A White Paper from the North American
Leader in Supply Chain Management

Transformation of the U.S. Medical Device Supply Chain

AN EVOLUTION IN AMERICA'S HEALTHCARE

EXECUTIVE SUMMARY

Business as usual ended in 2013 for the U.S. medical device industry. Although it sounds dramatic, the statement is justified.

The U.S. healthcare sector is undergoing massive change – thanks to a convergence of factors that include:

- Phased implementation of the Obama Administration's new healthcare plan – the Patient Protection and Affordable Care Act (PPACA) HR 3590, which will ultimately extend health insurance coverage to an estimated 32 million Americans who do not have any form of health insurance
- A new 2.3 percent federal excise tax on medical devices that took effect in January 2013
- Intense price pressure from payers – insurance companies, corporations and government - which is shifting buying behavior and authority
- A payer-driven shift in performance requirements — from selling devices and treating episodes to delivering positive patient outcomes
- Transition from the hospital-centric care delivery model to one that is more dispersed – i.e., retail clinics, mobile care units, assisted living facilities and home health care

While these developments did not come as a surprise to the industry, they are driving medical device companies in the United States to rethink everything – including their supply chains.

This white paper, based on research, surveys and interviews with supply chain, operations and purchasing executives from the medical device sector, takes a closer look at these dynamics, the challenges and opportunities they present, and how supply chains are adapting to tackle them. Specifically, the paper discusses:

- The current state of the U.S. healthcare system – key trends and issues
- How these developments affect the U.S. medical device supply chain
- What innovative supply chain strategies, practices and solutions are available to address these developments

STATE OF THE U.S. MEDICAL DEVICE INDUSTRY

AN INDUSTRY IN TRANSITION

The traditional medical device supply chain was built on the back of enviable profit margins – frequently as great as 20 to 40 percent according to a recent report by Deloitte.[1] High returns, such as these, are deemed appropriate by the industry since they succeed in meeting some of the toughest service challenges in innovating and delivering products that heal, maintain or save lives in a manner that meets exacting service demands.

At the same time, though, the traditional medical device supply chain is costly. Manufacturers load the supply chain with buffer inventory – everywhere – so as to avoid stock outs. Effective inventory visibility and control across the supply chain is limited or nonexistent. Emergency orders (same day and before 9 a.m.) drive the design of the entire system – even the non-emergency devices supply chain. Track and trace requirements keep growing, and a difficult reverse product flow further complicates the picture.

Furthermore, today's medical devices are part of a global manufacturing and customer network leaving manufacturers to contend with complex regulatory, customs, excise, and security regulations as well as rapidly expanding product ranges (up to 150,000 items or SKU's). This process becomes even more complicated when products require controls for temperature, hazards or sterilization.

The result: While the supply chain delivers extraordinary service – it does so at a high cost structure that is unsustainable going forward.

Even though medical device manufacturers recognize this, at present, there is no clear roadmap for how these changes will ultimately play out. One thing is certain, though, the days of the traditional high margin medical device business model are over. Companies must figure out new solutions and many of these either come from or are enabled by supply chain innovation.

Their challenge is to develop a new business model that supports the future of healthcare, and design supply chains that deliver this new model. Thus, leading companies are redesigning and retooling their supply chains – to embrace strategies and tactics that reduce inventory and cost, improve visibility and responsiveness and eliminate waste while guaranteeing the highest service levels.

THE U.S. HEALTHCARE ENVIRONMENT

There are a number of forces driving change in the U.S. medical devices industry, the most significant is healthcare reform. Implementation of the PPACA, signed into law on March 23, 2010, has created a perfect storm of disruption for the U.S. healthcare system. This disruption is driven by new regulations and taxes, enormous pressure to reduce costs, a continued shift in buying power from doctors to administrators, payers and procurement organizations, and a rise in patient power; effectively reversing what was in place for generations.

The relatively new law requires virtually all Americans to obtain health insurance coverage or pay a penalty for non-compliance. States will simultaneously be responsible

[1] Sanjay Behl, Terry Hisey and Ralph Marcello, "Moving Target: Life sciences, health care reform and the new marketplace", Deloitte Review, 2011.

for coverage for a larger number of people and also for implementing health information programs and health insurance exchanges, mostly during a time of budget shortfalls. It is conceivable that implementation will vary substantially by state, requiring medical device companies to potentially treat each state as a separate account and dedicate resources to meeting the particular and specific needs of those large accounts.[2]

One of the key provisions of the PPACA is a new 2.3 percent tax on medical devices which went into effect January 1, 2013. The highly controversial tax is expected to generate about $29 billion USD in additional tax revenue over the next 10 years. It is a key funding mechanism for the PPACA. According to one report, Medtronic, a large medical device manufacturer, estimates that the tax will increase its annual tax liability by $125 million to $175 million USD, or 1 – 2 percent of its U.S. sales.[3] It is unlikely that device makers will be able to pass these costs on to payers and consumers.

"Our nation's fiscal challenges and our industry's bulk are on a collision course," writes Paul Keckley, executive director, Deloitte Center for Health Solutions in a recent report.[4] According to the Congressional Budget Office, national health spending is projected to grow at an average rate of 5.7 percent annually between now and 2021, which would be 0.9 percent faster than the expected annual increase in gross domestic product (GDP) during this period. As a result, the health share of GDP is projected to rise from 17.9 percent in 2010 to 19.6 percent by 2021.[5]

Hospitals and facility operators are being squeezed: tighter margins and reduced revenues mean tougher negotiations, leaner operations and increased pressures to reduce costs. Medical device manufacturers are caught in the cross fire: hospitals and other medical providers require better prices, health plans demand steeper discounts, and the federal government wants increased regulatory oversight to assure greater safety and improved outcomes.[6]

A recent article in The Economist summed up these changes: "America's new health-care law includes a 2.3 percent tax on medical devices, but this is trivial compared with other shifts. Health plans are forcing patients to pay a larger share of costs, so those who

[2] Ibid.

[3] Bourne Partners, *The Medical Device Excise Tax – Ramifications for Device Makers*, http://bournepartners.wordpress.com/2012/03/27/ the-medical-device-excise-tax-mdet-ramifications-for-device-makers/, March 27, 2012.

[4] Deloitte Center for Health Solutions, 5 C's for 2013 – Clarity, Costs, Compliance, Consolidation and Consumers, http://blogs.deloitte.com/centerforhealthsolutions/2013/01/five-cs-for-2013clarity-costs-compliance-consolidation-and-consumers-.html#UrBgLk13uUl, January 7, 2013.

[5] Congressional Budget Office projections for 2011-2021.

[6] Deloitte Center for Health Solutions, Health Care Reform Memo, http://www.deloitte.com/view/en_US/us/Insights/Browse-by-Content-Type/Newsletters/health-care-reform-memo/eae2a4232e41c310VgnVCM3000003456f70aRCRD.htm, January 7, 2013.

do not need a device urgently are slow to buy them…. Firms used to boost sales by wooing doctors, but doctors are now increasingly employed by hospitals, and companies themselves are adopting stricter ethics rules. Meanwhile the pressure on prices is only growing more intense. Hospitals, squeezed by lower government payments, are squeezing companies in turn, refusing to pay more for a new product that is only slightly better than the old version."[7]

THE EVOLVING SALES MODEL

Increasingly, unless the medical device is highly differentiated, sales will depend on the procurement process rather than on physician preference. "Once formularies and reimbursement rates are locked down, product negotiations could move into the realm of the medical administrator or other institutional purchaser, a non-caregiver who becomes the gatekeeper into the provider organization. Doctors are losing purchase decision-making power especially over devices that are more readily substituted. Hospitals and patients will increasingly make the decisions about these products."[8]

As a result, the industry's traditional use of influence, which was directed at physicians, will no longer be relevant except for those devices that are most clinically unique – such as an innovative new knee implant design. Instead, hospitals will likely shift more decisions to a procurement model or, in cases where the patient bears the cost; those decisions will likely be shifted to the patient.[9]

At the same time, insurance companies and regulators are shifting toward performance-based healthcare management, focusing on patient outcomes vs. procedures. This puts pressure on the medical device manufacturers to compete either on cost, or differentiate their products based on superior patient results.

This creates a need to track therapy solutions and results. "It's about tracking the continuum of care rather than just selling a pacemaker," notes Rob Varner, senior director, Americas distribution for Medtronic.

[7] Left to their own devices," *The Economist*, http://www.economist.com/node/21528644, Sept. 10, 2011.
[8] Sanjay Behl, Terry Hisey and Ralph Marcello, 2011.
[9] Ibid.

THE AGING OF AMERICA

As the Obama Administration and the healthcare sector grapple with these immediate pressures, they do so with an eye to the future — specifically to the aging of America, and the impact that inflation will have on the nation's healthcare bill.

"The growth in the number and proportion of older adults is unprecedented in the history of the United States. Two factors — longer life spans and aging baby boomers — will combine to double the population of Americans aged 65 years or older during the next 25 years to about 72 million. Currently, about 14 percent of the population is 65 years or older. By 2030, older adults will account for roughly 20 percent of the U.S. population."[10]

This is the primary reason why Medicare is the fastest growing major entitlement in the federal budget, rising 68 percent since 2002.[11]

Simultaneously, there has been a major shift in the leading causes of death for all age groups from infectious diseases and acute illnesses to chronic diseases and degenerative illnesses, including diabetes, cancer and heart disease. Treatment for conditions such as these consumes more healthcare resources over a far longer period of time – another contributor to escalating U.S. healthcare costs.

These health trends, combined with the expansion of healthcare coverage, have not only led to an increase in volumes through current distribution channels, but have created new and more dispersed distribution outlets. The medical devices supply chain must now be able to provide the needed products to hospitals, clinics, mobile clinics, physicians' offices, and individual homes as well as retail stores, which carry a growing array of consumable and smaller type medical devices (e.g., diabetic meters and testing products).

[10] Centers for Disease Control and Prevention, U.S. Dept. of Health and Human Services, *The State of Aging & Health in America 2013*, p. ii.
[11] Alison Acosta Fraser, Thomas A. Roe Institute for Economic Policy Studies, *Federal Spending by the Numbers 2012*, October 16, 2012.

THE TRADITIONAL MEDICAL DEVICES SUPPLY CHAIN

How are these developments affecting the medical devices sector and its supply chain? Before exploring the answer, first look at how these supply chains have operated in the past.

This section covers how medical devices traditionally moved to market, and then discusses some of the issues and problems this system has produced.

PATH TO MARKET

In the traditional supply chain, medical devices move to market directly from manufacturers, or through distributors and are either sold to inventory or positioned in the market on a consignment basis.

- **Make-to-order.** Expensive, non-consumable equipment is sent straight from the manufacturer to final clients under a make-to-order system. Typical products include imaging equipment, diagnostic and surgery capital equipment (Figure 1). Participants in this supply chain must be able to handle mostly oversized equipment and have expertise in international logistics. These products can originate from anywhere in the world, so in-depth knowledge of the Unites States' regulations, restrictions, licensing, permitting, along with expertise in import requirements are critical.

- **In-house-inventoried products.** Products that need constant replenishment necessitate in-house inventory. Typical products include consumables/ disposables, implantable devices and surgical procedure equipment (Figure 1). These items represent the majority of products in the medical devices supply chain. This supply chain calls for adequately planned inventories with the means to reach highly distributed locations with fast and reliable delivery. In-house inventoried products can be owned or held as consignment inventory.

Under the consigned sales model, a device maker positions inventory at customer sites throughout the healthcare network. The hospital and device manufacturer agree to hold certain stock at the hospital (funded by the manufacturer) and replenish these items as the hospital uses up stock. For example, a hospital uses a knee implant in surgery. It reports that fact to the

Figure 1: **TYPES OF MEDICAL DEVICES**

	CONSUMABLES-DISPOSABLES	IMPLANTABLE DEVICES AND SURGICAL EQUIPMENT	DIAGNOSTIC AGENTS AND COMBINATION PRODUCTS	IMAGING	LONG TERM – TREATMENT & EQUIPMENT
Description	Devices and supplies used in a one-time or temporary basis for the treatment or care of patients	Surgically implanted devices and equipment to perform surgery	Reagents, bacterial cultures, combination of products with active ingredients	Sophisticated equipment for diagnostic, therapeutic or surgical purposes	Durable equipment used for patients in need of long-term care
Examples	Vision care, injuries, wound care, incontinence, disposable supplies for hospitals, syringes and needles	High-priced small devices, joint replacements, pacemakers, spinal cord implants, implant kits, surgical instruments	High-priced small batches, controlled temperature reagents, special handled products (i.e., fragile or hazardous), in-vitro	High-priced large items, X-rays, MRT, CT, hybrid imaging equipment	Orthopedic, auditory and respiratory devices, patient monitoring, special medical furniture
Channels	Patients, homes, supermarkets, pharmacies, medical offices, hospitals, clinics, laboratories, distributors	Medical specialists or hospitals	Laboratories, medical specialists and hospitals	Hospitals and very specialized laboratories	Specialized (e.g., nursing homes, physical therapy, hospice)

Source: Edge Consulting and Strategic Research, 2012

device manufacturer, which then ships a replacement, usually via some form of express delivery service.

This strategy places the burden of inventory ownership on the manufacturers rather than the hospital. This benefits the hospital – reducing inventory investment costs as well as eliminating attendant inventory management responsibilities. For the manufacturer, though, the system quickly gets expensive if inventory is not consumed or is poorly stored or tracked leading to potential damage and obsolescence.

One global manufacturer of medical implants elaborates on this issue in a recent article.[12] "One of our greatest challenges," says one of the company's regional supply chain directors, "is to make sure we have the right product in the right quantity at the right location, at the right time. Our surgical "kits" – everything the surgeon needs to perform the surgery - range in value from $30,000 to $70,000."

Depending on the surgical procedure - whether it is a knee or a hip replacement - the total number of kit components varies from 150 to 400 items, the director goes on to say. The instruments in the kits are not universal, meaning the surgeon cannot substitute components from different original equipment manufacturers (OEMs) because most of the components are uniquely engineered to support that specific implant.[13]

"If our kit is not there when the surgeon goes to perform the surgery—he or she will use a product from a different OEM," the supply chain director explains. "So we lose the entire sale. That can easily add up to millions of dollars in lost opportunity in just a few weeks. Being able to manage our inventory better can directly increase our revenue in a very big way."[14]

[12] Lisa Harrington, Inbound Logistics, *Scantastic Bar-Code Tracking Tools*, August 2013.
[13] Ibid.
[14] Ibid.

SUPPLY CHAIN CHALLENGES

As we describe below, the traditional medical device market channel carries a number of challenges. We characterize these as follows:

- Inventory everywhere
- The unknown in the operating room
- The high cost of service

- **Inventory everywhere.** As the above section indicates, the medical devices industry operates on the 'inventory everywhere' model. "It is a highly fragmented supply chain from the standpoint that a lot of people potentially touch the product once it leaves the large DC," says Scott Cubbler, president, Life Sciences and Healthcare - Americas, DHL Supply Chain.

"There is inventory in the regional distribution center, the forward stocking locations, the logistics service provider's warehouse, the sales reps' trunks, on consignment in hospital, and inventory at the sterilization point," Cubbler explains. "Essentially, you have inventory everywhere."

With regard to the forward stocking points, "It is not uncommon for a medical device company to operate a network of small distribution points sprinkled across their markets – anywhere from 40 to 100 such locations," notes Phil Siewert, senior director business development, DHL Supply Chain. These facilities are small – about 2,000 sq. ft. – and are used to feed product to end customers in final mile delivery."

This inventory everywhere system is not only very expensive, but the complexity of trying to track product throughout the chain is enormous. As a result, product visibility can easily become lost.

- **The unknown in the operating room.** Another factor that adds complexity and cost to the devices supply chain – particularly implants – is the need to hedge against the unknown in the OR and order the most likely sizes. Siewert comments, "In preparation for an implant procedure, the surgeon may request a tremendous amount of parts. For a left knee replacement, the doctor could order several surgical kits with knee sizes three through five, and only use size 4. Each implant comes with essentially a closet-sized tote bin of product going into a surgery."

Unused equipment, which is still owned by the device maker, effectively is out of circulation and unavailable for sales. Varner of Medtronic observes, "With devices such as pacemakers, only one or a few units may be sent to a surgery – not too much of a burden from a cost of inventory perspective. In spinal orthopedics however, many kits containing hundreds of different parts and sizes must be brought into surgery; a very small number of the items sent are used in the surgery. The remainder to be returned must be decontaminated, inventoried, inspected, and replenished before returning to inventory to begin the cycle all over again."

This means that turn rates for costly consignment inventory are very low and days on hand across the supply chain often exceed 100 days.

- **The high cost of service.** Intense competition among medical device manufacturers has prompted many to use delivery as a competitive lever. Manufacturers try to outdo each other on service, so they further complicate the supply chain by saying to the hospital, 'If you give us an order by 7 p.m., we'll have it to you by 9.am. the next morning.'

As a result, hospitals often wait until the last minute, close to cut-off times, to place orders, which forces manufacturers to rely on a premium delivery system to fulfill these next day orders. This means manufacturers must have DCs located next to air express hubs, and use costly premium express delivery service to get product to the hospitals by the next day. They also load the system with inventory in order to fulfill their high level of order promising.

For third-party logistics providers managing medical device distribution centers, this last-minute order profile drives tremendous variation in workflow. It also means the supply chain must operate in an emergency-like mode, with a huge spike in workload occurring at the end of the day when many shipments must be sent via expensive next-day delivery service.

THE FUTURE OF MEDICAL DEVICES SUPPLY CHAIN

As the medical devices sector adapts to the new healthcare environment, the central problem is getting product to the hospital point of use, and doing so at a far lower cost structure without sacrificing service, quality and product integrity. Leading manufacturers are working with their business partners, including logistics service providers, to tackle these issues. Two areas of supply chain innovation are emerging from this effort:

1. Leveraging shared capacity
2. Collaborating toward lean

LEVERAGING SHARED CAPACITY

Hospitals and healthcare facilities need a few basic things from device manufacturers. For consumables, hospitals require availability to meet forecast and demand; while for implants, they demand full kits of inventory. For large capital equipment, hospitals require the equipment but just as important, they need ongoing after-sales service and support for that equipment. Because these machines are critical and expensive, lengthy downtime is unacceptable. As the head of supply chain for a global device manufacturer explains, "We have to be prepared to respond to equipment breakdowns in less than 24 hours. Patients' health cannot wait."

Medical device manufacturers typically have customer overlap, meaning that multiple companies are shipping to the same group of customers. This means that across manufacturers, there is considerable duplication of supply chain assets, resources and costs – all geared toward serving the same customer cluster.

It would make sense, therefore, for manufacturers to reduce this redundancy by using a single logistics service provider to create a shared, multi-customer supply chain solution. This solution would manage the flow of medical device goods and services to and from the hospital. For example, a cluster of manufacturers' product would be located in a single warehouse near the hospitals that are being serviced with consolidated deliveries and services.

"Having six different deliveries to a hospital, going to six different wards, with four different highly trained drivers

doesn't make a lot of sense," explains Cubbler. Instead, the third-party logistics firm (3PL) could create a metro hub, consolidate deliveries, eliminate overlapping deliveries, and provide full service with just two drivers.

This kind of operation is similar to the just-in-time "milk run" delivery systems that feed automotive plant assembly lines. As proven in the automotive sector, such a system reduces costs for the manufacturers by eliminating production line downtime, and could greatly simplify the hospitals' receiving activities.

Under such arrangements, the 3PL manages the forward and reverse supply chains, and spreads the costs of technology, infrastructure, services, people and expertise across multiple clients. Sitting atop the shared network, the third-party logistics company has visibility of the supply chain from order to delivery and return.

Sharing transportation can offer distribution synergies among manufacturers shipping to the same end customer by consolidating shipments of compatible products to achieve fewer half-empty delivery runs, less duplication and greater efficiency. The aggregation of cargo can enable new direct delivery routes that eliminate unnecessary hand offs and shorten delivery cycles.

To gain even more efficiencies, return product sterilization activities (instrument cleaning and autoclaving) could be attached to or become part of this leveraged capacity network. Figure 2 depicts what the shared services supply chain model might look like.

"This shared capabilities model would enable manufacturers to compete on the basis of their product, rather than on the final mile delivery," Cubbler says.

In the pharmaceutical products sector, where the shared services model is widely used, companies realize significant savings. At the same time, product security and quality is maintained.

COLLABORATING TOWARD LEAN

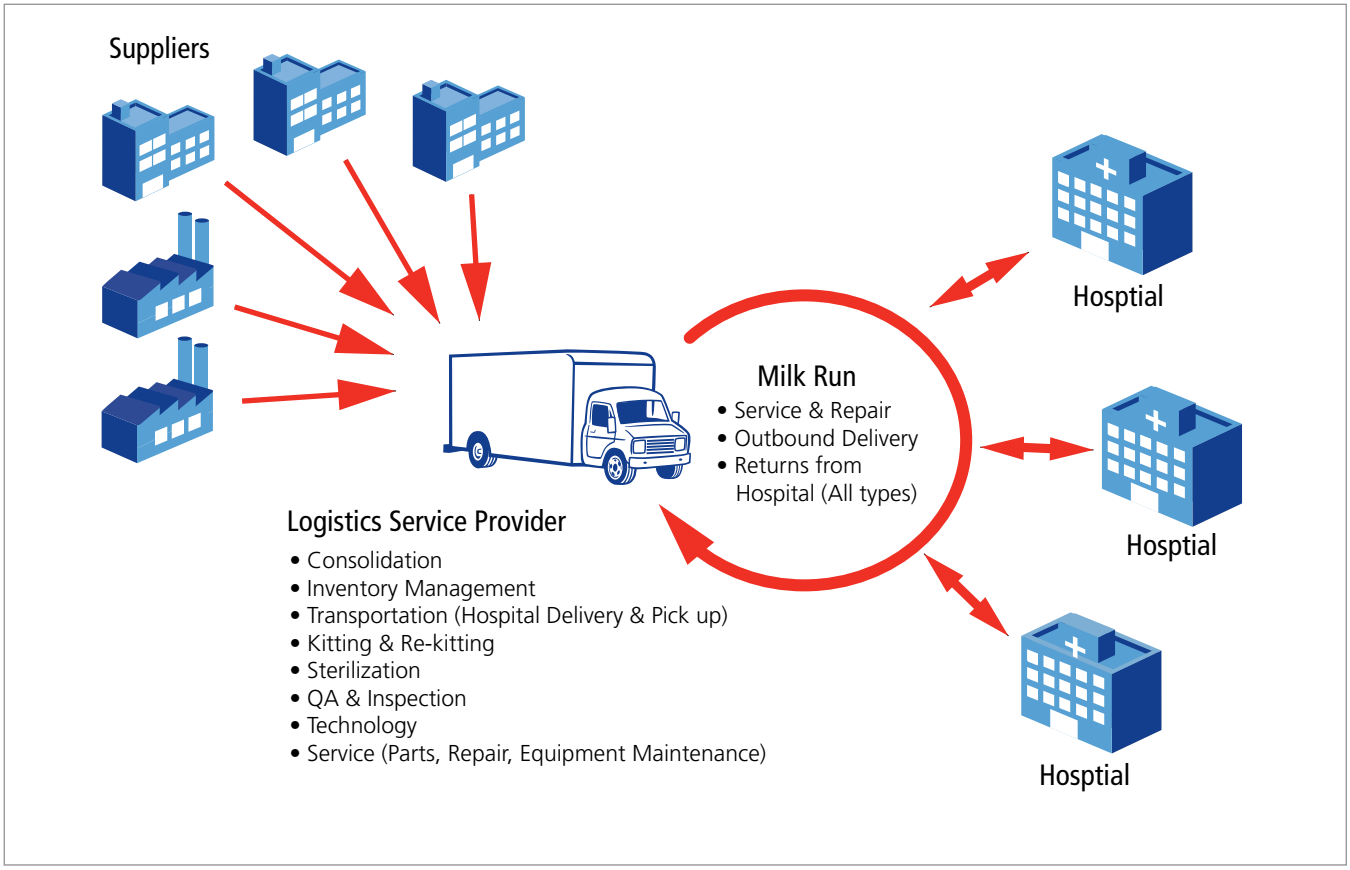
One practice that would complement this shared services supply chain is greater collaboration among all trading partners in the devices supply chain – manufacturers, their customers and the third-party logistics providers that support them.

"We're working with our customers to improve our scheduling," reports the supply chain director for one device manufacturer. "The more time we have to react to something, the better we can plan. From a reconstructive perspective, if we know the schedule of surgeries in advance, we can plan and sequence our implants to the hospital on a just-in-time basis. Every knee set is $55,000, so the better we plan, the less inventory we have out in the field sitting idle, the more we reduce our costs."

Better forecasted demand visibility will enable device companies to pool inventory farther upstream in the channel, in fewer, more centralized locations. "The challenge is to streamline inventories in the field, maximize velocity and at the same time not miss surgeries," notes the supply chain director.

More advanced planning and forecasting would also include more details about the exact requirements for orders. This is particularly important for implants because it would

Figure 2: **THE SHARED SERVICES SUPPLY CHAIN MODEL**



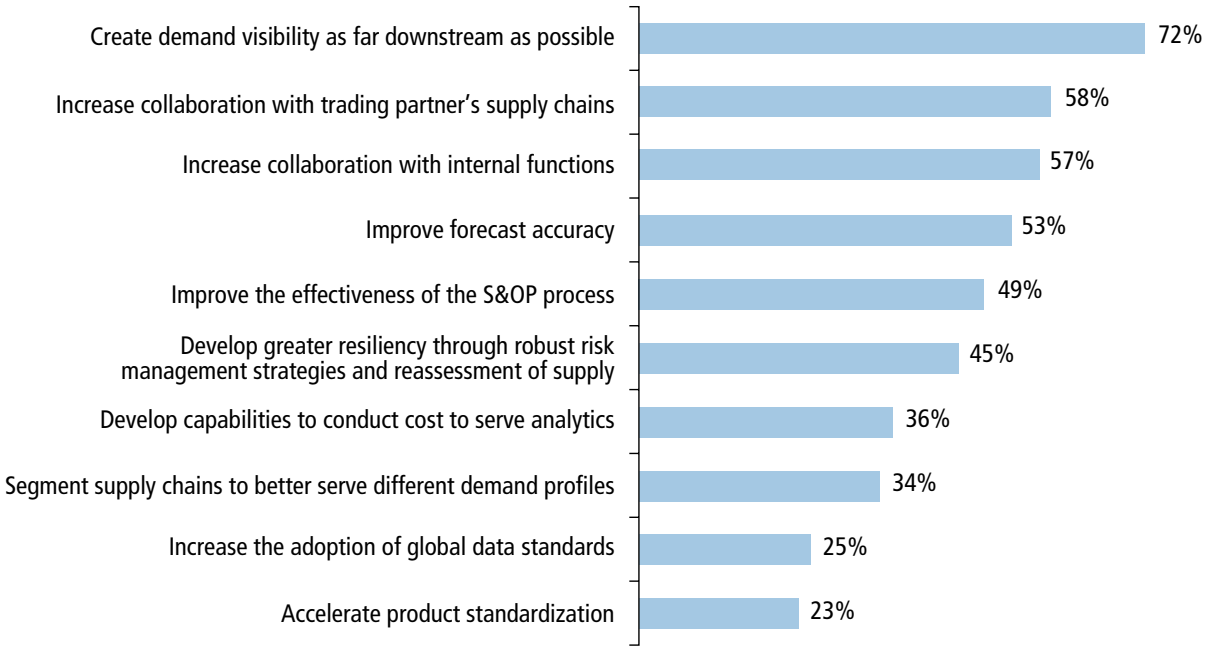
reduce the amount of product being exchanged with the hospital in operating room surgical kits. A recent study by Gartner found that leading medical device companies consider supply chain collaboration a cornerstone of a more effective business practice (Figure 3).

"If we had more exact, accurate information about what's needed for a procedure, we could deliver a tackle box-sized kit to a spinal procedure instead of a tool truck-sized kit," comments Varner. "If you can kit a procedure into a sterile package, it greatly enhances controllability. I cannot sterile package 1,500 items, but if you can reduce that number to 20 pieces, I could do it. That simplifies the supply chain – and tracking and tracing product."

Advances in medical diagnostic technology may help resolve this issue. Digital templating systems reduce the time it takes orthopedic surgeons to perform preoperative planning, predict component size and configuration, and simulate the expected results weeks in advance of the surgery. "This means we'll be able to ship out only what is needed for that exact surgery, as opposed to eight different complete kits," says Chris Oswalt, Director of Commercial Logistics at Smith & Nephew.

Longer lead times and better forecast information would enable manufacturers and their logistics service providers to manage the flow of product in a more controlled manner across the distribution network. This would reduce reliance on high-cost express delivery systems. It would also reduce the need for buffer inventory at hundreds of stocking points. At the same time, the collaborative supply chain would still be able to deliver the high levels of availability and service expected of medical device manufacturers.

Figure 3: **INCREASING COLLABORATION TO IMPROVE THE SUPPLY CHAIN**



Q06A. How is your organization's supply chain responding to these industry trends today? Multiple responses allowed.

Source: Gartner

CONCLUSION

NEW THINKING FOR A NEW ERA

The U.S. medical devices industry is undergoing a transformation as it adapts to the new realities of the country's healthcare landscape. Healthcare reform, new taxes on devices, rising cost pressures, a changing sales channel environment, product tracking regulations, and escalating service demands in all customer segments are straining the current supply chain model.

Manufacturers, as a result, are exploring new supply chain solutions to manage both their inbound-to-manufacturing and their outbound-to-customer supply chains. Third-party logistics providers bring a wealth of industry experience and best practices to the medical devices supply chain challenge. Third-party logistics providers can deliver significant bottom line benefits through forward and reverse delivery network optimization, shared distribution, inventory optimization and control, collaborative planning/forecasting, and advanced visibility tools. In addition, these services can provide high customer satisfaction and ultimately support an improved healthcare system.

The path forward is not an easy one for the medical device sector, as it reengineers its business model and the supporting supply chain. "Fortunately," Varner observes, "healthcare institutions in particular, and the industry as a whole, are beginning to realize that this level of cost savings won't come just from squeezing suppliers for price concessions. One major hospital system emphasized, '...We know to reach our cost objectives... we need to take a more systemic, strategic approach for reducing costs.'"

If the industry can improve the quality and flow of information, and reduce uncertainty, among all the players in the supply chain, it can meet the twin challenges of controlling and reducing costs, while delivering required service levels.

"This is not something we can accomplish alone," Varner emphasizes. "We need to bring all of our partners to the table, including our 3PLs, and all work together to streamline how we get product to the customer."

Benefits of using a 3PL

What are the potential benefits of transitioning to a 3PL outsourced supply chain management model for the U.S. medical device sector?

1. Improved cost efficiency
2. Consistent, reliable, cost-effective transportation and delivery
3. Greater service and network flexibility
4. Increased end-to-end supply chain visibility
5. Sophisticated track and trace, and condition management
6. Demonstrated supply chain best practices
7. Established continuous improvement processes

U.S. Medical Device Sector at a Glance[15, 16]

- At an estimated $127 billion USD in 2013, the U.S. medical device market is the world's largest, accounting for 40 percent of the global market.
- Per capita expenditure on medical devices, at $399 USD, is the highest in the world.
- Seven out of the world's top 10 medical device manufacturers are U.S. companies. These include Baxter, Boston Scientific, Covidien, General Electric, Johnson & Johnson, Medtronic and Zimmer.
- Imports represent an increasingly significant part of the market, and now account for around 30 percent of the total. This growth is partly due to U.S. manufacturers shifting some production to lower-cost labor markets such as Mexico. In 2011, consumables achieved the fastest growth rate at 12.1 percent ($5.3 billion USD), while diagnostic imaging rose by 7.4 percent ($8.9 billion USD).

[15] Espicom, The Medical Device Market: USA, Opportunities and Challenges, www.espicom.com/usa-medical-device-market, 2013.

[16] Medical Device and Diagnostic Industry, The U.S. Medical Device Industry in 2012: Challenges at Home and Abroad, http://www.mddionline.com/article/medtech-2012-SWOT.

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