INDUSTRIAL ENGINEER
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A hard sell

Carolina Logistics Services reverses the route of controlled substances

By Candi S. Cross

Foxy Methoxy, Blue Mystic, and Maria Pastora are not names of entertainers. Street names for counterfeited, widely used pharmaceuticals have clever, catchy enunciations because they are easier to reference than pharmacological names of origin such as phencyclidine. How these drugs get into illegal possession in the first place yields debate between politicians and manufacturers because product returns feed a great deal of counterfeiting activities and other illegal operations if the inventory is not handled correctly. Pitfalls in security have trounced the distribution system, exposing the overwhelming consequences of drug abuse and profit loss for all related businesses in the supply chain.

One certainty is that a drug product undergoing multiple transactions between the time it is sold by the manufacturer and the time it's bought by an end user is highly vulnerable to illegal activity. Reverse logistics companies that specialize in pharmaceutical inventory do measure some control over the sensitive channels that these products flow through. Firms such as Carolina Logistics Services manage returns with a systemic approach that offers powerful, comprehensive safeguards.

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According to *Supply Chain Management Review,* companies in the United States spend $950 billion annually on logistics; approximately $43 billion is spent on returns. A dreaded aspect of any business that sells consumer goods, returns often present challenges that are too sizeable for retailers and manufacturers to address internally. Therefore, third-party logistics providers handle every type of the unused — from damaged stock to overstock. Of course, most goods don't just get repackaged and transported to second-hand consumers. When typical consumer goods enter a returns center, they are first assessed. Based on the condition of the returned merchandise and the manufacturer's choice for disposition, items then meet one of several possible options for cost recovery: repair, upgrade, repackaging and refurbishing, remanufacture, and recycling. Some returned items and components are sent back to the base customer, but the majority will end up elsewhere.

As manufacturers would rather concentrate on making and selling new items for their designated value and reaping the profits they bring, outsourcing a sometimes messy, very costly process is becoming common, particularly when attached to specialized goods such as hazardous materials and controlled substances. If they are not expertly assessed and steered to the appropriate course, more goods categorized as biological/infectious, chemical, reactive, acidic (as in battery material), electronic, and laboratory glass may depreciate to the unsaleable slot instantly, requiring an entirely different recycling or destruction method than textiles or food products, for example.

These prospects motivate more than 130 clients, including leading grocery retailers and wholesalers, drugstore chains, and mass merchandisers throughout the United States, Canada, Puerto Rico, and the Virgin Islands to partner with Carolina Logistics Services. The company processes tens of millions of returned items each month.

Reversing the pressure

One of five logistics companies to deal with approximately 85 percent of reverse logistics in the United States, Carolina Logistics Services has kept a finger on the pulse of domestic and international supply chain solutions from its headquarters in Winston-Salem, N.C., since 1985. With enormous changes in manufacturing processes, the expansion of pharmaceutical companies, and revolutionary business communications such as the Internet, the health care market in particular has demanded better labeling and tracking applications as well as sound inventory management. Last year, CLS gravitated to this need and acquired two companies, MedTurn and USF Processors. The merge resulted in subsidiary CLS MedTurn, Healthcare Services, now the processor of 24,000 of the 53,000 retail pharmacies in existence and the returns manager for a major wholesaler (undisclosed to *Industrial Engineer*), accounting for 30 distribution centers and up to 2,500 of their independent pharmacies.

The Drug Enforcement Administration reported that at least 1.9 million Americans admitted to illegitimately taking OxyContin, one of the most abused painkillers transported through the pharmaceutical supply chain.

"Over the course of our company's history, we have built a solid reverse logistics and disposition practice by continuous returns process improvement, certified and compliant disposition practices, proactive client returns analysis, and application of our knowledge and best practices to current customers, new prospects, and all industries," said Sharon Joyner-Payne, CLS vice president of marketing. "Not only is CLS MedTurn the most experienced team in the reverse logistics industry, but we have become the most diverse by spreading our best practices knowledge across multiple industries and investing them in each new client with which we partner."

The procedures, intertwined with asset recovery liquidation, policy administration, and data assessment of controlled substance pharmaceutical returns, must be ambitious to recover more money than what is spent. MedTurn's field project managers and contract chemists satisfy a balance between action and information because of the sensitive issues that the health care industry automatically presents. Products that pertain to human health often carry high cost and high risk. Controlled substances entail further costs and risks associated with the manufacturer's liability, the medical community's strict standards, and society's rate of misuse and abuse.

Defined by the Federal Drug Administration, controlled substances are materials containing any quantity of a substance with a stimulant, depressant, or hallucinogenic effect on the higher functions of the central nervous system and having the tendency to promote abuse or physiological or psychological dependence, as designated in state and federal controlled substance schedules. Most pooled through the supply chain are Schedule III compounds, which include many stimulants, depressants, painkillers, and cough suppressants, the veterinary anesthetic ketamine, and anabolic steroids.

In sizing up just one component of the Schedule III collection, painkillers alone require an all-encompassing, bulletproof management system. In an April issue of *Newsweek,* the Drug

Carolina Logistics Services processes approximately 50 million returned goods per month, including controlled substances from hospitals and pharmacies.

Enforcement Administration reported that at least 1.9 million Americans admitted to taking OxyContin illegitimately. It's safe to say that the reverse logistics process plays a part in sealing off criminal channels at any given stage of the drug's life.

"Our standard is to receive and inventory controlled substances within one day of receipt. Once inventoried, the product will reside in the controlled substance cage or vault until the client's current processing period expires," said Rodney Bias, CLS vice president of regulatory. "At this point a manufacturer debit invoice is issued, and we can receive disposition. Once disposition is received, the product will either be destroyed or returned to the manufacturer within five days of receiving that disposition. Processing period windows are determined by the client and vary in length. They can be as long as three months or as short as a week."

CLS MedTurn and similar service providers such as Guaranteed Returns handle quantities of drugs that are occasionally unidentified on the exterior by the sender. A code may be embedded in the packaging indicating its high-risk category, and project managers will assume their respective duties. According to Bias, the company occasionally receives controlled substances in bulk directly from manufacturers. Earlier in the year, one of the company's processing spaces received six pallets of a bulk controlled substance, a liquid that filled 55-gallon drums. "It was considered waste by the manufacturer for reasons unknown, and standard procedures applied," Bias said.

Every manufacturer incorporates its own return policy. Once the inventory touches a CLS MedTurn location, the company has to consider the manufacturer's stipulations: What condition it will accept the returns in, how the drugs have to be packaged for the return operation, the direct contact who handles the return (in some cases, it's a specific pharmacist, in others, an information specialist or inventory manager), and within what department credit will be applied. The return's course also depends on whether it was physically pulled from a retail shelf as expired, sent to CLS MedTurn in bulk, or is the subject of a mandated or voluntary recall.

Point of no return

Recall risk management is perhaps the most time-sensitive aspect of reverse operations. Whether items are voluntarily withdrawn or recalled under governmental mandate, a plan must be enacted with precision and swiftness. Equal care for a client's distributors and consumers goes into a risk management assessment. Using a matrix-based assessment tool, the

Returned Schedule III controlled substances such as prescription depressants or stimulants are kept in a caged vault at one of CLS MedTurn's processing facilities.

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All handlers of controlled substance inventory are subject to annual hazardous waste identification training and proper Department of Transportation shipping regulations.

company qualifies the complexity of an event, outlines steps, and completes a direct notification on behalf of the client. This measure is done to protect brand image.

Next, retrieval of product from the public domain is executed by CLS Medturn's recall handling team. Products are usually collected through on-site removal. At this stage, experts are taught to be vigilant while acting in accordance with the client's future. Processing and disposition occurs at one of five centralized returns centers, which contain a specific amount of DEA-approved square footage as well as in-house information technology support. At this time, the client is consulted on a recall script and return instructions that will minimize public impact. Detailed information is provided with the payment or credit to answer proactively questions for the purpose of reducing the administrative costs of issuing large amounts of credit and payments.

Recalls and waste are inevitable aspects of CLS MedTurn clients such as pharmaceutical companies. Consider that high-volume centralized returns centers receive millions of consumer items annually from virtually every retail outlet in the United States. Naturally, holidays spawn returns that can't be accounted for in an easy head count, figuring in all the seasonal toys, garments, and decorations. Fortunately, many of those items will have a second swing through the retail process the following year, eventually bringing profit. However, a company that deals with 50 million return transactions per month will inevitably see a lot of products that cannot be repaired, redesigned, or repackaged. Once an item is deemed waste, disposal or destruction is imminent.

"Our contracted chemists are used for all regulated pharmaceutical hazardous waste. These chemists perform a chemical evaluation on each ingredient to determine the proper handling and disposal of each hazardous waste characteristic," Joyner-Payne said. "The characteristics are categorized by profiles and communicated systematically to the line processors and sorters for proper handling and disposal of the materials. All handlers are subject to annual hazardous waste identification training and proper DOT [Department of Transportation] shipping regulations."

Based on product ingredients, chemists determine the type of disposition necessary: Through computer-aided sorting, they can quantify, characterize, dispose, report, and provide destruction manifests in a variety of ways. Waste characterization specialists manage

Through computer-aided sorting, chemists can quantify, characterize, dispose, report, and provide destruction manifests of controlled substances in a variety of ways.

the process of identifying waste streams for products in compliance with the Environmental Protection Agency and the Occupational Safety and Health Administration as well as medical waste, state, and local regulations. CLS MedTurn supplies complete documentation of the products' disposition that is made in accordance with a client's policy, and those items will not reenter distribution channels.

Occasionally, companies that perform their own method of disposition have been found to be making sweeping mistakes. For instance, companies that destroy non-hazardous waste as hazardous will spend as much as 10 times the necessary cost for product destruction, says Joyner-Payne.

"The company has audited numerous hazardous and non-hazardous waste destruction facilities as well as nonprofit destinations. Witnessed burn services ensure proper disposition has occurred," she said. "It is at this point that if destruction does not pertain to the materials, alternative disposition options such as recycling and reworking can help offset the cost of disposition as well as reduce the amount of waste while maintaining regulatory compliance. Depending on the waste characterization expertise needs, either internal or external resources are utilized."

In order to match ingredients with disposition tasks, experts complete HAZWOPER (Hazardous Waste Operations and Emergency Response Standard) and hazardous waste management training. In addition, they are educated in how to record material handling data sheets and how to use them in conjunction with state and local requirements. The material safety data sheets provide the ingredient information for analysis of the proper waste stream requirements. Once the product is characterized, then the information is entered into the system for computer-aided sorting to the proper waste stream. When categorizing non-regulated waste, a specialist uses the system-generated policy disposition to determine how to handle the materials. If a product has no National Drug Code identification number or if the alcohol level or ingredient flashpoint is borderline, the company takes precautionary steps and characterizes it as hazardous.

Storage distinctions for controlled substances and hazardous waste must meet a plethora of requirements and regulations. The controlled substance is stored in a secure/controlled caged area, which is restricted to a limited number of people for safety and security. Hazardous materials are also kept separate from other materials in the facility. Once deemed hazardous waste, the product must be destroyed within 90 days.

Partnerships that boost bottom lines

With the help of third-party logistics firms, many companies have determined which actions and information produce the best results in reducing or eliminating the conditions that impact returns. In line with supply chain best practices, CLS MedTurn has broadened its services to include full-scale consultations. The company offers specific assessments with a best practices gap analysis and an operational improvement plan that incorporates investment resources before assigning its project implementation manager to the client. The need for specific services deepens with the scale of counterfeiting that has surfaced around controlled substances.

"The introduction of counterfeit products into the supply chain poses a significant threat to manufacturers, distributors, and especially consumers," Joyner-Payne said. "Unfortunately, the cost and time-intensive tools required to authenticate good product and/or identify potentially counterfeit products can be a deterrent to developing a suc-

As indated inventories of controlled substances are processed, they are bar coded and warehoused in a segregated, date-specific morgue.

cessful anti-counterfeit program."

From a proactive monitoring system to help identify and capture incidences of counterfeit products to targeted investigations and recoveries to the testing, processing, and disposal of counterfeit products at the company's facilities, CLS MedTurn combats illegal activity in force. Its own investigators are deployed to target areas, where items identified as or suspected of being counterfeit can be collected in the field and forwarded to processing facilities or to a location of choice for quarantine and further testing. Personnel physically handle every item returned, which enables them to detect variations in both product packaging and content. Line-item detail, including shipper and lot code information, is captured and recorded for each item processed.

Solutions are positioned through the company's formal partnerships with clients. Studies are conducted and customized for clients, which sets up the opportunity for manufacturing and distribution trading partners to work side by side to address the root causes for returns and unsaleables and to put measures into place to implement key changes that will reduce overall damage. The study includes a hidden damage assessment in which trained personnel randomly select shipments to check for damage conditions and construction issues.

Another key component of the partnership study is the delivery accuracy assessment. Personnel mirror the receiving process from the customer's perspective to determine the impact of product handling and shipment processing. In addition, an assessment of the performance of products on the shelf at a representative sample of retail stores is conducted to evaluate the final portion of the supply chain process.

Since the study begins and ends with an agreed upon common objective, changes recommended can be implemented quickly. The result aims for an immediate return on investment. For the goal of packaging, process, and practice improvements, the partnership and collaborative study provides hard physical data but instigates dialogue about soft data. The combination of the two identifies not only packaging design and manufacturing handling, it also defines sales and buying practices, store rotation, and product discontinuation practices. Finally, by conducting a retail store assessment, pertinent information is revealed about a product's condition, shelf position, price, and remaining shelf life.

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Under the same umbrella of services, thorough supply chain analysis is geared toward improving the bottom line. Using process flow mapping, specialists identify and observe the touch points along the entire product path, from production to retail shelf placement. A comprehensive overview of product movement is created to determine opportunities for handling practices. Unit load building accuracy studies determine the effectiveness of selecting specified products and quantities to make up a completed unit load.

Tracking assets is yet another aspect of supply chain movement. It is known in the pharmaceutical world as a profit cruncher. CLS MedTurn employs a single-scan, paperless invoice technique called FAIR, which provides enhanced control of returns and unsaleables validation, reimbursement, and disposition for both distributors and manufacturers. Items are scanned one time on behalf of trading partners at centralized reverse logistics centers. The distributor agrees to apply the manufacturer's policy and price file to all transactions, eliminating the possibility of deductions related to item count, pricing, and handling variances. Distributors reduce returns center handling and disposition charges for items that belong to manufacturers that participate in the FAIR program. A cost-reduction partnership ensues, and participating manufacturers are billed by CLS for their product disposition. Because the distributor and the manufacturer share the processing facility, shipping, and freight costs can be reduced immediately.

In these bottom-line partnerships, recovery is the mutual reward. CLS MedTurn has the means for processing returned goods from any origination, including distribution centers, manufacturing plants, returns centers, and retail stores. According to the company, because a high proportion of returned goods are eligible to be placed back into inventory (and, more so, those contained in full cases), the mission for all parties is to recover dollar for dollar.