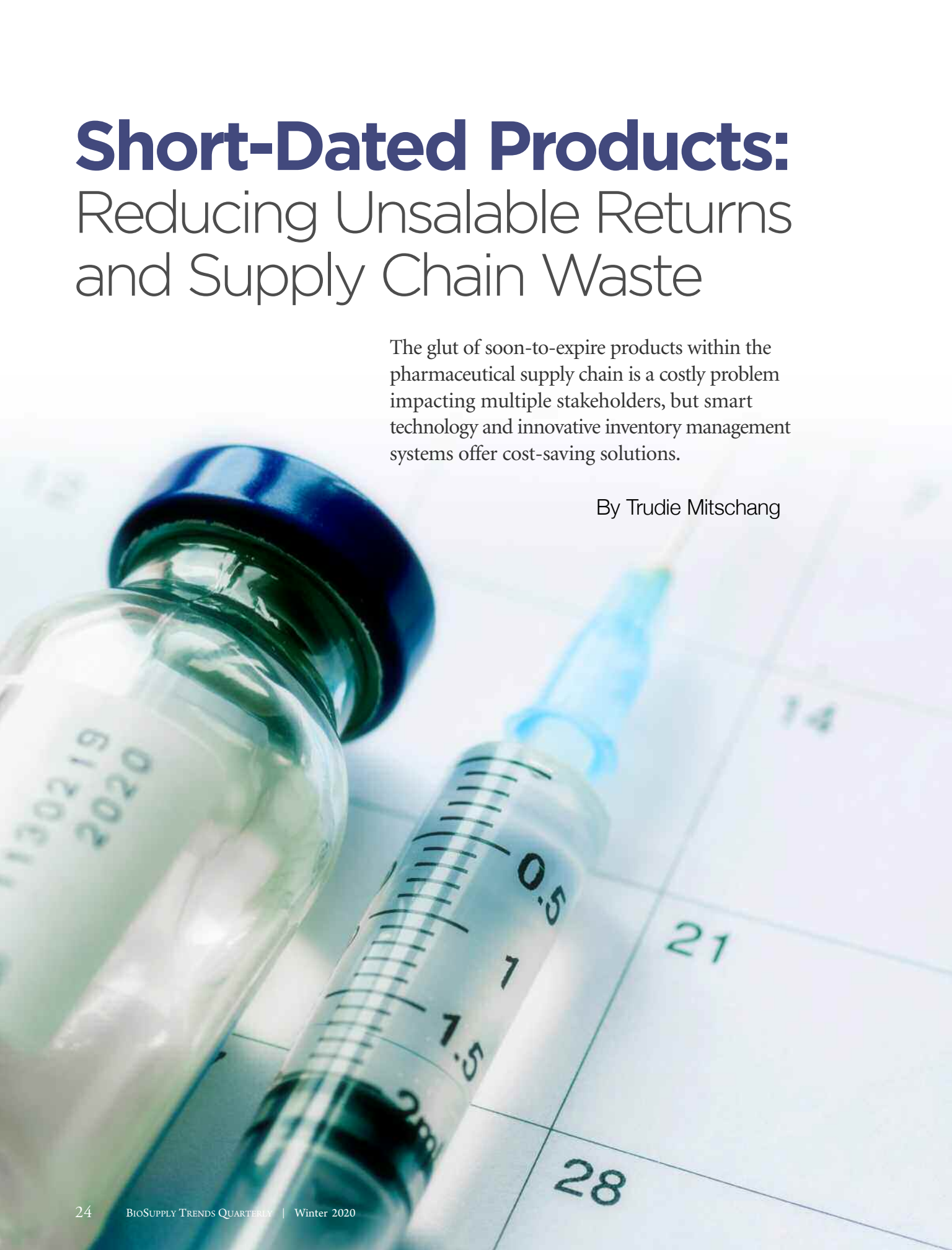
Short-Dated Products: Reducing Unsalable Returns and Supply Chain Waste

The glut of soon-to-expire products within the pharmaceutical supply chain is a costly problem impacting multiple stakeholders, but smart technology and innovative inventory management systems offer cost-saving solutions.

By Trudie Mitschang



LIKE MANY OTHER industries, manufacturers of pharmaceutical products have historically created return policies that offer customers credit for unsold items, assuming those product returns meet specified guidelines. In general, six scenarios would support a pharmaceutical manufacturer accepting a product back from regular distribution channels: The product has expired; a research-and-development failed batch is identified; a product is recalled either by the U.S. Food and Drug Administration (FDA) or the manufacturer; a product is withdrawn by FDA; the product has damaged packaging; or the product is identified as short-dated.[1]

Products are considered short-dated when they are nearing their expiration date and are not yet consigned to a buyer. In an inventory management system, this product would be flagged for return, and the process could begin anywhere from less than six months to 18 months from expiration, depending on manufacturer requirements for the product.

But what are the drivers that cause an excess of short-dated products to become unusable within the supply chain? A report by Healthcare Distribution Management Association (HDMA) suggests increasingly streamlined return processes may have resulted in an overdependence on returns rather than a more proactive inventory management effort. Other influencing factors include the specific guidelines each entity practices when managing inventory flow. "Retailers often pull short-dated products off the shelf 90 days prior to expiration. Distributors usually work with a six-month window (shipping at seven months). Biotech or specialty products generally have shorter shelf lives, e.g., three months," states the HDMA report. "In addition, some states may have requirements regarding the date on which the prescription is filled as it relates to expiration date. These conditions and practices can result in expired products being returned to manufacturers for credit after being held in a 'morgue' inventory location until they expire."[1]

Drug waste due to product expiration dates can be extremely costly, particularly at the hospital level. For example, according to sources at Newton-Wellesley Hospital in Massachusetts, the facility is able to return some expired drugs for credit, but in 2017 alone, it had to destroy nearly $200,000 worth of outdated medication. And, a commentary in *Mayo Clinic Proceedings* cited comparable losses at Tufts Medical Center in Boston. Extrapolating those costs for hospitals nationwide, it amounts to nearly $800 million annually, not including the costs of expired drugs at long-term-care facilities and retail pharmacies and those still sitting forgotten in consumer medicine cabinets.[2]

Even given those statistics, a follow-up report by HDMA indicates the true cost impact of short-dated products may frequently be underestimated: "Most trading partners underestimate the true cost of returns. The projected value of all prescription products returned in the U.S. for which manufacturer credit is requested is between $2.6 and $4.2 billion (1 percent to 2 percent of manufacturer selling units), the vast majority of which are either 'outdated' or 'short-dated' (72 percent)."[3]

Understanding Industry Safeguards

Drug expiration dates reflect the time period during which the product is known to remain stable, meaning it retains its strength, quality and purity when it is stored according to label guidelines. FDA regulations require drug applicants to provide stability testing data with a proposed expiration date and storage conditions when they submit an application for FDA approval of their drug. This testing provides confidence that the product will meet the applicable standards of strength, quality and purity throughout its shelf -life.

Products are considered short-dated when they are nearing their expiration date and are not yet consigned to a buyer.

Industry safeguards that address the problem of short-dated products also include processes that ensure pharmaceutical shipments operate on a "first-expiration-first-out" schedule, with products shipped according to the proximity of their expiration dates. This assures older inventory is moved first and also creates an efficient stock rotation system. Additionally, as referenced in the HDMA report, distributors normally ship product with at least six months remaining until the expiration date.[4]

Another option that exists when short-dated products are flagged for return involves donation to charitable organizations. Often, these nonprofits collect short-dated pharmaceuticals donated by manufacturers and distribute them to low-income, uninsured patients. In fact, there are specific pharmaceutical donation and reuse programs that allow unused prescription drugs to be donated and redispensed to patients. Such drug repository programs began with state legislative action in 1997, and as of fall 2018, there were 38 states and Guam with enacted laws for donation and reuse.[5]

Still, the problems created by short-dated products and their resulting returns or donation impact numerous industry stakeholders, including distributors, manufacturers, healthcare providers and service providers. And, while there are product- and demand-related drivers of soon-to-expire pharmaceutical returns,

there are also potential process improvements that may address and reduce the quantity of short-dated products that are returned, including the adoption of track-and-trace technologies designed to enhance inventory management. Indeed, pharmaceutical track-and-trace regulations have been taking shape for several years. Industry guidelines enacted in 2017 require U.S. manufacturers to serialize products using 2-D bar codes and a unique identifier that includes product ID, serial number, expiration date and lot number. And, by 2023, regulations that are a part of the Drug Supply Security Act require each bottle or package of a drug be trackable to the original manufacturer.[6]

Considerations for a Consignment Strategy

Specialty pharmaceuticals pose unique challenges when it comes to inventory management. By 2021, the specialty market is expected to make up 50 percent of total pharmaceutical spend, or $285 billion. In comparison, this market accounted for only 28 percent of pharmaceutical spend in 2011 and 39 percent in 2016, according to a Drug Channels Institute report.[7]

One of the key issues surrounding high-cost specialty therapies is unpredictable demand, which requires a different inventory strategy than traditional pharmaceuticals. To minimize the risk of short-dated product returns, some health systems are increasingly turning to a consignment model to better manage these specialty drugs, a move that can also reduce costs. IQVIA Institute for Human Data Science[8] noted specialty drugs represent 60 percent of invoice spending and 2.3 percent of standard unit volumes in nonretail settings. With a higher invoice cost comes higher inventory carrying costs, and hospital pharmacies cannot afford to let costly specialty drugs expire. Some medications may also be cold chain products requiring refrigeration, so pharmacies must additionally plan for proper storage to avoid waste.

Return systems for short-dated products serve several useful purposes, the most important of which is to protect patient safety.

With that in mind, a consignment strategy can streamline and automate inventory management processes and reduce carrying costs for specialty pharmaceuticals. The approach allows hospitals to store products in their pharmacies and pay for them only when they are used.

In a webinar discussion sponsored by Ohio-based Cardinal Health, the organization outlined its approach to utilizing the consignment model and described how radio-frequency identification (RFID)-enabled consignment solutions can help reduce waste. "If you buy too much, you could risk waste due to expiration. If you buy too little, you could risk not having a product for a patient," said James Roof, national director of consignment and technology programs. "Consignment ensures you have the products you need at the right time without incurring costs due to waste."

The Cardinal Health Consignment Program uses RFID technology to monitor inventory in real time, set par levels based on actual pharmacy usage and send alerts for recalled products. Consigned inventory can be tracked and traced within a cloud-based platform, which allows health systems to gain real-time visibility into inventory levels. And, if there are multiple facilities in a network, consigned products can be transferred within the network.[7]

Another smart system worth noting was developed by FFF Enterprises, a nationwide distributor of plasma products, vaccines and biopharmaceuticals. The system, known as Verified Inventory Program-Consignment (VIPc), is a streamlined inventory management solution designed for high-value and critical-care products. This RFID-based consignment solution tracks and monitors products and the conditions in which they are stored. The cabinets are monitored by FFF Enterprises' VIPc team on a 24/7 basis for both temperature and inventory. In the event of a temperature excursion, the team responds immediately to ensure product integrity is not compromised. Likewise, when product is loaded or removed from the cabinet, the RFID technology updates the inventory of the cabinet without any manual intervention on the part of the customer. Throughout each day, the facility's staff can dispense product from the cabinet as it is needed for patient dosing, and once a minimum par level (a minimum quantity of a given item that must be kept on hand) is reached, an alert will go to the VIPc team, and replenishment will arrive the next day.

From a waste-management perspective, the VIPc team proactively monitors product expiration to ensure these high-cost critical-care products do not become short-dated. In the event a customer is unable to use a product and it is projected to become short-dated, the team will reach out to facilitate return of the product well before it reaches its expiration date so it can be sent to a customer who can immediately use it. The team then replenishes that facility's cabinet with longer-dated product.

Currently, VIPc is being used in acute facilities and hospital pharmacies, particularly for coagulation factors, which are costly and have unpredictable usage, but are critical to have on hand when lifesaving situations arise. Other specialty products at risk of becoming short-dated can be stored using VIPc, including treatments for

snake bites, heart attacks, strokes and even cataract surgeries.

FFF also pioneered an innovative solution specifically for vaccine storage. MinibarRx (MBRx) was developed in 2013 as a stand-alone joint venture of affiliates of Minibar Systems (the world's largest maker of refrigerated platforms to the hospitality industry) and InstantDx (a leader in electronic prescribing and healthcare-transaction services). MBRx streamlines the process of purchasing, storing, administering and billing for refrigerated vaccines in physician offices, retail pharmacies and nonacute, ambulatory surgery centers and urgent care facilities.

As an affiliate, FFF Enterprises provides the MBRx refrigerators with the vaccines it distributes and automates the MBRx process using its proprietary software that sets a reorder point for each refrigerated vaccine at each location based on average usage. To avoid product expiry, electronic notifications are communicated to providers starting 45 days prior to the medication's expiration date. An LCD screen on the unit also displays all vaccines close to expiring for proper management. As an additional safeguard, if a product does expire before being used, the LED indicator light on the dispenser will turn red to indicate not to use the product. And, if the product is removed for use, an alarm will sound triggering an email notification. The product would then be returned for possible credit based on the manufacturer's guidelines.

According to Shay Reid, chief operating officer who leads development of the smart refrigerator technology at FFF, MBRx also complies with the Centers for Disease Control and Prevention's regulatory requirements for storage and handling of vaccines and biologics, creating what is essentially a worry-free system for inventory purchase and management. Reid notes that MBRx also has some unique differentiators compared to other smart refrigeration technologies. "MBRx does not require any additional product labeling such as the use of RFID tags. It is also an interactive technology capable of presenting temperature and inventory information on screen to the user, as well as directing the user to dispense first expiring products to help eliminate product expiry in the machine," he explains. "Additionally, MBRx's unique design helps to maintain the correct temperature and block light even when the main door is open, which serves to further protect the very sensitive inventory the machine dispenses without limiting accessibility."

Pursuing Innovation and Safety

Return systems for short-dated products serve several useful purposes, the most important of which is to protect patient safety, and any efforts to minimize returns must keep end-user well-being at the forefront of proposed innovation. Given the complexity of the issue and the multiple product-related and demand-related drivers, clearly, there is no one-size-fits-all solution to reducing the number of short-dated products in the supply chain. Process improvements and technological advances are definitely steps in the right direction, and moving forward, a collaborative effort spearheaded by manufacturers, distributors, retailers and dispensers alike has the potential to reduce the overall quantity of expired and soon-to-expire pharmaceutical products; reduce total supply chain costs associated with unsalable returned goods; and preserve or improve the safety and security of the healthcare supply chain. ❖

TRUDIE MITSCHANG is a contributing writer for *BioSupply Trends Quarterly* magazine.

References

1. Healthcare Distribution Management Association. Understanding the Drivers of Expired Pharmaceutical Returns. Accessed at www.nacds.org/pdfs/membership/understanding_drivers.pdf.
2. Allen M. That Drug Expiration Date May Be More Myth Than Fact. NPR, July 18, 2017. Accessed at www.npr.org/sections/health-shots/2017/07/18/537257884/that-drug-expiration-date-may-bemore-myth-than-fact.
3. HDMA's Practical Tips to Address Returns Drivers. Accessed at hda.org/~/media/pdfs/publications/2011-02-10-practical-tips-to-address-returns.ashx.
4. No Room for Error: Avoid These Six Reasons for Bulk Pharmaceutical Returns. Accessed at www.wdsrx.com/no-room-error-avoid-six-reasons-bulk-pharmaceutical-returns.
5. National Conference of State Legislatures. State Prescription Drug Return, Reuse and Recycling Laws, Oct. 1, 2018. Accessed at www.ncsl.org/research/health/state-prescription-drug-return-reuse-and-recycling.aspx.
6. Shanley A. Waking Up to Track-and-Trace Benefits. PharmaTech.com, March 2, 2016. Accessed at www.pharmtech.com/waking-track-and-trace-benefits.
7. Korol S. How to Reduce Specialty Pharma Inventory Costs, Boost Visibility with a Consignment Model. Becker's Hospital Review, Oct. 26, 2018. Accessed at www.beckershospitalreview.com/supply-chain/how-to-reduce-specialty-pharma-inventory-costs-boost-visibility-with-a-consignment-model.html.
8. The IQVIA Institute. Medicine Use and Spending in the U.S., April 19, 2018. Accessed at www.iqvia.com/insights/the-iqvia-institute/reports/medicine-use-and-spending-in-the-us-review-of-2017-outlook-to-2022.