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Conclusion

Given the pace of change, the tremendous cost pressures, and the increasing risks facing health care supply chains, medical device and pharmaceutical manufacturers are evaluating options for more adaptable, nimble, secure and collaborative supply chain solutions at a lower cost. These options range from total redesign and rethinking of their supply chain strategies to experimentation with new supply chain models in select locations. A qualified supply chain management partner adds value by giving manufacturers options for optimizing service, quality and cost within applicable legislative and regulatory frameworks. DSC Logistics has 20 years of experience partnering with medical device and pharmaceutical companies in delivering customized supply chain management solutions that align with their business goals. Our disciplined execution, operational and regulatory leadership, and a sense-and-respond culture make us ready for anything...in health care.

DSC Logistics, a leading supply chain management company, focuses on designing, integrating, managing, and adapting supply chain solutions for medical device and pharmaceutical companies. DSC provides a comprehensive range of Lead Logistics Partner (LLP) and third-party logistics (3PL) solutions for Logistics Center management, transportation management, business process integration, regulatory compliance, supply chain visibility, and value-added services. DSC enables health care companies to leverage the supply chain as a competitive advantage.
Operational Leadership

The health care supply chain is particularly complex, intense and dynamic. The number of trading partners, complexity of orders, diverse Provider segments, volume of regulatory and licensure requirements, rate of mergers and acquisitions, and scrutiny from the public and private sector test a supply chain leader’s mettle on a daily basis. The ramifications of a supply chain failure and the penalties for non-compliance are severe. FDA cease and desist orders and mandatory recalls not only impact revenue, but also market share and potentially brand loyalty. Successful leaders must keep their teams motivated and focused on performance, customer service and efficiency. They must also have a working knowledge of what drives value for their customers, and be able to lead their team to deliver that value.

Another component of regulatory compliance and licensure involves Designated Representatives (DR). As on-site employees of a wholesaler, distributor or third-party logistics provider, DRs have primary responsibility for ensuring that all licensure activities and processes at their facility are being followed to the letter every day. They have a detailed understanding of the laws and regulations pertaining to the specific medical devices and pharmaceutical products in their facility. They take the lead on coaching and overseeing the inspection of packaging and labeling to ensure that fraud, tampering or diversion is not occurring.

With a strategic commitment to health care, DSC Logistics recognizes the importance and value of having on-site DRs with significant supply chain experience. In 2004, DSC initiated a training program to prepare its top supply chain operators for DR certification. To date, this program has produced DRs in DSC Logistics Centers across the U.S., plus a team of “flex” DRs who are available for short-term assignments such as startups. These flex resources enable DSC Logistics Centers to commence operations while a team of permanent DRs are being trained and certified. What DSC health care leadership learned is that the presence of DRs, along with a code of personal accountability throughout the Logistics Center staff, provides the best assurance of product integrity and adherence to proper processes and procedures.

Consistent Execution

It’s one thing to demonstrate proficiency in a rigorous licensing or accreditation process when there’s plenty of time to prepare. It’s another to live the process every day. More and more states are recognizing the comprehensive scope of VAWD and are either enacting laws based on it, or incorporating key components in their own licensing process. Either way, compliance is achieved through the implementation of new processes, total operations team training in these processes and operator-level discipline to consistently execute every step of every process every day. Improper packaging and labeling, for example, may be signs of fraud, theft and diversion in the supply chain. Consistent execution means inspecting the labels and packaging of every pallet, case and piece (e.g. selling unit) that comes through the door. It means having a supply chain team that knows how to identify, document and report non-compliance. It means being able to recognize unauthorized SKUs, incorrect SKU formats, missing information and suspicious addresses and packaging.

This kind of discipline will catch a number of non-compliant incidents. Most will be unintentional, many will be simple mistakes. But the bar must remain high because the one that gets past all the supply chain safeguards is the only one that matters...to legislators, health care providers and patients.

Sense-and-Respond Culture

The importance of a sense-and-respond culture is that health care supply chains – and the requisite compliance with FDA regulations and diverse state licensing criteria – must be adapted without disruption to service or efficiency. The optimal supply chain partner will anticipate change and be positioned to respond quickly and effectively – in other words: be ready for anything!
In the U.S. health care supply chain, before a medical device or drug can be shipped -- state and county licenses must be secured, FDA Quality Systems regulations must be complied with, and accreditations must be earned. The health care supply chain plays a key role in patient safety by ensuring the integrity of products from the time they are manufactured to the time they are delivered to a health care provider or patient.

Instances of theft, diversion and counterfeiting in the supply chain are on the rise. They have heightened public awareness and concern over the quality and integrity of prescription drugs and medical devices. As Dr. Margaret Hamburg, commissioner of the U.S. Food and Drug Administration stated in 2010, “We have seen that the threat from economically motivated adulteration, counterfeiting and cargo theft is real.” Counterfeiters and thieves have demonstrated tremendous creativity and boldness in pirating and diverting product for black and gray market sales. They find buyers for any type of product or drug. All drugs and devices are at risk.

Solutions to this problem must be system-wide, adaptive, highly responsive, and not add incremental cost to the health care system. A tall order by any measure. Proposals for protecting the health care supply chain are coming from both the public and private sectors. State legislators and Boards of Pharmacies are continually reviewing their licensing criteria and exchanging strategies with other states to determine how best to ensure the safety of pharmaceutical and medical device supply chains in their respective states. States such as California and Florida have been on the leading edge of licensure reform, but a number of other states aren’t far behind.

The National Association of Boards of Pharmacy (NABP), a non-profit organization comprising many State Board of Pharmacy members, works closely with the State Boards and other state agencies in advancing best practices and regulatory uniformity designed to protect public health. NABP has developed a comprehensive process for ensuring that wholesalers and distributors of prescription drugs and medical devices are meeting rigorous criteria for safely operating in their states. Because of their strong ties to state agencies they have the ability to influence the standards in many states. They recommend a wide range of operational, human resource, information management and product authentication requirements for reducing the risk of fraud, theft, diversion and adulteration. Only those wholesalers and distributors who meet the most stringent requirements achieve the highest standard of supply chain integrity, Verified-Accredited Wholesale Distributors (VAWD) certification.

Receiving VAWD certification means that a wholesaler, distributor or third-party logistics company has demonstrated best practices in safeguarding products during shipping, storage, returns, recall, re-packaging, and kitting. As of July 2011, four states have enacted laws based on VAWD and 22 states recognize or leverage VAWD criteria in their licensing process. DSC Logistics became involved in the VAWD process as part of obtaining certification for its Logistics Centers that handle medical devices and pharmaceuticals. VAWD certification was achieved at a DSC Logistics Center in Texas in 2010 and at an additional LC in California in 2011. The certification process is underway at a third LC in Georgia.

On the private sector side, stakeholders in the pharmaceutical and medical device supply chains are increasing their pressure on lawmakers to understand the patient safety and cost ramifications of health care reform, proposed regulatory changes, new state licensure requirements, and supply chain safeguards. They are collaborating more to influence federal and state agendas on a wide range of topics. Self-defined and imposed improvements and checks and balances are far more desirable to health care supply chain stakeholders than legislated mandates.

But legislation, regulation and accreditation are only half the solution. Even when every trading partner in the supply chain is meeting their legal and ethical obligations to protect the products under their control, the bottom line is that product integrity in the supply chain is in the hands of the people who move the product to market. Essential to effective compliance are operational leadership, consistent execution and a sense-and-respond culture.

DSC has experience as the supply chain partner to companies involved in the manufacture and/or distribution of pharmaceuticals, medical devices, or health care products dates back two decades. Current and former customers include: Cardinal Health, Bristol-Myers Squibb, Nestle Clinical Nutrition, Kimberly-Clark Health Care, Abbott, Care Fusion, Fresenius, Cypress Medical, Encore, Kramer Labs and Zevex.

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