue for the next several years, significantly outpacing the 6% to 7% growth rate we see in traditional pharma.

The sector's improving prospects are driven by a surge of innovation in the underlying science of disease prevention as well as the increasing importance that national health systems attach to vaccines as their primary tool in the fight against communicable disease. These factors are driving change across manufacturers and their products as well as with markets and key customers. In the era of patent cliffs and shrinking pipelines, the high rates of post-Phase III R&D success in vaccines combined with a long product life cycle—often extending well beyond patent expiry—has forced the broader industry to look at vaccines anew. Nevertheless, companies seeking to benefit from this growth must adapt to a fast-evolving environment that includes lengthy clinical development timeframes, large investments in complex manufacturing platforms, and an often politicized price

and reimbursement structure that demands significant attention to building relationships with numerous external stakeholders.

Key growth factors

There is significant untapped potential in the preventive vaccines market. Unmet needs remain since many diseases still have low immunization rates or no available vaccine. Financial analysts have projected the market to reach $39 billion in 2015. The World Health Organization (WHO) expects the global market to soar to $100 billion by 2025, with 120 new products flowing from company pipelines over the next decade.

A range of factors are driving this growth. Our experience in the industry has highlighted three: **An increase in awareness of infectious diseases**: Changes in the global reimbursement landscape, and higher prices for new vaccines. Increased awareness of infectious and communicative diseases: National governments are the dominant customer globally and play a substantial role in purchasing, enforcing safety regulations, and influencing uptake. Over the past decade, governments and supranational organizations have expressed growing concern over public awareness of infectious disease prevention, dedicating substantial investment in mass immunizations and outreach programs in efforts that translate into opportunity for manufacturers.

> "IMPROVING PROSPECTS ARE DRIVEN BY A SURGE OF INNOVATION IN THE UNDERLYING SCIENCE OF DISEASE PREVENTION."

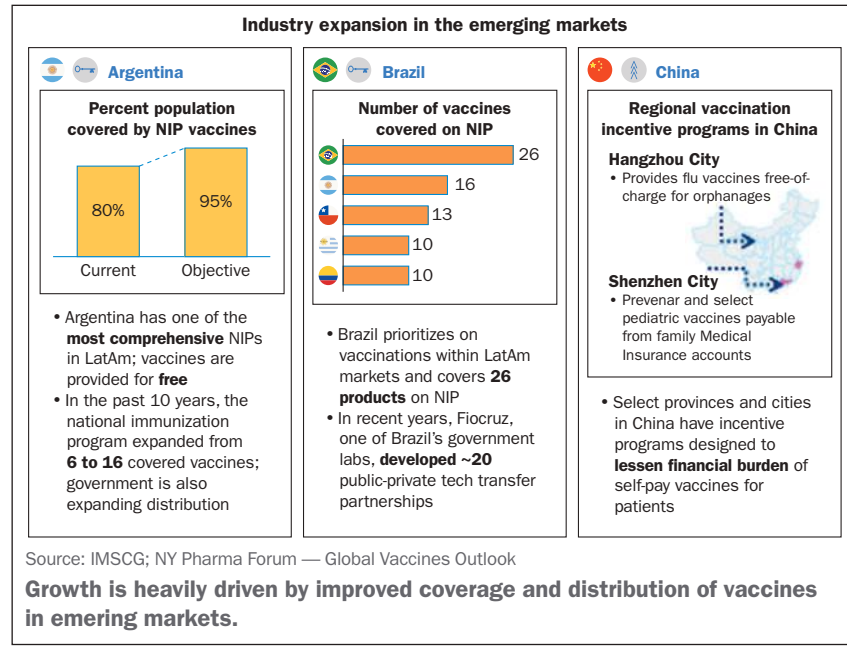
Global outbreaks of vaccine-preventable diseases have driven much of the growth in public awareness. Seasonal influenza outbreaks like the H1N1 strain have claimed many thousands of lives and taken enormous tolls on national health expenditure. Growing awareness provides the impetus for governments to invest in programs aimed at preventing onset of future outbreaks. These programs supply funding for mass immunization programs, which play an instrumental role in elevating uptake. The WHO, for instance, now supports campaigns that provide not only funding but bottom-up infrastructural support, through numerous public outreach programs for vaccination, including sponsorship of the annual World Immunization Week.

Recent examples of how outbreaks can impact awareness and government policy are the meningococcal B (MenB) outbreaks, which led to meningitis cases and at least one death on a handful of US college campuses. In response, the US CDC and FDA made Novartis' Bexsero vaccine available for use with limited populations despite the product not being broadly licensed for use in the US. In addition, Bexsero and Pfizer's rLP2086 recently received "breakthrough" designation from the FDA, making these two products eligible for accelerated review. We anticipate an updated Advisory Committee on Immunization Practices (ACIP) recommendation for MenB vaccine use. Such a recommendation is expected to compel most payers to cover the product for eligible populations.

Non-profit and non-governmental organizations, such as the Gates Foundation, the Clinton Health Access Initiative, Global Alliance for Vaccines and Immunization (GAVI), as well as many others are increasingly influential as brokers in the negotiation of vaccine purchasing for ministries

of health for developing nations and/or as advocates for vaccine use. Each of these groups are receiving more philanthropic support. They also provide access to medications in emerging and developing markets, prioritize vaccination on public health agendas, and help shape national immunization program strategies on coverage, pricing, and uptake.

Better access and more predictable pricing: Immunization is attracting more attention on national health agendas; governments, in collaboration with supranational organizations, have responded by improving or adding vaccine coverage linked to preventive public health interventions. Provisions in the 2010 US Affordable Care Act mandate all health insurance plans to make recommended vaccines available with no out-of-pocket deductible or co-payment incurred to the patient, a provision that is intended to bring improved prevention coverage for 88 million beneficiaries by 2013.



Source: IMSCG; NY Pharma Forum — Global Vaccines Outlook

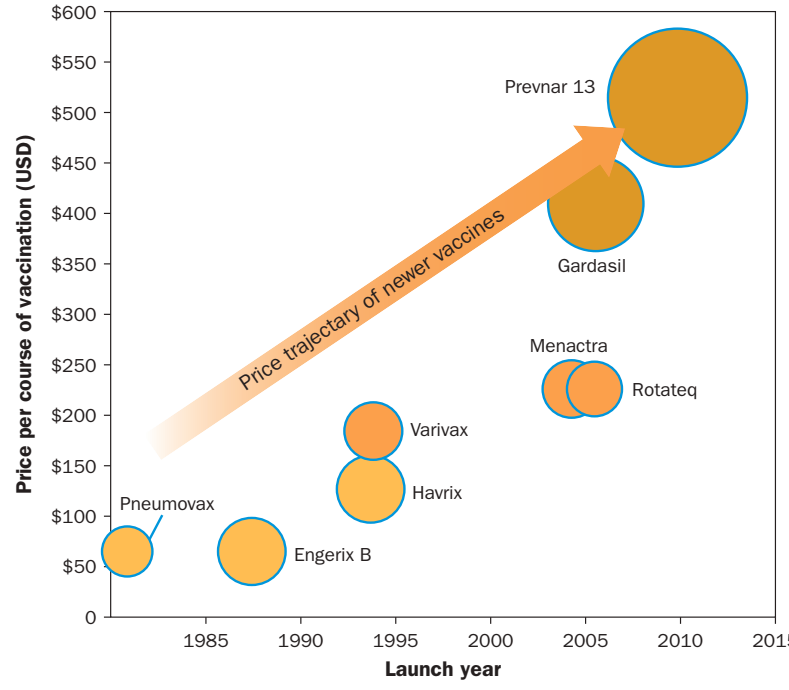
Growth is heavily driven by improved coverage and distribution of vaccines in emering markets.

Other mature markets, including Japan, have increased their emphasis on vaccination as a public health priority. In an effort to narrow the country's historical "coverage gap," Japan's Ministry of Health, Labor, and Welfare (MHLW) has poured investments into the vaccines manufacturing and R&D pipelines of Takeda, Astellas, Daiichi Sankyo, and Mitsubishi Tanabe to promote immunizations against prevalent infectious conditions. The MHLW has provided generous incentives for vaccine manufacturers, funded awareness programs, and by 2015, aims to include HPV, Hib, pneumococcal, varicella, mumps, and hepatitis B vaccinations as part of the national immunization program. The Japanese vaccines market has grown at a 28% CAGR from 2006-2011.

Uptake is also heavily driven by improved vaccine coverage and distribution in emerging markets (see chart below). Argentina, which currently has one of the most comprehensive national immunization programs in Latin America, provides vaccines for free and has expanded the number of mandatory vaccines from six to 16 over the past ten years. Moreover, Argentina's Ministry of Health aims to increase the percentage of covered individuals from 80% to 95% and has drafted plans to expand its vaccine distribution system to ensure universal access. Brazil currently leads Latin American countries in immunization protection, with 26 products covered under the

national immunization program. In China, select provinces and cities have instituted regional programs for flu and select pediatric vaccines designed to lessen the individual financial burden of vaccines that are not covered for patients.

More evidence of the importance of immunization in emerging markets is the increasing activity of local mid-sized manufacturers and government labs. China's Sinovac, Brazil's Butantan Institute, South Africa's Biovac, Mexico's Birmex, and the Government of India's Serum Institute are developing newer vaccines, investing in more advanced manufacturing technologies, and experiencing higher uptake of in-line products. Brazil has made technology transfer a critical part of its overall national vaccine policy as was seen with Brazil's Ministry of Health agreement to purchase $2.2 billion worth of GSK's Synflorix in return for a gradual receipt of the technology to independently manufacture the vaccine after the end of the 10-year-long contract. Sanofi has partnered with Birmex in Mexico and Butantan in Brazil in a tech transfer agreement for its influenza vaccine. Many of the mid-size institutes have entered into purchasing agreements with supranational organizations such as GAVI, the Bill and Melinda Gates Foundation, and the Program for Appropriate Technology in Health (PATH).



Source: US CDC; IMS Knowledge Link; NY Pharma Forum — Global Vaccines Outlook

Prices for new vaccines are increasing relative to traditionally mandated products.

Strong innovation is reflected in elevated price levels: Part of the sector's growth is derived from the higher prices newer first-in-class products have commanded based on the value they provide (see chart below). Wyeth launched Prevnar-7 in 2000 at a price that exceeded most other pediatric vaccines combined while still demonstrating high cost-effectiveness. Merck's Gardasil for human papillomavirus was priced at near $400 upon launch in 2006. With increased value driven by six additional strains, Pfizer's launched Prevnar-13 at a price of approximately $513 per course.

Even in categories that are crowded with competition, innovation has enabled price differentiation, as evidenced by Sanofi Pasteur's Fluzone HD, which is targeted at the elderly sub-segment of the overall flu market where unmet need is most pronounced. While Fluzone HD has not

demonstrated greater protection from influenza disease than regular flu vaccines at the time of this writing, it has demonstrated improved immune response in clinical trials. Significantly, the private list price for Fluzone HD is more than twice that of multiple standard dose flu products. AstraZeneca's FluMist was recently able to gain a CDC recommendation at the other end of the age spectrum. The CDC indicated that influenza incidence was markedly lower in the 2- to 8-year-old age group when vaccinated with a nasally administered vaccine. FluMist also commands a premium price in the market.

> "VACCINES ARE NO LONGER A FRINGE BUSINESS—IT'S THE "MUST HAVE" IN ANY PUBLIC HEALTH AGENDA."

In addition to the drivers already mentioned, we have also seen growth from successful lifecycle management strategies. The two largest-grossing products in the preventative vaccine industry, Gardasil and Prevnar, are perfect examples. Gardasil for instance, doubled its eligible recipient base after receiving approval for male anal cancer, genital warts, and pre-cancerous lesion indications. In January 2013, Pfizer's Prevnar similarly received a nod from the FDA for an age 50+ expansion, a decision that has led Wall Street analysts to project an increase in sales from $4 billion to $5 billion a year. Vaccines that currently lead market sales have and will continue to provide a steady source of growth, and manufacturers intend to leverage R&D, manufacturing, and marketing capacity and increase year-on-year investments on promotional spend, post-marketing surveillance studies, and indication expansions.

Industry growth has led to M&A activity: Many large-scale manufacturers have turned to vaccines to drive sustained growth and branded revenue. In 2010, the industry reported over 195 vaccine partnering deals, including Johnson & Johnson's acquisition of Crucell, a $2.3-billion deal which strategically introduced the big pharma conglomerate to the mid-size vaccine manufacturer's portfolio of pediatric, endemic, and travel vaccine assets.

Other notable deals include GSK's recent $5.25 billion initial cash purchase of Novartis's non-influenza vaccine assets, in return for the transfer of GSK's oncology franchise and the development of a distinct consumer healthcare business. This brings to GSK a portfolio of travel assets that includes a promising meningitis vaccine franchise. Sanofi Pasteur's acquisition of Acambis in 2008 augmented the second-largest vaccine manufacturer's flu and tailored multivalent combinations with West Nile and dengue fever travel vaccine assets. In 2007, AstraZeneca acquired MedImmune for $15.6 billion in a deal that through Synagis and FluMist, positioned the company as the sixth-largest vaccines manufacturer. Takeda (see sidebar) launched a new business unit dedicated to vaccines in early 2012, and Mitsubishi Tanabe acquired Canadian company Medicago, thereby getting access to Medicago's innovative technology for producing vaccine-like particles from tobacco plant leaves.

What's next in vaccines

The next generation in vaccines development will rely on platform strategies founded on genomics, reverse vaccinology, high throughput DNA sequencing, new plant and insect

based expression and production systems, and new more potent vaccine adjuvants. These developments carry the potential to rapidly produce novel, optimal and cost-effective vaccine targets that carry high chances of success in clinical development programs. Promising new vaccine candidates such as meningococcal-B, GBS, methicillin-resistant Staphylococcus aureus, pneumococcal, and pathogenic E. coli are already in development. Not only do these new platforms improve the prospects for vaccines against major infectious diseases such as AIDS, tuberculosis, dengue, and malaria, they also provide a basis for therapeutic-based vaccine development against other new and emerging conditions, including allergies, autoimmune disorders, and cancer.

Business points to ponder

New markets and diseases, specialized target populations, and increasing needs for preventive vaccines all lead to new opportunity, but also impose new challenges. The key strategic questions manufacturers will need to address include:

- How to price products whose commercial benefit will rest predominantly in emerging markets?
- How to effectively capture niche populations within an established vaccine disease area?
- Within the structure of public health requirements and recommendations, how can technology advances be effectively translated into commercial advantage?

The benefits that the vaccine market offers will accrue to those who are able to creatively adapt and build on past approaches while incorporating the advances of new science and a more supportive policy environment: vaccines are no longer a fringe business—it's the "must have" in any public health agenda.

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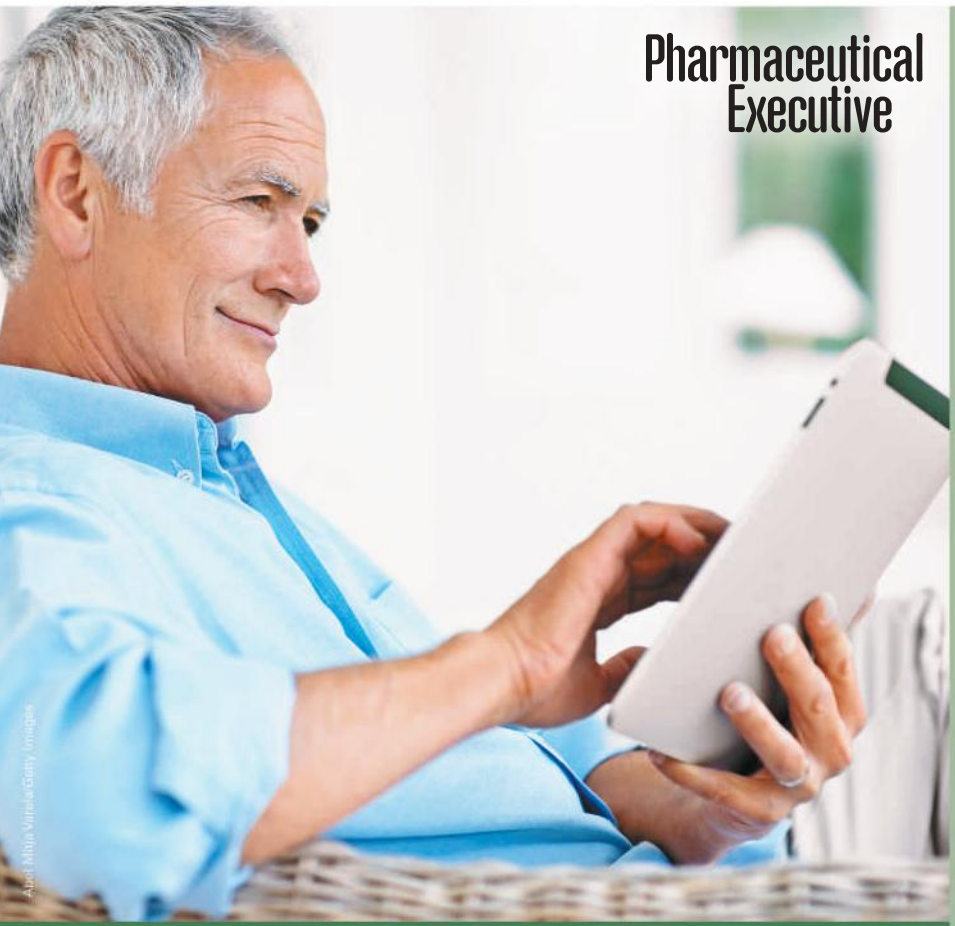

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NETWORKS

THE URGENT PUSH FOR A PULL SUPPLY CHAIN

BY JULIAN UPTON

In *Pharm Exec's* 2013 end-of-year supply chain roundup, we began with a three-word vision of the immediate future that left little room for ambiguity: "Serialization is coming." With the impending laws regarding "track and trace" promising to alter the way pharmaceuticals are packaged and shipped, we outlined how global pharma was gearing up to deal with the effects of serialization, and how companies needed to review their own internal practices and those of their outsourcing partners, as the need for technology solutions for both sides of the outsourcing relationship became more evident.

Of course, that message still stands, and it is arguably even more urgent if we are to believe Ian Haynes of 3C Integrity Consulting, who unnerved many in the audience at London's recent FlyPharma 2015 conference when he said that pharma is still not ready to meet the obligations of track and trace. But since 2013, a number of other concerns—some equally as transparent, others less immediately visible—have emerged to stand alongside the move to serialization as potentially major disruptions in the way the industry operates. Indeed, as we head into 2016, one industry insider believes the pharma supply chain is facing a confluence of challenges "the likes of which it has never seen before."

Daunting path

Alan Kennedy, director at PartnerSave, pulls no punches when he outlines the litany of challenges that he sees confronting the pharma supply chain over the next five years. He points to "the escalating good distribution practice (GDP) demands on the industry (and the need for greater harmonization); the pressures from the marketplace for cheaper medicines; shifting consumer expectations, with the trend towards more specific, personalized medicines; and rocketing costs."

The crises are already starting to hit. Kennedy says: "A lot of pharma companies are waking up to the fact that they need to sharpen up their act in terms of compliance with the regulations. But while a lot of the need for change is regulatory driven, it's also competitive. There's a lot of lip service paid to the need for reform, but the problem is translating the intention into action."

One of Kennedy's "perfect storms" on the horizon is gathering around outsourcing from, and supply to, emerging markets. As these are the markets "where growth is coming from," he stresses that pharma companies must be better integrated and work more closely with their partners if they are to continue to expand in developing countries. "They've got to make sure that the best practices that apply here also apply there. There's no use having a state-of-the-art facility in the US but not in, say, India or Latin America, where you're doing business; products have to be reliably protected from start to finish."

> "FAST-GROWING FIRMS MUST ESTABLISH THEIR EMERGING MARKET NETWORKS IN A MUCH SMARTER, MORE FLEXIBLE WAY....BY INVESTING IN A HUB IN, FOR EXAMPLE, DUBAI AND THEN OUTSOURCING THE HUB'S 'ARMS AND LEGS' TO LOCAL DISTRIBUTION WAREHOUSES ACROSS THE MIDDLE EAST, A COMPANY CAN MINIMIZE ITS CAPEX INVESTMENT AND ACHIEVE FLEXIBILITY."
>
> *– Vitaly Glozman, partner at PwC*

John Menna, vice president of strategy, healthcare logistics, at UPS, often observes companies "doing a fantastic job of maintaining the efficacy of their products from manufacturer all the way to the destination country." But when the products get to their destination, where there isn't the same commitment to rigorous procedures, "they end up not being stored at the proper temperature, in the right environment, and with the right protocols." And companies may be unaware of this, Menna adds. "If a vice president of supply chain at a big Pharma company flies out to the destination and sees how products are being stored there, they may be in for a shock. Companies need to take a hard look at their supply chain endpoints, and at the providers that they're using."

Fast-growing firms must establish their emerging market networks in a "much smarter, more flexible way," Vitaly Glozman, partner at PwC, told *Pharm Exec*. Traditionally, big Pharma's "huge,

static networks" have been difficult to change or use effectively. Glozman believes that a "hub-and-spoke" model could provide the key. "By investing in a hub in, for example, Dubai and then outsourcing the hub's 'arms and legs' to local distribution warehouses across the Middle East, a company can minimize its CAPEX investment and achieve flexibility," he explains. "Or, if things go south, it has the ability to reduce volumes and spend, kind of like transitioning its CAPEX to its OPEX."

As companies gear up to expand into more countries with more products, however, there will be, accordingly, more threats to data and product security. "A lot of companies are going to be selling so-called drug-device combination products that include data collection capabilities. These products will enable the patient to communicate the results. How that data will be transitioned back to the pharma company or provider presents a big challenge. Companies will not only have to deal with product security but also patient information security," says Glozman.

The patient 'pull'

Certainly, pharma seems somewhat unprepared for the supply chain demands of an increasingly patient-focused future. This is largely a result of the healthcare supply chain remaining, says Menna, a "push supply chain, where manufacturers, wholesalers and distributors push products into the channel and downstream to the hospitals, doctors' officers and ultimately to the patient."

But things are moving to a point where patients are pulling products through the supply chain for their own consumption. "This is similar to a retail environment; to take an extreme example, it's like an online purchase of audio-visual equipment to be delivered to the home." With more personalized medicine procedures being done outside the institutional setting and closer to the patient— either in an outpatient facility or even patients' homes—logistics solutions will need to start providing for the sending of alerts to patients, allowing them to determine when and how a product is delivered, and facilitating the transportation of critical specimens from the patient to diagnostic labs.

Data: Key cog in chain

As the pharma supply chain evolves from "push" to "pull," analytics will become a more vital part of the process. Much has been written about analytics and big data, but now more than ever, leveraging the data that pharma has been collecting and investing in predictive and prescriptive analytics will be key to maximizing the promise of data, for issues ranging from temperature

FAST FOCUS

- Several challenges threaten to impede the pharma supply chain in the coming years, among them: Rising GDP pressures, demand for cheaper drugs, evolving patient expectations amid emergence of personalized medicine, and soaring costs.
- Pharma must adapt its supply chain model to an increasingly patient-focused future, shedding its allegiance to the product "push" mentality, and embracing today's patient-driven "pull" reality. Greater investment in predictive and prescriptive analytics is key to that effort.
- Best practices going forward include more effective supply chain integration, bending the supply chain cost curve, increased collaboration with regulators, better use of end-to-end data, and raising the profile of supply chain management in the overall value equation.

tracking to warnings of drug shortages and recalls. "You'll start to see companies making more use of big data to develop better therapies and leaner supply chains in the next five years," says Menna. The challenge of analytics begins with determining the different business questions you want the data to answer, Glozman says. "Otherwise, analytics is a very strategic tool that can be misunderstood and misused." He goes on: "You need bright, capable people managing your supply chain. You don't just want people who say, 'Let's do some analytics.' They need to say, 'Wait a second, what is the specific problem we need to understand better? Let's identify the data attributes and then define our analytics.'"

For Kevin Pegels, VP, global supply chain management – PS Biotech, Bayer HealthCare, there are ongoing issues around end-to-end data availability and decision-making that also need addressing. "There is a gap right now in pharma with regard to the visibility of data concerning suppliers' capacity and inventory and customer inventory," he says. "What inventory do customers have? What is patients' consumption? This information is critical for an efficient supply chain."

Non-pharma lessons

Pegels formerly worked in the consumer packaged goods business, which he says "is about 15–20 years ahead of pharma in terms of best practice supply chain management" He points out that as soon as consumption is seen, for example, at a Walmart store, that immediately drives orders to the suppliers for replenishment shipments to the Walmart warehouses. "Pharma is long way from that kind of end-to-end visibility, but it is catching up, says Pegels, "because we are finally realizing that the supply chain can add a lot of value."

Outside of consumer packaged goods, which other industries can pharma look to for lessons on optimizing the supply chain? Alan Kennedy notes that one industry that has been a big advocate of supply chain integration for the last two decades is construction. "The construction industry has the disadvantage of having one of the most complex supply chains out there," he says. "Every project is a one-off, every project needs a different supply chain, and every one is organized in a different way, all for relatively short periods of time. Construction has all sorts of challenges that are driving real, close collaboration." The automotive industry's supply chain management also "is right at the forefront,"says Kennedy, along with retail and electronics.

But while best practices from other industry supply chains can be adopted by healthcare, "it is very important to note that healthcare is different," says Menna. "The first thing to remember is that at the end of the healthcare supply chain is the patient, whose quality of life will be affected, and hopefully improved, by the treatments he or she receives. So there is a certain level of urgency, because we are talking life or death, or at least quality of life." Second, the sensitivity of the products and the regulatory environment surrounding their movement and storage "are unlike anything in any other industry."

Own innovation is vital

Given those dynamics, pharma still needs to find its own solutions for its own supply chain challenges. The "big answer" for Kennedy is that companies have to start integrating more successfully. "An integrated supply chain is more than just a collection of collaborative

organizations," he notes. "If you look at it as a box, within that box you've got all the network controls and tools: quality management, shipment visibility, inventory management, regulatory compliance, network communications, education, and training. A properly integrated supply chain addresses all these issues as a unified network."

For Glozman, cost will become key. "I believe there'll be a push for the lowest common denominator in terms of cost. I don't think companies have yet begun to address this issue properly. Bending the supply chain cost curve is going to be critical." Glozman also sees more focus on collaborating with regulators. "The industry still currently deals with the regulator as a separate entity rather than as a collaborator," he says. But with so many changes looming over the next five to 10 years, certainly as far as manufacturing technologies are concerned, "the industry will change to have a much more collaborative relationship with regulators." Similar to what has taken place in other regulated industries, Glozman sees pharma companies "actually co-locating a regulator staff member within their facility and working with them on new product development."

The industry "is currently about 30-35% over capacity and it will take a little while to subsume this, because some of this capacity is not ready for the future," Glozman adds. There will be "a lot more flexible, single-use manufacturing, particularly for complex and biologic products where companies want to minimize the cross-contamination risks." For more high-volume manufacturing, he adds, "I think we are going to see continuous manufacturing become more of a standard over the next five years."

Better leveraging of end-to-end data and decision-making will shorten lead times within the pharma supply chain, says Kevin Pegels. He also sees supply chain management gaining more stature within pharma companies. "You may see a chief supply chain officer reporting to the CEO in the next five years," he says. "With all the competition and downward pressure on pricing, the supply chain needs to play a bigger role to maximize cost efficiency. And just to be part of the game with customers, companies have to have reliable and predictive supply. Pharma is realizing that it has to start investing now."

Against the clock

The time the industry has to re-engineer its supply chain is hardly in abundance. Is such a revamp of current practices achievable in such a relatively short time? Despite his concerns for the future, Alan Kennedy, for one, is confident that "there's always someone to take the lead, and some companies will do that. Once that happens, they will see a big competitive advantage coming in their direction. They will see quality improvements, profitability improvements—all the advantages that come with better integration."

Maybe then pharma's supply chain reaction will start in earnest.

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