Robin Robinson

GLOBAL Supply Chain: Information Drives Transformation

Connecting directly with patients will be a new role for the supply chain function.

There are a number of factors that are expected to reshape global supply chain processes, but none more than the onset of comparative effectiveness and the need to monitor and document patient outcomes in the United States. This alone will dramatically drive change in the way the entire industry manufactures and distributes its products.

According to PwC reports, many pharmaceutical companies have started tweaking their supply chains, but mostly for cost-savings and improved safety and security, using short-term solutions. What the industry must prepare for is a total transformation of its global supply chain, evolving from a cost-bearing, but necessary function, into a strategic asset that will meet the needs of tomorrow's consumer. The supply chain of the future will play a key role in providing value by managing certain elements of patient services that will encourage and facilitate better health management.

For example, with the advent of comparative effectiveness, the industry supply chain will not only have to manage the manufacturing and distribution of medicines and companion diagnostics, it will also have to ensure that patients receive the most from those therapies by offering a wide range of supporting services.

Wynn Bailey, U.S. supply chain leader, pharmaceutical and life sciences practice at PwC, tells us that the industry will soon be operating in an environment where companies will be compensated not on their ability to simply supply a product to patients, but on patient outcomes related to the treatment, so it is crucial for the supply chain of the future to have the ability to connect with patients.

"Companies are beginning to view the supply chain as a link to patients that provides strategic value by building connections," Mr. Bailey says. "Companies will have to provide a wide range of services to help patients comply with their medical regimens and monitor the effectiveness of their interventions, activities that have traditionally been the province of healthcare providers and payers. And they will have to ensure the products and services they develop are fully integrated with the care pathways and disease states they address."

Patient Outcomes Driving Change

Leveraging the supply chain as a tool for demonstrating patient outcomes is the next great area of growth for the industry, Mr. Bailey says.

"As many elements of the U.S. healthcare reform become effective and as reimbursement models for providers begin to shift more toward outcomes-based reimbursement models, providers will expect suppliers to help them not only achieve better outcomes for patients but also to demonstrate that those outcomes have been achieved," he says. "This trend will unfold within the next five to 10 years; it won't happen overnight, but it is certainly coming."

The suppliers in the best position to add value around outcomes are companies that manufacture multiple products and services that address a particular patient group or disease state, as they can provide a more comprehensive array of products and services to

their customers. With multiple medications, diagnostic tools, and other types of therapies, a company can combine products and services together for customers and create payment incentives and commercial arrangements that jointly reward both the hospital customer and the supplier for achieving the same types of outcomes.

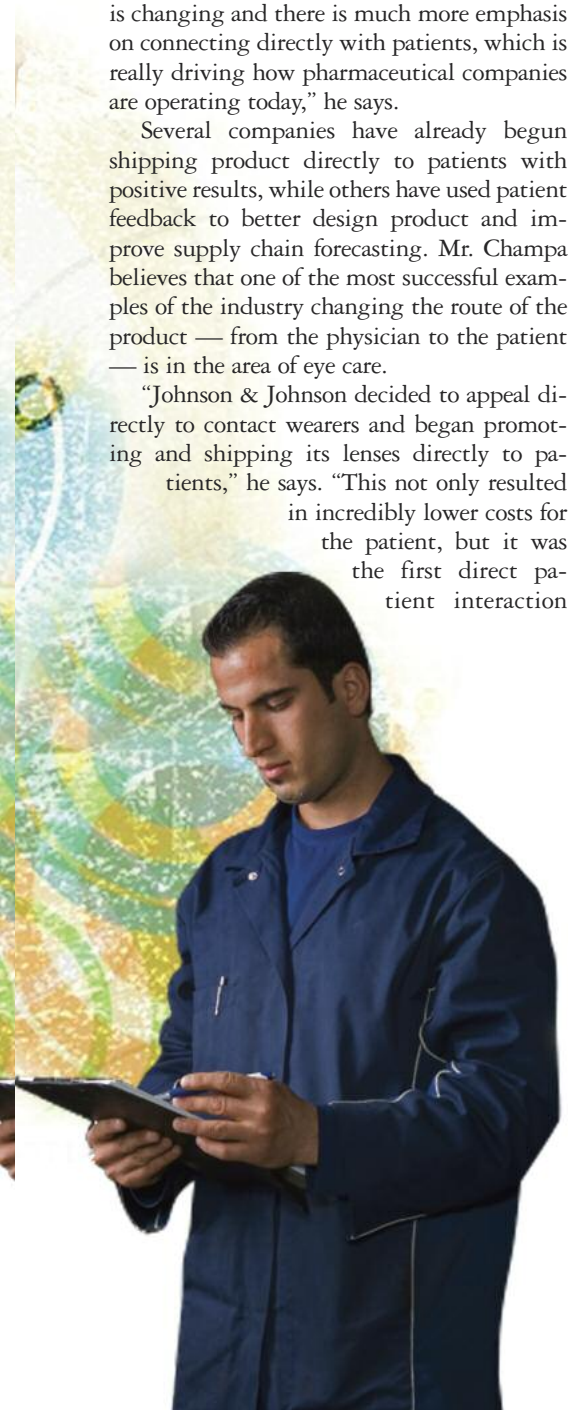
"This approach is theoretical now, but there are some companies experimenting with this model," Mr. Bailey says.

The new focus on patient outcomes throughout the supply chain will require companies to have greater interactivity with patients, says Domenic Champa, managing director, Protiviti.

"In the past, patients sat to the side while physicians, hospitals, and managed care groups managed their health affairs, but this is changing and there is much more emphasis on connecting directly with patients, which is really driving how pharmaceutical companies are operating today," he says.

Several companies have already begun shipping product directly to patients with positive results, while others have used patient feedback to better design product and improve supply chain forecasting. Mr. Champa believes that one of the most successful examples of the industry changing the route of the product — from the physician to the patient — is in the area of eye care.

"Johnson & Johnson decided to appeal directly to contact wearers and began promoting and shipping its lenses directly to patients," he says. "This not only resulted in incredibly lower costs for the patient, but it was the first direct patient interaction for the brand, and had enormous implications on the supply chain."



Social and mobile networking is similarly impacting the supply chain by creating channels to connect with patients, providing manufacturers with the opportunity to better understand what patients need, and design and plan for product supply accordingly.

"As technologies continually become available to interface with patients from a diagnostic perspective, companies will gain a better understanding of their patients, including what they do, what their medical needs are, and consequently, how best to treat their disease," Mr. Champa says. "Ten years ago, companies would not have had the opportunity to understand what the individual patient needed in regard to treatment options. Today however, there are technologies being developed that leverage patient input and help improve supply-chain forecasting and product requirements more efficiently than in the past."

Mr. Bailey agrees that the landscape has changed radically in terms of the interaction between patients and suppliers.

"Today, many companies are addressing the heart of their business strategy by connecting to patients and determining how to create direct routes to customers, where in the past, the industry didn't even have visibility into who their customers were," he says.

Understanding patient needs through patient interaction can help tremendously in forecasting for product supply and product improvement.

For example, according to Mr. Champa, patients with multiple sclerosis have recently benefited from this type of visibility. Previously, all MS treatments were self-injected or infused. One manufacturer of MS treatments discovered by talking with patients that this was not ideal.

"By gleaning pertinent information from patients through its service centers, one company realized it needed to come up with a better way for patients to manage their treatment," Mr. Champa says. "After spending an enormous amount of time and effort understanding what patients needed and wanted, the company developed and launched the first oral treatment for MS, as well as an auto injection pen delivery device — neither of which had been previously available."

Pharma companies will also need to make significant changes in supply chain distribution as healthcare shifts from hospitals and healthcare clinics to a more diffused network of nurses and community caregivers.

"Companies will need to distribute their products to many more locations, including patients' homes," Mr. Bailey says. "Harnessing the most efficient final mile distribution networks to deliver medicines to the door as economically as possible will be a new challenge, but it will have benefits."

> "Twenty years ago, relatively speaking, pharmaceutical companies didn't even think of supply chain costs as an issue."
>
> **DOMENIC CHAMPA** / Protiviti

The digitalization of healthcare delivery, with greater use of electronic health records, e-prescribing, and remote monitoring, will provide pharma with one of the key components needed to make the transition. Access to these data will enable pharma companies to build demand-driven supply chains in which healthcare packages for different patients are assembled at super hubs before being delivered to their homes, PwC reports.

According to Mr. Bailey, in a new world where outcomes will become paramount, it will no longer be the products that create value but, rather, the supplier's ability to integrate data, products, and services in a coherent business offering. By 2020, information about patients and the medicines they need will thus be as important as the products themselves.

"Understanding this shift of emphasis from products to patient outcomes is critical; those firms that can develop and supply integrated product-service packages will be able to deliver significant benefits to every stakeholder in the healthcare value chain," Mr. Bailey says.

Reducing Costs and Improving Flexibility

Industry supply chains have not been known for being flexible or cost-effective, and up until today's new market environment, there was no need for them to be. Historically, pharma companies' economies of scale easily absorbed any unexpected costs caused by production, workflow, or distribution issues. However, with generic competition, looming patent cliffs, and healthcare reform pressures creating a tougher landscape, supply chains need to operate lean and be more responsive to market factors.

The lack of blockbuster drugs contributes significantly to this new need for efficiency. "Twenty years ago, pharma didn't even think of supply chain costs as an issue because when a company makes 95% gross margin on drugs, supply chain costs is simply not a factor that drives how a company behaves," Mr. Champa says.

Mr. Bailey adds that the high margins that made it feasible to tie up capital in large stocks of raw materials and finished goods are ending.

"From my perspective, companies today are dealing with three critical factors driving their decision-making in supply chain management and they are struggling to find balance," he says. "The first area is assuring the supply is available; no company wants to be short of product when a patient requires it. The second area involves security and integrity of the supply chain to prevent counterfeit, fraudulent, or contaminated products from reaching patients. And third, of course, is the supply chain's new role in helping companies measure and assure outcomes for patients."

In Ireland, manufacturers are meeting these challenges by developing new organizational functions in the form of special groups tasked with finding lower-cost alternatives to manufacturing drug ingredients in house. According to Dave Shanahan, global head of life sciences, IDA Ireland, the agency responsible for Ireland's industrial development, nine out of the top 10 pharmaceutical companies have manufacturing plants in Ireland. He notes that Ireland is the largest exporter per capita of pharma chemical products in the world, at EUR 46 billion ($59.9 billion) annually.

"It's interesting to note that now in addition to manufacturers' internal product sourcing and product development, companies are also creating external supply groups whose job it is to look for alternative supply sites, particularly for active pharmaceutical ingredients or drug intermediates," he says. "There is a new recognition within these companies that if there is an alternative supply of a quality product and it's cheaper than what the company can produce internally, there's pressure being placed to source that to the outside organization network."

Other challenges include operating manufacturing plants that are becoming inadequate for producing new therapies, the increased need for cold chain management, and increasing pressure to be environmentally friendly.

"The increasing presence of biological molecules in the drug development pipeline will require the use of cold chain management solutions to protect the integrity of the drug," says Joseph Bedford, Ph.D., director of marketing, Almac Group. "Biologics also often have more limited expiration dates than chemical entities."

Just as new technologies are emerging to help pharma companies manufacture a wider and more complex range of medicines, new technologies also are emerging to help them distribute those medicines.

Global supply chain providers can manage these challenges by reducing shipping times, leveraging advances in packaging technologies, and using IVR/IWR technologies to closely track cold chain custody and drug inventory expirations, Dr. Bedford says.

"Cloud computing will provide the information platforms needed to share data securely and economically with suppliers around the world, to analyze the data rapidly and respond to sudden changes in supply and demand, as well as advanced tracking technologies to monitor products from the factory gate to the patient, an increasingly important feature, as the industry manufactures more biologics with high unit values and specialist delivery requirements," Mr. Bailey says.

The advances in personalized and translational medicine, such as the application of biomarkers, imaging technologies, laboratory testing, and other diagnostic testing in clinical trials, are also reshaping how biopharmaceutical companies manage their global supply chains.

"Supply chain management firms will have to more quickly respond to changes or adaptations in trials through the timely provision of clinical supplies," Dr. Bedford says. "This can be achieved, in part, through the application and integration of supply chain technologies, such as IVR/IWR and enterprisewide supply chain management systems. But it will also require global supply chain management firms and sponsors to become more responsive and proactive in the management of clinical supplies than they are today." PV

> "In Ireland, we see external supply companies being used as a means to leverage and enhance productivity for internal supply chains."
>
> **DAVE SHANAHAN** / IDA Ireland

> "New technologies are emerging to help pharma distribute its medicines."
>
> **DR. JOSEPH BEDFORD** / Almac Group

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Supply Chain: Outsourcing

One of the ways the industry can reduce costs and improve efficiencies in the supply chain is through outsourcing or partnering. Today, most companies still build, own, and operate their own supply chain infrastructures, however, PwC reports that a few companies are moving toward sharing manufacturing and distribution resources with other companies, or outsourcing to third parties.

Outsourcing for Global Efficiency

According to Dave Shanahan, global head of life sciences, IDA Ireland, outsourcing will be a practice that certain manufacturers will engage in with increasing frequency.

"With consolidation a big factor in the great race and with global capacity at about 50% in small molecules, a lot of companies are rationalizing their operations," he says.

This can create some discord within the company if manufacturing is not on board with outsourcing.

"For some very complex manufacturing of proprietary products, companies often find that outsourcing partners can't maintain the same level of quality that internal supply chains can," Mr. Shanahan says. "This can create tension between manufacturing groups wanting to hold on to the process and commercial folks arguing that they need to lower the cost of goods."

Wynn Bailey, U.S. supply chain leader, pharmaceutical and life sciences practice, PwC, says outsourcing depends on manufacturer capacity and core competency.

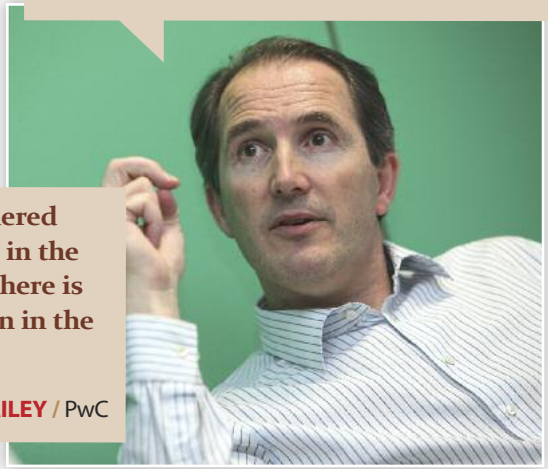
"We see a bifurcation in strategy — companies either want to maintain manufacturing in house or they don't," he says. "Outsourcing is being considered more in the early API stages or at the far other end in final packaging. There is much less outsourcing going on in the drug production phases."

Mr. Shanahan adds that a company that is producing multiple products may be more skilled at manufacturing than a company making only one or two products."

Mr. Bailey also notes that there is a difference between the amount of outsourcing between biotech companies and pharmaceutical manufacturers.

> "Outsourcing is being considered more in the early API stages or in the other end in final packaging. There is much less outsourcing going on in the drug product phases."
>
> **WYNN BAILEY** / PwC

> "Risk and challenges are definitely increased with outsourcing, but the benefit can often outweigh the extra effort needed to maintain control and communication of the product development."
>
> **DAVE SHANAHAN** / IDA Ireland



"Looking at different patterns or predictors, it seems clear that there is less interest in outsourcing among biotechs than among chemical-based pharma companies," Mr. Bailey says. "And within companies that have both types of products, there is more openness to outsourcing on the chemical side than the biotech side, and part of that is a reflection of what constitutes product differentiation."

The more sophisticated third-party logistics providers (3PLs) — companies that offer freight management and warehousing — are expanding into supply chain management and coordination services, and it is these logistics providers that can deliver the greatest improvements.

"Pharma companies are outsourcing more of the logistics, warehousing, and transportation functions, indicating that these are not core competencies they want to maintain in-house," Mr. Bailey says. "We are seeing the industry outsource these functions more consistently to 3PLs."

According to Joseph Bedford, Ph.D., director of marketing, Almac Group, the current level of outsourcing of global supply chain services is difficult to determine due to the variety of services offered, the lack of public information on rates of outsourcing, and sponsors' tendencies to keep supply chain information confidential.

"However, we can assume that supply chain outsourcing is part of a larger trend by biopharmaceutical companies to increase outsourcing and improve R&D productivity," Dr. Bedford says. "Hence it is likely that outsourcing will continue to grow in the next few years at about 6% to 9% per year, similar to the CRO and technologies markets. In terms of how increases in outsourcing will affect the global supply chain, we are likely to see expansion of the current large supply chain providers into emerging areas where market growth and clinical trials for pharmaceutical products are increasing, such as the BRIC countries, Asia, and Latin America. We will also likely see more uniformity in how supply chains are managed on a global level, as sponsors will begin to adopt some of the best practices of the large clinical supply chain providers."

Risks and challenges are definitely in-

Four Options for Restructuring the Pharmaceutical Supply Chain

Operations Strategy

Specialist Therapies	Mass-Market Medicines
Virtual Manufacturer Create a virtual network of integrated supply partners: The first option for companies making specialist therapies is to outsource the entire supply chain from production of the earliest clinical batches to full-scale manufacturing, packaging and distribution, and become virtual manufacturers.	**Low-Cost Provider** Build a reliable, no-frills supply chain to deliver products as economically as possible: Mass market manufacturers, including generics producers, can first borrow from best practice in other sectors and become a low-cost provider.
Service Innovator Build a service-oriented supply chain to enhance brands and differentiate company from its competitors: The second option is companies making specialist therapies can become service innovators — i.e., build supply chains that are capable both of manufacturing and distributing complex treatments, and of commissioning and managing a multitude of suppliers to provide supporting health management services.	**Profit Center** Combine agile, economic manufacturing and distribution with the provision of satellite services to generate profits: This second option allows mass-market manufacturers to combine agile, economic manufacturing and distribution with the provision of satellite services for patients — and do this as a service for both internal and external customers.

Source: PwC Pharma 2020 report, Supplying the future: Which path will you take? For more information, visit pwc.com.

creased with outsourcing, Mr. Shanahan says, but the benefits can often outweigh the extra effort needed to maintain control and communication of the product development. In an outsourcing model, building a good relationship with the partner is key to success.

"In an outsourcing situation, the sponsor is very reliant on the quality of the third-party producers, which means it has to create a relationship to ensure adequate oversight, control, and early notification if problems arise," Mr. Shanahan says. "It is well-documented that there is risk, evident even in the U.S. marketplace where there are several examples of companies that have gone outside for external product manufacturing and the FDA has had problems with certain sites."

Another challenge that impacts the process is the wide and stringent regulatory conditions the industry must operate within.

"If a company is going to outsource its supply chain, it needs to work with manufacturers that can adhere to the guidelines that European and U.S. regulators impose, which are clearly more strict than those in emerging markets," Mr. Shanahan says.

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> "A manufacturer needs to be able to track a product through the supply chain and code it with a unique serial number or an identifier."
>
> **JOE MARTTILA** / Revitas

Safety and Security

There is no place along the supply chain process where safety is not an issue. Counterfeit and diversion of product is happening all over the world. Many examples have reached the headlines lately, and no manufacturer is immune. However, those that focus on taking precautions, such as using serialization and pedigree on the end product, will reduce their risk. According to Joe Marttila, senior director, life sciences strategy and solutions, Revitas, while companies are focused on track and trace for their finished product they also must not overlook the suppliers of the raw materials that are utilized in their manufacturing processes.

"At the very least a manufacturer needs to be able to track product through the supply chain and code it with a unique serial number or an identifier," Mr. Marttila says.

Additionally e-pedigree allows a product to be traced along the complete route, from the manufacturer, wholesaler, pharmacy and individual consumer and any other location the product may journey. Mr. Marttila believes this type of safety measure needs to become an industry standard, but right now only some states and countries are leading the charge, for example California is at the forefront and will require e-pedigree starting in 2015, and a few countries, such as Turkey and India, have passed limited serialization laws that are aleady in place.

"Serialization alone is not enough, with a e-pedigree, product can be tracked all the way along the supply chain," Mr. Marttila says. "The industry needs a federal program or industry-wide standard because soon there will be disparate laws and it will be very difficult for a manufacturer to handle all of the different regulations. It will be much easier if there is one universal standard to manage the safety of the supply chain." PV