HDA RESEARCH FOUNDATION

THE ROLE OF REVERSE DISTRIBUTION

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HDA RESEARCH FOUNDATION

THE ROLE OF REVERSE DISTRIBUTION

The HDA Research Foundation is the 501(c)(3) non-profit charitable organization of the Healthcare Distribution Alliance (HDA). The Foundation serves the healthcare industry by providing research and education focused on healthcare supply chain issues. The Foundation's mission is to conduct research and disseminate information that will enhance the knowledge base, efficiency and effectiveness of the total healthcare supply chain; and to provide thought leadership to further enhance the safety and security of the healthcare supply chain through future-focused study and programming.

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PUBLICATION SPONSORS

SILVER

PharmaLink is a nationwide top tier reverse distributor providing ethical and transparent pharmaceutical returns services including compliant disposal and optimized reporting services to the entire spectrum of pharmaceutical classes of trade since 2000.

PharmaLink's passion for consummate customer service is exemplified in every aspect of our operations; from personalized customer service to a devotion for responsible and professional practices. Personifying excellence in recall and returns processing as well as inventory and receivables analysis, PharmaLink continues to be the clear choice of pharmacies, manufacturers and wholesalers for all of their pharmaceutical returns.

PROJECT TASK FORCE MEMBERS

The HDA Research Foundation, Kindler & Crimmins Associates and Bradford Rx Solutions would like to recognize the following individuals and companies who invested their time and expertise as project task force members to assist with the development of this report through their participation in group discussions, individual interviews and collective review.

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INTERVIEW AND SURVEY PARTICIPANTS

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EXECUTIVE SUMMARY

OVERVIEW

A great deal of industry focus has been placed on enhancing forward distribution processes, increasing efficiencies and developing a safe and secure supply chain. With similar focus, key stakeholders, including manufacturers, wholesale distributors, dispensers and reverse logistics providers, manage the reverse distribution of pharmaceutical products. They have invested capital, assigned resources and developed technology resulting in a robust reverse channel focused on operational productivity, financial controls and regulatory compliance. Though difficult to measure, it is estimated that the reverse distribution channel manages between 3.5 and 4 percent of all pharmaceutical sales, consisting of more than 120 million units with a product value exceeding $13 billion.

Pharmaceutical reverse distribution is designed to support stakeholders' business requirements to handle saleable, unsaleable, damaged and recalled products while operating in and being governed by multiple levels of regulatory oversight, including federal, state and local authorities. This highly complex process may require numerous touch points to account for the product and various reimbursement models that also define the value of returned products. Reverse distribution is costly and all stakeholders bear the responsibility for safely dispositioning pharmaceutical products that are in a stakeholder's control, but, for various reasons, it has elected to not sell, dispense or administer for patient care.

Understanding the importance of reverse distribution to all pharmaceutical industry stakeholders and recognizing the lack of a current, comprehensive, singular resource, the HDA Research Foundation contracted with Kindler & Crimmins Associates, LLC, and Bradford Rx Solutions, LLC, to perform a comprehensive analysis of the reverse distribution process for pharmaceutical products (prescription and non-prescription). The objective of the report is to provide current pharmaceutical supply chain stakeholders with an educational, practical reference that is applicable to those new to the industry and others who may be interested in expanding their knowledge of pharmaceutical reverse distribution processes.

In developing the report, the authors used their collective 65 years of pharmaceutical industry experience and leveraged additional resources to supplement industry information while mitigating research and experience biases. The supplemental information was derived from a combination of interviews with representatives from key stakeholder groups, a survey of reverse logistics providers and a review of publicly available literature and information about the reverse distribution industry.

APPROACH AND FOCUS

The report differentiates the various types of product returns and details the current reverse distribution processes for them, including:

- The physical, financial and informational flows;
- Product return volumes;
- Causes and drivers for returns; and,
- Supply chain stakeholder roles and responsibilities.

Additionally, the report details the current security measures and practices that help ensure a safe and secure supply chain and explores the value of pharmaceutical reverse distribution for all supply chain stakeholders, specifically focusing on:

- Cost savings and financial benefits;
- Process improvement opportunities;
- Risk mitigation and supply chain security; and,
- Environmental stewardship.

KEY FINDINGS

The report highlights that there always will be a need for an efficient and cost-effective reverse distribution function to assist dispensers and wholesale distributors with managing excess saleable inventory and providing a regulated, efficient process to remove unsaleable pharmaceutical products from the supply chain safely and securely.

SALEABLE RETURNS

Wholesale distributors play a critical role in the reverse distribution process by receiving and processing saleable returns totaling more than $7 billion annually. These returns are estimated to be 2.1 percent of sales volume and approximately 59 million units each year. Despite improvements in demand forecasting, dispensers need a reliable and efficient process to manage excess and non-productive inventory. The current trend for larger retail chain pharmacies to move away from the self-distribution of pharmaceutical products to a direct store delivery model further supports the critical need for an efficient and productive saleable return process managed by wholesale distributors.

Both the manufacturer and dispenser benefit greatly from the wholesale distributor saleable returns service offering, as this process:

- Helps ensure product integrity and legitimacy;
- Enhances product availability;
- Improves dispenser inventory productivity by facilitating the redeployment of excess inventory;

- Mitigates financial losses that would be otherwise incurred by the dispenser if the product could not be returned and becomes unsaleable;
- Is automated, efficient and cost-effective;
- Avoids unnecessary logistical and administrative costs; and,
- Reduces the volume of waste generated by the supply chain.

UNSALEABLE AND RECALL RETURNS

Despite efforts by wholesale distributors and dispensers to manage inventory levels, inevitably, some inventory will become unsaleable. Therefore, it is essential to have a process for managing these products at the end of their commercial life and removing them from the pharmaceutical supply chain safely and securely. Annual unsaleable return volume is estimated to be between 1.5 and 2 percent of sales, comprising 60 million to 80 million units and totaling more than $6 billion.

Reverse logistics providers play a critical role in the supply chain by managing unsaleable product returns on behalf of wholesale distributors, dispensers and manufacturers.

The returns process:

- Provides a safe, secure and reliable method for removing unsaleable inventory and helps ensure that product is properly dispositioned;
- Provides expertise to manage and administer many manufacturers' returned goods policies with frequent policy changes;
- Identifies product that is eligible for manufacturer credit and assists with the credit and collection process, thereby mitigating financial risks for downstream trading partners;
- Removes costs from the supply chain by providing a more efficient and cost-effective return and disposition process;
- Minimizes the environmental impact of returns by helping to ensure all pharmaceutical waste is handled in an environmentally sound manner;
- Creates a standardized, centralized, controlled processing environment in a highly regulated pharmaceutical supply chain process;
- Provides access to valuable data and analytics, which can be used by all stakeholders to proactively reduce unsaleable returns volume; and,
- Creates specialized providers for returns processing, allowing stakeholders to focus instead on core competencies, such as product manufacturing, distribution and patient care.

Reverse logistics providers also can play an important role in the recall process by providing a comprehensive, tested solution to the manufacturer managing a recall event, including notification, response administration, product processing and reporting.

OPPORTUNITIES TO ENHANCE THE RETURN PROCESS

Opportunities currently exist for key stakeholders to modify existing practices to reduce the quantity of returned products and to improve the efficiency and effectiveness of the reverse distribution supply chain. Improvement areas include:

- **Data access and availability:** Access to current and relevant industry-wide unsaleable returns volume information is very limited. An opportunity exists for trading partners to share more comprehensive data, which may be used for benchmarking, developing key metrics and identifying opportunities to remove duplicative or non-value-added costs.
- **Inventory management:** In addition to managing the physical inventory and disposal of unsaleable product returns, reverse logistics providers deliver valuable product analytics that have the potential to assist all key stakeholders to better manage inventory and unsaleable returns volume. A large percentage (20–25 percent) of dispenser inventory is non-productive and may be considered excess inventory. Manufacturers, wholesale distributors and dispensers all stand to realize significant financial savings by collaboratively focusing on inventory management practices, improving inventory productivity and reducing unsaleable returns volume.
- **Redundant handling costs:** Many unsaleable product returns are handled by multiple reverse logistics providers, creating redundant handling costs and processing delays. Adoption of a more streamlined processing model that eliminates these redundancies could result in an estimated annual savings of $15 million to $40 million.

FUTURE CONSIDERATIONS

Regulations in the proposal stage or future regulatory changes may significantly impact future saleable and unsaleable product return models. The absence of an efficient and cost-effective saleable return process will lead to increased levels of non-productive and excess inventory, which may ultimately result in higher levels of unsaleable product returns. Trading partners, regulatory entities and other stakeholders are encouraged to work together to ensure that new or amended requirements support and enhance the operation of the current model. This collaboration could help avoid business, statutory or regulatory disruptions that could impair the operation of the current model and the normal flow of product which may have a dramatic and detrimental impact on the quantities and costs associated with the reverse distribution process.

The implementation of unit-level traceability as required by the Drug Supply Chain Security Act (DSCSA) has presented significant challenges and changes to the industry. The use of standardized product identifiers and the possibility of linking critical data elements may present business process improvement opportunities beyond regulatory compliance and adherence. However, systems and processes will need to be properly designed so the information can be captured and presented in a useful and actionable format.

PROJECT BACKGROUND AND OVERVIEW

Pharmaceutical reverse distribution is the process of moving unsold saleable inventory within the pharmaceutical supply chain or, as a last stop in the supply chain before final disposition, removing unsaleable inventory from the supply chain in a safe, secure and reliable manner. This highly complex process requires several supply chain partners to handle pharmaceutical products while adhering to federal and state legal requirements. It is estimated that more than 120 million units with a product value in excess of $13 billion flows through the combined saleable and unsaleable pharmaceutical reverse distribution channel annually.

Understanding the importance of reverse distribution to all pharmaceutical industry stakeholders, and recognizing the lack of a current, comprehensive, singular reference, the HDA Research Foundation contracted with Kindler & Crimmins Associates, LLC, and Bradford Rx Solutions, LLC, to perform a comprehensive analysis of the reverse distribution process for pharmaceutical products (prescription and non-prescription). The objective of the report is to provide pharmaceutical supply chain stakeholders with an educational, practical resource that is applicable to those new to the industry, as well as those interested in expanding their knowledge of pharmaceutical reverse distribution processes.

The report will:

- Explain the pharmaceutical reverse distribution process, including:
    - The current physical, financial and informational flows of saleable, unsaleable and recalled product through the supply chain;
    - A discussion of the product return types, volumes, reasons for the return(s) and their disposition; and,
    - The processes performed by various stakeholders in the healthcare supply chain.

- Describe existing security measures and practices related to reverse distribution and designed to help ensure supply chain safety;

- Analyze the value of reverse distribution for all stakeholders in the pharmaceutical supply chain by reviewing:
    - Cost savings and financial benefits;
    - Potential process improvements;
    - Risk mitigation, product security and environmental stewardship; and,
    - Product availability.

This report is particularly timely as the industry is actively adopting and implementing the new requirements enacted as part of the U.S. Food and Drug Administration's (FDA) Drug Supply Chain Security Act (DSCSA).[1] The DSCSA contains a 10-year implementation timeline and "outlines steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States. This will enhance the supply chain's and FDA's ability to help protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated or otherwise harmful. The system also will improve detection and removal of potentially dangerous drugs from the drug supply chain to protect U.S. consumers."[2]

To generate the report, the research team relied on its collective 65 years of industry experience and leveraged additional resources to supplement industry information and mitigate potential research biases. Supplemental resources were derived from the following:

- Stakeholder interviews with representatives in each of the identified key stakeholder groups to develop industry insights from experts in the physical, financial and informational reverse distribution processes.
- A survey of reverse logistics providers, focused on the collection of product processing information, product traits, markets served, data captured and other metrics.
- A literature review of publicly available industry information and other publications referenced throughout the report.

1- Drug Supply Chain Security Act, Title II of Public Law 113-54 (November 27,2013) https://www.gpo.gov/fdsys/pkg/PLAW-113publ54/pdf/PLAW-113publ54.pdf#page=13.

2- https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ (May 11, 2018).

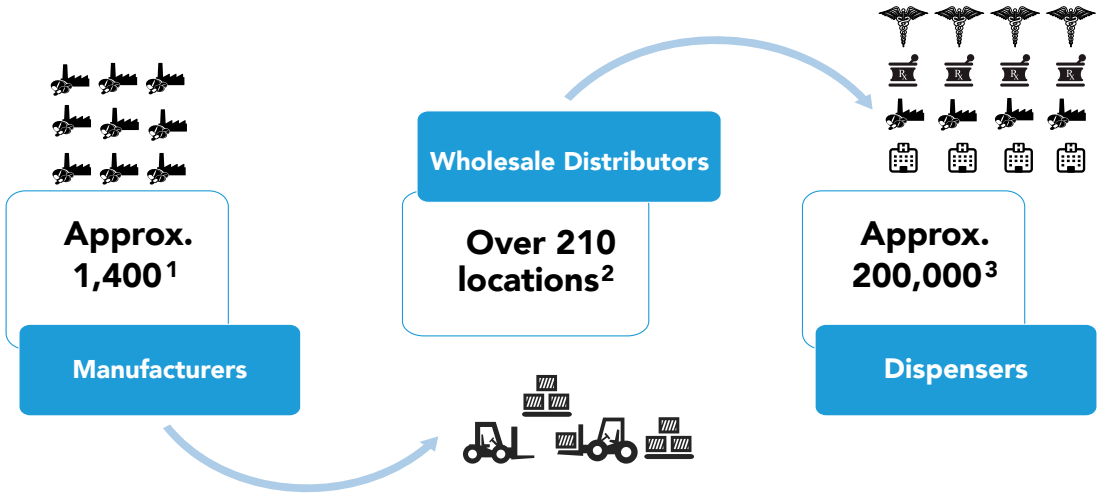
PHARMACEUTICAL DISTRIBUTION

To better understand the issues and challenges of reverse distribution, a background of forward distribution will aid in highlighting the similarities and differences.

There are three key stakeholders in the forward distribution process:

- Manufacturers (including third-party logistics providers or 3PLs);
- Wholesale distributors; and,
- Dispensers (including hospitals, chain and independent pharmacies, physician offices and long-term care facilities).

Figure 1: General Illustration of Pharmaceutical Distribution



Sources:
1. HDA Research Foundation, *88th Edition HDA Factbook: The Facts, Figures and Trends in Healthcare (2017-2018)*, Table 53; and KCA proprietary information.
2. HDA Research Foundation, *88th Edition HDA Factbook*, Table 6.
3. Center for Healthcare Supply Chain Research, *2013–2014 HDMA Factbook*, Table 84.

MANUFACTURERS

Manufacturers produce prescription and non-prescription or "over-the-counter" (OTC) pharmaceuticals for sale in the commercial supply chain. Manufacturers primarily employ wholesale distributors to streamline the delivery of prescription product destined for dispensers. OTC products may be shipped directly from the manufacturer to dispensers or through wholesale distributors. The wholesale distribution channel accounts for 95.68 percent of manufacturers' prescription product sales.[3] Some manufacturers use 3PLs to manage product distribution and logistics related services. A small percentage of manufacturers' pharmaceutical products is distributed directly to dispensers or dispenser-operated distribution facilities (self-distributors).

3- HDA Research Foundation, *88th Edition HDA Factbook: The Facts, Figures and Trends in Healthcare* (2017-2018) (Arlington, HDA Research Foundation, 2017), Table 1.

Every prescription pharmaceutical product has a unique National Drug Code (NDC), which, with the product manufacturing lot number and an expiration date, is included on each product label.[4] OTC products have an NDC but also a unique Universal Product Code (UPC) in addition to the lot number and expiration date. Manufacturers generally label their pharmaceutical products with an expiration date of 24 months after date of manufacturing, though expiration dating varies widely. The combination of NDC or UPC, lot number and expiration date are vital data elements in the forward and reverse distribution processes. These elements are so critical to the supply chain that they have been included in the DSCSA product identifier, which manufacturers and repackagers must affix to every prescription product introduced into commerce as of November 27, 2018.[5] The product identifier comprises the NDC, lot number, expiration date and a unique serial number.

Some prescription pharmaceutical products are produced by the manufacturer with less than 12 months before expiration date, as this is often the best dating possible due to product ingredients and other factors. For example, biological products frequently have an extremely limited shelf life. For the purposes of this report, these products are referred to as "manufacturer short-dated" products.

Manufacturers have developed and implemented returned goods policies that set out the terms and conditions for dispensers and wholesale distributors to return unsaleable products, as well as the eligibility requirements for obtaining reimbursement. Importantly, returned goods policies also provide a means for manufacturers to account for unsold products and to ensure their safe and secure dispositioning. Manufacturers consider this to be an important component of life-cycle management. Further, the policies are used to encourage dispensers and wholesale distributors to carry their products, helping to mitigate the financial risks a buyer assumes when stocking the manufacturer's pharmaceutical products in anticipation of demand and to satisfy patient need in a timely manner. A more detailed discussion of manufacturer returned goods policies can be found in the "Unsaleable Returns" section.

WHOLESALE DISTRIBUTORS

Wholesale distributors purchase products from manufacturers, receive and hold the inventory in their distribution centers, accept dispensers' orders and ship products to them. Ordering and delivery frequency, as well as other service level requirements, are contractually defined in supply agreements or terms of sale between trading partners. Using wholesale distributors and their extensive national and regional distribution networks helps a manufacturer ensure that its products are delivered to dispensers in a safe and timely manner so they can be effectively dispensed to patients and consumers.[6]

HDA members include 36 wholesale distributors operating 211 distribution centers,[7] represent 98 percent[8] of U.S. pharmaceutical distribution sales and serve approximately 200,000 dispensers across the U.S. By aggregating transaction volumes and inventory for manufacturers and dispensers, wholesale distributors provide an efficient, lower-cost operation that delivers the lifesaving medicines and healthcare products dispensers need, when they need them, and alleviate the financial and logistical burdens dispensers would otherwise bear of buying and maintaining extensive, costly inventory.

4- NDC numbers are assigned pursuant to 21 C.F.R. Part 207 and are commonly included to aid in distribution, dispensing and reimbursement. Expiration dates are determined through stability testing as described in 21 C.F.R. § 211.166- Current Good Manufacturing Practice for Finished Pharmaceuticals- Stability Testing. Expiration dates and lot numbers are required on pharmaceutical labels [§ 21 C.F.R. § 201.17, § 201.18, § 211.137, § 201.100(b)(6)].

5- The DSCSA originally required affixing of product identifiers by November 27, 2017, for manufacturers and November 27, 2018, for repackagers. FDA issued a draft guidance proposing to grant enforcement discretion to effectively extend the date of compliance for manufacturers to November 27, 2018. See "Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy – Draft Guidance for Industry" (June 2017), https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM565272.pdf.

6- Booz & Company, *The Role of Distributors in the Healthcare Industry* (Arlington, Center for Healthcare Supply Chain Research, 2011), pg. 1.

7- HDA membership database.

8- HDA Research Foundation, *88th Edition HDA Factbook: The Facts, Figures and Trends in Healthcare*, Table 2.

A typical wholesale distributor's ordering process from a manufacturer is based on sophisticated replenishment algorithms considering current inventory, previous sales activity, forecasted demand, seasonality and other data elements. Wholesale distributors generally require prescription pharmaceutical products to have at least one year of shelf life upon receipt from the manufacturer and typically only will ship to dispensers if products have at least six months remaining before expiration. Some dispensers, in their contractual agreements with wholesale distributors, require pharmaceutical products to have more than six months dating remaining before expiration or they may not accept the product.

However, manufacturer short-dated pharmaceutical products often continue to move in the supply chain where necessary to meet patient need or demand, despite having an extremely limited shelf life. As a response, wholesale distributors have developed and implemented unique processes to distribute manufacturer short-dated products to dispensers. Dispensers also have developed alternate receiving and handling processes to ensure manufacturer short-dated products are available to meet patient needs.

Many manufacturers and wholesale distributors manage inventory and other distribution services for prescription products through contractual distribution agreements or sales agreements. These agreements may require wholesalers to provide manufacturers with certain inventory information for their products, including on-hand inventory, service level and other distribution service measures. These agreements have played a significant role in reducing supply chain costs and improving overall inventory management.

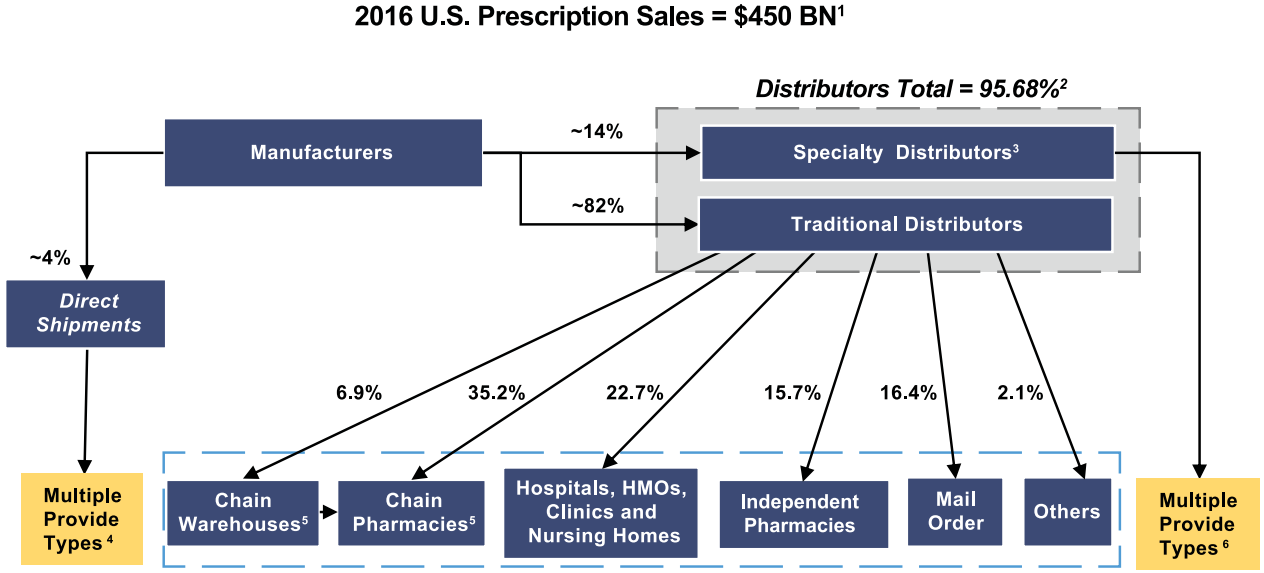
A further example of collaboration between manufacturers and wholesale distributors is the donation of certain excess inventories of prescription pharmaceutical products to charitable organizations for patient care. Charitable organizations often provide medicines in response to medical emergencies, disaster-relief efforts and to underserved populations. Although these donations originate from the manufacturer, the manufacturer's 3PL or wholesale distributor facilities, the charitable organizations often facilitate the transportation and distribution of these products at the direction of the manufacturer and in accordance with their requirements.

In addition to the product distribution services outlined above, wholesale distributors provide a wide variety of other services. An in-depth analysis of wholesale distributors can be found in the Center for Healthcare Supply Chain Research (now HDA Research Foundation) publication, T*he Role of Distributors in the U.S. Healthcare Industry.*

DISPENSERS

A dispenser is any pharmacy or person authorized or licensed to dispense or administer prescription pharmaceuticals. Dispenser types include chain and independent retail pharmacies, specialty pharmacies, hospitals, long-term care facilities, mail-order pharmacies, clinics, physician offices and others. Dispensers purchase branded, generic, specialty and OTC products to administer or sell them to patients. Dispensers can order from multiple sources, including directly from the manufacturer; from a wholesale distributor (or multiple wholesale distributors); or from their own distribution center, if it is a larger operation that self-distributes. Over the last several years, self-distribution activity has decreased as some retail chain drug stores, for example, have changed their sourcing models, requiring their pharmacies to order and receive all of their pharmaceuticals directly from the wholesale distributor instead of their own distribution centers.[9] Generic products may be procured through several distribution channels, including primary wholesale distributors and distributors specializing in generic products. Figure 2 depicts the flow of products by dispenser type.

Figure 2: Flow of U.S. Prescription Sales ($B) and Contribution by Dispenser Type (%)



Source: HDA Research Foundation, "2018 Understanding Pharmaceutical Distribution" presentation https://www.hda.org/resources/2018-understanding-pharmaceutical-distribution-presentation, slide 10. Updated 4/5/18.

Notes:
1. Total value of goods flowing through the supply chain as per IMS National Sales Perspectives™. Percentages represent contribution by channel toward the total flow of $ BN.
2. Total value of goods flowing through traditional distributors, 2016–2017 *HDA Factbook* (Tables 2, 3)
— excludes all non prescription products, and sales to other distributors.
3. Specialty distributors defined as per the *Specialty Pharmaceuticals and Role of the Specialty Distributor* report published by the Center for Healthcare Supply Chain Research (HDA Research Foundation) in April 2015.
4. Manufacturers ship directly to multiple provider types, including those served primarily by pharmaceutical distributors
5. Chain pharmacies include national and regional drug store chains, mass merchandisers and food stores. Chain warehouses represent centralized warehouses for chain pharmacies.
6. Specialty distributors provide services to many provider types, including physicians offices and clinics, home care providers, hospital pharmacies and specialty pharmacies.

9- Adam J. Fein, *The 2017 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers* (Pembroke Consulting, Inc., 2017), pg. 169-170.

CAUSES OF EXCESS INVENTORY

Wholesale distributors and dispensers carry a wide variety of pharmaceutical products in their inventory. Properly balancing inventory supply and customer demand may be disrupted by external factors beyond the control of the wholesale distributor or dispenser. Scenarios include:

- The FDA approves one or more generics of a branded pharmaceutical (referred to as a "Loss of Exclusivity" event) and, under the insurer's policies and as permitted under state law, patients are automatically converted to the generic equivalent which results in excess inventory of the brand pharmaceutical;
- Wholesale distributors or dispensers change their preferred generic product;
- Patients transfer prescriptions to another pharmacy and the original pharmacy lacks demand from other customers to dispense the product;
- Patients alter or discontinue their prescribed treatment;
- Negative information, such as an unanticipated adverse event, regarding a pharmaceutical product arises, resulting in fewer prescriptions;
- The manufacturer or other supply chain partner misjudges product demand, especially for newly approved products, resulting in fewer prescriptions written and lower product sales than anticipated;
- Fluctuations in demand for seasonal flu vaccines;
- Unpredictable demand for seasonal products, such as antiviral medications and cough, cold and allergy products;
- Discrepancies between amounts of products in commercial packaging versus amounts prescribed. For instance, prescriptions often are written for quantities fewer than the standard package size (90-day prescription dispensed, but the pharmaceutical is packaged by the manufacturer in a 100-count bottle), resulting in residual inventory ("partial containers") that may be difficult to dispense;
- Prescription benefit managers (PBMs) and insurance payers may institute formulary changes or restrictions, resulting in reduced reimbursements to patients for certain products.

Wholesale distributors operate a limited number of facilities, carrying and distributing the inventory necessary to supply the U.S. healthcare market, creating significant efficiencies, economies of scale and process standardization. The use of sophisticated ordering, replenishment and inventory management systems; sharing inventory information with manufacturers to help manage inventory levels; and balancing supply and customer demand results in reduced excess inventory and fewer returns.

Operating in approximately 200,000 locations in various market channels, dispensers face additional challenges that may result in less than optimal inventory management practices. Dispensers carry, manage and dispense pharmaceutical products using a variety of different inventory management systems. These systems vary greatly in level of sophistication and range from fully automated and integrated to completely manual. Inaccuracies and inefficiencies in demand forecasting, ordering,

perpetual inventory, replenishment and stock rotation may lead to excess inventory at various dispenser locations. The process of identifying and managing excess inventory is more complex as some dispensers may have limited visibility into the amount of product they have on hand and available for administration or sale to patients. Furthermore, the lot number and expiration date of the product, which might help with inventory management by identifying older products that should be sold first, are rarely captured.

Dispensing practices also may have the unintended consequence of creating or increasing the number of product returns. For example, automated prescription refill programs have been implemented as a convenience for patients and to promote adherence to maintenance medications. Refill prescriptions are generally filled several days in advance of the anticipated patient need. If the patient does not pick up the prescription within a specified time, the product may be placed back into inventory. The opportunity to dispense the product may be limited if the product was removed from its original container, placed into a prescription vial, but not dispensed. State regulatory authorities may have issued regulations in some states that prevent dispensers from returning filled but not sold products back into inventory (i.e., product that has not left the pharmacy) or otherwise shorten the shelf life for products not in the original manufacturer container.

Despite dispensers' best efforts to manage pharmaceutical inventory, some portion of their inventory will not be dispensed. Demand fluctuations, changes in products and dispenser inventory management practices all may contribute to the accumulation of excess inventory. For a retail dispenser, excess inventory may be as high as 20–25 percent[10] of total inventory. Dispensers have a limited number of options to address and resolve excess inventory. Generally, the product may be transferred to another location within the same retail chain or hospital system where the product may be sold or dispensed.[11] Unused, unopened, intact products may be returned through the wholesale distributor saleable return process. If either of those options are not available or used and no new demand exists, the product will eventually become unsaleable and will be handled through the unsaleable return process.

Additional information about inventory related issues can be found in the following HDMA- (now HDA-) published documents:

- *Unsaleable Returned Goods in the Healthcare Supply Chain* (2007);
- *Understanding the Drivers of Expired Pharmaceutical Returns* (2009); and,
- *Loss of Exclusivity: An Inventory Management Case Study* (2013).

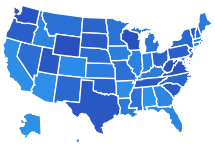
10- Based on Kindler & Crimmins industry experience and proprietary information.

11- The intracompany transfer process is outside of the scope of this report.

REVERSE DISTRIBUTION

Reverse distribution is the process of moving unsold saleable inventory within the pharmaceutical supply chain or removing unsaleable inventory from the supply chain in a safe, secure and reliable manner. At a very high level, reverse distribution of products is similar to the forward distribution process described earlier in the report, however there are key differences. A chart comparing the forward and reverse distribution processes can be found in Figure A2 of the Appendix.

Figure 3: Reverse Distribution Key Metrics

U.S. Prescription Sales Market	Total Reverse Distribution [2]		
	Annual Units	% Sales ($)	Annual $ Volume
 $450 BN [1]	119 million to 139 million	3.5% to 4%	$13 BN- $16 BN

Sources:
1. HDA Research Foundation, *88th Edition HDA Factbook*, pg. 1.
2. Figures are calculated using specific totals from Figure 4 (Saleable Return Metrics) and Figure 6 (Unsaleable Return Metrics).

Due to the existence of multiple reverse distribution channels, stakeholders and processes, quantifying reverse distribution volume is challenging. Return volume is significant and primarily driven by dispensers returning saleable product to their selling wholesale distributor and unsaleable product returns to manufacturers. A critical element of the reverse distribution supply chain is the flow of uniform data and information between multiple trading partners. The product handling, system integration, primary stakeholders and financial transaction processing involved in the saleable and unsaleable return processes differ substantially among supply chain participants. A chart comparing them can be found in Figure A3 of the Appendix.

Because of the growth of pharmaceutical products distributed in the U.S., as well as the increased costs and compliance requirements related to managing returns and recalls, dispensers and wholesale distributors have focused more resources on the process, created organizational structures, implemented operational/financial metrics and closely monitored activities of their reverse distribution processes. Supply chain stakeholders have recognized the importance of developing more consistent and sustaining processes to account for the volume and diversity of products that enter the reverse distribution channels. Over the past several years, reverse distribution has matured into a robust channel with operational, financial and regulatory controls intended to promote supply chain security and patient safety, required regardless of the variable product flows and stakeholder involvement.

Reverse distribution of pharmaceutical products is a complex process that requires several supply chain partners to handle pharmaceutical products while adhering to numerous federal and state regulations. Product returns may be full case, cartons, full containers, partial units, individual vials, ampules or pills. Furthermore, they originate from approximately 200,000 dispenser and wholesale distributor locations (Figure 1). Other factors may further contribute to the complex processing environment, including:

- Initiation and frequency of returns;
- Destination;
- Transportation method; and,
- Handling requirements.

Product returns may be initiated upon receipt of product from the shipper or may occur after the product has been placed into inventory and made available for sale. Product may be returned to the shipper or may be sent to a reverse logistics provider or recall provider, which will be discussed later in this document. The reverse distribution product flow will vary based on the type of return and business process used to initiate a return request. The return request is a notification and approval process used by the recipient of the returned product to help ensure proper control and handling. Generally, the products that move through the reverse distribution process can be categorized and described as follows:

- **Delivery damages:** The product was damaged while in transit to the wholesale distributor or dispenser.
- **Mis-shipments:** The product quantity was shipped in error and the recipient has elected to return it.
- **Saleable:** The product was removed from the dispenser or wholesale distributor inventory and is eligible to be redistributed, sold or dispensed to patients.
- **Unsaleable:** The product was removed from the dispenser or wholesale distributor inventory and generally is not available to be distributed, sold, dispensed or administered in the normal course of business. For the purposes of this report and in this context, "unsaleable" is a business term commonly used in pharmaceutical commercial trade and does not mean that a product is adulterated, deemed to be waste or otherwise has no value.
- **Recall:** The product was removed from dispenser or wholesale distributor inventory at the direction of the manufacturer or other recalling party.

The term "damage" has a specific business meaning in the wholesale distribution and returns-processing trade. In this context, "damage" or "damaged" means any prescription or OTC pharmaceutical product that is generally not available to be distributed, sold, dispensed or administered in the normal course of business. "Damaged" product includes product contents that may be intact but the selling unit packaging and/or label is torn, stained, crushed, unreadable or incomplete. Damaged product generally follows the reverse distribution processes detailed in this report and may be eligible for credit by the wholesale distributor or manufacturer. A relatively small percentage of returns to wholesalers from dispensers is reported as damaged. [12]

12- HDA Research Foundation, *88th Edition HDA Factbook: The Facts, Figures and Trends in Healthcare*, Table 50.

In contrast, product that is broken, leaking or otherwise not secure is considered waste and requires on-site resolution, possibly by a licensed and permitted waste handler when appropriate. Typically, this product is not returned through the traditional reverse distribution processes, and for the purposes of this report, is not included in the definition of damaged product.

Product returns eligible for reimbursement are subject to wholesale distributor and manufacturer returned goods policies. Generally, payments for eligible product returns are in the form of a credit memo; however, in some instances they may be in the form of a check. For purposes of this report, payments issued by manufacturers and wholesale distributors for product returns will be referred to as a "credit."

Although each of the key stakeholders perform reverse distribution functions, another entity, the reverse logistics provider (also referred to as a "reverse distributor" or "returns processor"), specializes in handling unsaleable and recalled products.

REVERSE LOGISTICS PROVIDERS

Dispensers, wholesale distributors and manufacturers use reverse logistics providers due to the complexities and challenges associated with administering and managing physical products, as well as the financial and informational flows of unsaleable returns and recalls. By contracting with reverse logistics providers, key stakeholders can outsource the reverse distribution processes that may be considered non-core business functions. Companies can avoid investing time, resources, physical space and capital to develop and operate these complex systems and processes when that sophisticated capability already exists with reverse logistics providers. For many years, reverse logistics providers have demonstrated the ability to operate in an efficient and cost-effective manner, offering supply chain expertise in reverse distribution.

Prior to the advent of the reverse logistics provider, stakeholders operated in a highly decentralized environment with limited visibility to data, system integration and process standardization for unsaleable product returns. Most dispensers and wholesale distributors returned product to each manufacturer from every warehouse or pharmacy location, which created variability in return volume and frequency. As a result, it was difficult to predict product return volume and efficiently assign resources among stakeholders. All of these factors contributed to an unsaleable returns process that required additional product handling, employee training, inventory tracking and transaction processing that was expensive and less efficient.

Stakeholders began using reverse logistics providers during the late 1980s and early 1990s; today, most dispensers, wholesale distributors and manufacturers have outsourced the processing of unsaleable and recall product returns. These highly specialized reverse logistics providers have become an integral part of the reverse distribution process. The Drug Enforcement Administration (DEA) defined the reverse distributor as a separate entity in 2003.[13] The industry continues to grow: the number of DEA-registered reverse logistics providers increased almost 61 percent in the past 10 years, and there were 66[14] such companies in operation as of December 2017. The DSCSA also recognizes the role of the reverse logistics provider and its processing, credit evaluation and dispositioning services in the pharmaceutical supply chain.

13- U.S. Drug Enforcement Administration, "*2003 Rules- Definition and Registration of Reverse Distributors,*" https://www.deadiversion.usdoj.gov/fed_regs/rules/2003/fr0711.htm, 21 C.F.R. § 1300.01.

14- U.S. Drug Enforcement Administration, "Registrant Population by Business Activity," https://apps.deadiversion.usdoj.gov/webforms/jsp/odrReports/odrBusActReportSelect.jsp;jsessionid=A99966B4BCAC4EA34CE88ECD766A6494, "Reverse Distributor (L)" Business Activity, "12-2007" vs. "12-2017" Cycle.

SERVICE OFFERINGS

Reverse logistics providers have made significant investments in systems and infrastructure so they can properly manage and administer the unsaleable and recall returns process on behalf of their clients. Similar to the automation implemented by wholesale distributors in forward distribution, they also have developed and implemented automated processes and invested in sophisticated equipment. As a result of such innovation, the cycle time to process returns in the reverse supply chain has been reduced while delivering more efficiencies to all stakeholders.

CORE SERVICES

Reverse logistics providers generally operate a single facility for receiving and processing unsaleable returns and recalled products. They offer the following core services to manufacturers, wholesale distributors and dispensers when managing product returns:

- Aggregating product and data;
- Evaluating product eligibility for credit by applying manufacturer returned goods policies and agreements;
- Systemically managing client-specific returned goods policy exceptions;
- Determining the value of returned products based on client pricing files and business rules;
- Receiving, handling, reporting and arranging for the disposition of all pharmaceutical products, including Scheduled II-V controlled substances;
- Handling products returned in non-standard selling units (partial containers and less than case, carton, outer-pack and loose units);
- Managing the information flow and requirements for product divestiture and recall notifications (which may differ from standard manufacturer returned goods policies);
- Determining if products are waste and, if hazardous, direct them for appropriate handling;
- Coordinating product disposition and disposal;
- Making return data available for client analysis;
- Providing online access to processing information, allowing clients to monitor or research return processing; and,
- Transmitting data that trading partners use to create financial transactions.

OTHER SERVICES

Some reverse logistics providers have expanded their service offerings and have developed other programs in response to client needs.

On-site Return Preparation
Hospital, long-term care and some independent retail pharmacies have requested assistance in managing the unsaleable return process. A field representative for the reverse logistics provider visits the dispenser on a periodic basis to prepare product returns. The field representative prepares and packages the returns for shipment to the return processing facility. In some instances, the field representative also may assist with identifying and removing unsaleable product from the shelf.

Recall Management and Administration
The reverse logistics provider, on behalf of the manufacturer or other recalling party, may distribute recall notifications. They then receive and process the returned product and conduct follow-up communications with the wholesale distributors and/or dispensers affected by the product recall.

Consumer Drug Take-Back Programs
An emerging service offering provided by some reverse logistics providers to retail dispensers are "drug take-back programs." These programs collect unused or unwanted pharmaceutical products from consumers through a kiosk or mail-back program and provide a safe and secure method for consumers to remove products from their homes. The needs for effective drug take-back programs and the challenges of administering them are discussed in the "Consumer Prescription Disposal" section.

OVERSIGHT

Reverse logistics providers operate in a highly regulated environment, ensuring the removal of unsaleable and recalled pharmaceutical products from the supply chain in a safe and secure manner. Reverse logistics providers are subject to multiple licensure and registration requirements which may include:

- **DEA registration:**
  - The requirements for controlled substance handling, storage security and reporting are similar to those required of wholesale distributors.

- **State licensure/registration:**
  - The provider must be licensed in the state in which the return processing facility is located; and,
  - Depending on state requirements, the provider also must register or become licensed by state regulatory authorities[15] in states from which their clients send products.

Reverse logistics providers are subject to periodic federal and state inspections under the DEA, the Department of Transportation (DOT) and state regulatory authorities. They also may obtain independent operational audits that certify the suitability of their financial reporting and internal controls.

15- In most instances, the licensing regulatory authority is the state's Board of Pharmacy.

REVERSE DISTRIBUTION PROCESSES

This section describes product returns from the wholesale distributor to the manufacturer, as well as returns from dispenser to wholesale distributor. Due to the similarity in processes and timing of communication to the shipper, process descriptions for delivery damages and mis-shipments are combined.

DELIVERY DAMAGES AND MIS-SHIPMENTS

RETURNS TO MANUFACTURERS

Manufacturer policies typically require wholesale distributors and self-distributors to notify companies within specified time periods upon receipt for an overage, damaged product and concealed product damages that the wholesale distributor or self-distributor elects to return.[16] Concealed damages may be discovered days or weeks later, when a full case or pallet of product is broken down into smaller units and there is a problem with an individual unit or units, such as smudged labeling or damaged containers. Although manufacturers' policies for notification timeframes and return processes may differ for damaged and mis-shipped product that the recipient elects to return, the manufacturer's typical process generally requires recipients to request a Return Authorization (RA) from the manufacturer's customer service department. The RA request process varies by manufacturer but typically includes the identification of product, quantity and reason for the return. Once the manufacturer authorizes the return, the recipient ships the product to that manufacturer's facility, manufacturer's 3PL or their reverse logistics provider.

RETURNS TO WHOLESALE DISTRIBUTORS

Wholesale distributor returns policies generally require notification by the dispenser within specified time periods after receipt of any mis-shipped product that the dispenser elects to return or of any damaged product. Wholesale distributors' policies for notification timeframes and return processes may differ for damaged and mis-shipped product. The wholesale distributor's typical process requires the dispenser to request an RA from the wholesale distributor's customer service department or to initiate an electronic request through the wholesale distributor's online ordering system. The RA request process varies by wholesale distributor but typically includes the identification of product, quantity and reason for the return. The wholesale distributor reviews the RA request and either authorizes the returning party to ship the product back, or denies it, typically providing an explanation for the denial. Once the wholesale distributor authorizes the return, the returning party ships the product to that wholesale distributor's facility and includes a copy of the RA document with the shipment. Upon receipt of the returned product, the wholesale distributor will determine if the product meets requirements to restock the product for sale or deem the product unsaleable.

16- Concealed damage is damage that is not noticeable or apparent at time of delivery and not necessarily indicative of intentional concealment.

SALEABLE RETURNS

RETURNS TO MANUFACTURERS

Generally, manufacturers do not accept saleable product returns. Once product has left their control, most manufacturers do not accept returns of prescription product back into their distribution facilities. In rare situations, a manufacturer may accept the return of full-case or carton product contingent upon the wholesale distributor or self-distributor completing a form attesting that the product has been handled and stored under proper conditions.

RETURNS TO WHOLESALE DISTRIBUTORS

Most dispensers have an opportunity to return unused, unopened product to the wholesale distributor[17] that sold it to them. Once received, the product is inspected and processed in accordance with applicable requirements, restocked where appropriate, and made available for sale.[18] In fact, more than 93 percent of all product returns to wholesale distributors is saleable.[19] Wholesale distributors are critical players in the reverse distribution process, handling equally as much or more product on a dollar basis than reverse logistics providers.

Figure 4: Saleable Prescription and Non-prescription Pharmaceutical Return Metrics from Dispensers to Wholesale Distributors

Annual $ Volume	Annual Units	% Sales ($)
$7 BN-$8 BN[1]	59 million[2]	2.0%[3]

Sources:
1. Calculation: [US Prescription Market (Figure 3)]*[Distributor portion of market (82.1%-93.79%)(Figure 3)]*[% Sales ($)].
2. Healthcare Distribution Alliance, "Healthcare Distribution Alliance (HDA) Saleable Returns Pilots Report" (Arlington, Healthcare Distribution Alliance, 2017), pg. 6.
3. HDA Research Foundation, *88th Edition HDA Factbook*, Table 47.

The return of saleable pharmaceutical product is an established and mature process that operates in a tightly controlled environment with integrated systems and process discipline. To reinforce the security of saleable product returns, wholesale distributors use dedicated equipment and segregate the returns process from other warehouse operations.

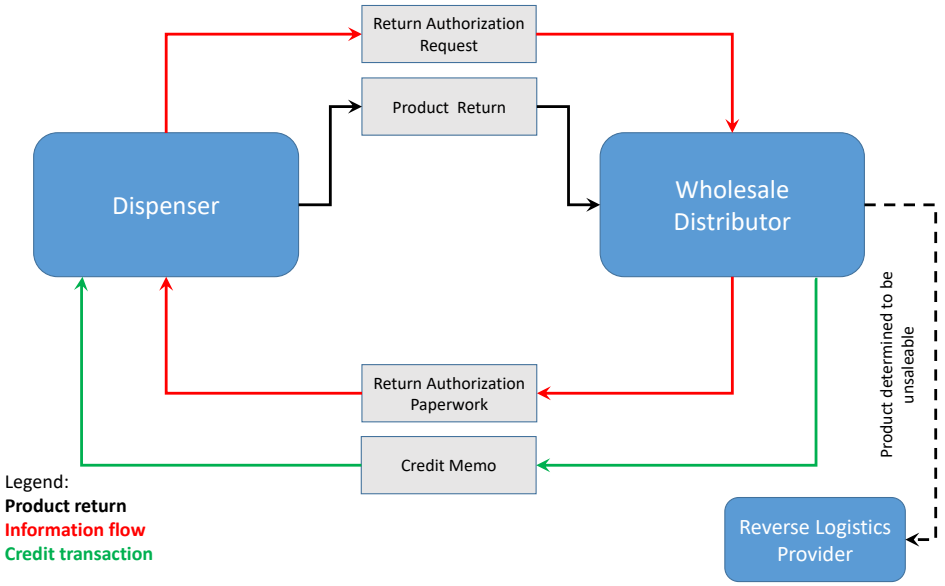
17- Self-distributing retail chains may handle saleable returns internally and through their wholesale distributor.

18- Effective in November of 2019, the DSCSA imposes additional requirements on a wholesale distributor before it may accept and resell a product received back from its dispenser customer. The wholesale distributor must be able to associate the product with certain transaction data associated with that product and verify that the product identifier on the product corresponds to the identifier the manufacturer assigned to the product. See § 582(c)(1)(B)(i)(II) and (g)(1)(F) of the federal Food, Drug and Cosmetic Act (FD&C Act), 21 U.S.C. § 360eee-1(c)(1)(B)(i)(II) and (g)(1)(F).

19- HDA Research Foundation, *87th Edition HDA Factbook: The Facts, Figures and Trends in Healthcare*, Table 49. The vast majority of products a wholesale distributor receives back from its dispenser customer are resaleable — a requirement often included in the wholesale distributor's supply contract with the dispenser. Occasionally, however, a dispenser does send unsaleable product back to its wholesale distributor, usually by mistake, or because products were damaged in transit. Also, wholesale distributors may be asked to accept recalled product back from their dispenser customers to facilitate an efficient recall.

The saleable return process from dispenser to wholesale distributor, depicted in Figure 5, highlights the product return, information flow and credit transaction that typically occur.

Figure 5: Saleable Return Process from Dispenser to Wholesale Distributor



As part of the saleable return process and industry best practices, dispensers generally:

- **Identify products eligible for return:**
  - Requirements and restrictions are illustrated in Figure 12 of the Appendix.
- **Initiate an RA request to a wholesale distributor:**
  - When returning Schedule II products, the dispenser also requests a completed DEA Form 222 from the wholesale distributor to meet DEA requirements.
- **Receive an RA from the wholesale distributor electronically or in hardcopy format:**
  - Prior to returning Schedule II products, dispensers also must receive the DEA-required Form 222 filled out by the wholesale distributor.
- **Prepare and package products for return:**
  - Fragile products are carefully wrapped to minimize breakage; and,
  - Products and RA usually are placed in a tote.
- **Sign the attestation (generally part of the RA document):**
  - The attestation notes that the products being returned were handled and maintained in proper storage conditions.
- **Ship the products approved for return:**
  - Typically, products are sent back on the next scheduled delivery truck.

Wholesale distributors stock and handle temperature-controlled products, controlled substances and product containing DOT-defined hazardous ingredients that in total comprise approximately 14 percent of the items they carry.[20] These products require special handling and may be eligible for return. In accordance with manufacturer product and regulatory requirements, wholesale distributor return processes may include:

- A separate RA;
- Use of specialized return containers, packaging or labeling; and,
- Use of an alternative transportation mode (small package carrier vs. delivery truck).

Additionally, temperature-controlled product returns may be restricted to specific shipment days to minimize transit time and maintain cold chain requirements.

Upon receipt at the wholesale distributor, all saleable product returns usually are processed in a dedicated area of the distribution center. The returned products received are reconciled with the RA and undergo a physical inspection to determine if they can be restocked for resale. During the physical inspection, a small percentage of products returned by a dispenser may be deemed unsaleable for failing to meet the wholesale distributor's saleable return requirements.[21] For example, if a product does not have the minimum required dating, has been opened or packaging has inadvertently been damaged during transit, the product would not be put back into inventory and distributed for sale. This product will then be moved to a secure location historically referred to as the "morgue" and now generally called "reclamation." This area is designated to temporarily hold unsaleable products that will be included in the wholesale distributor's unsaleable return process.

Once return processing is complete, a credit is issued according to the contractual terms between the dispenser and wholesale distributor.

THE VALUE OF THE SALEABLE RETURN PROCESS

Wholesale distributors play a critical role in the reverse distribution process by providing and administering saleable returns processes. While dispensers may use a variety of internal processes and programs to improve inventory productivity, dispensers will always need a reliable and efficient process to help them manage excess and non-productive inventory. With the current trend for some dispensers to move away from the self-distribution of pharmaceutical products to a direct store delivery model, an efficient and productive saleable return process managed by wholesale distributors remains critical.

20- HDA Research Foundation, *88th Edition HDA Factbook: The Facts, Figures and Trends in Healthcare*, Table 54.

21- HDA Research Foundation, *88th Edition HDA Factbook: The Facts, Figures and Trends in Healthcare*, Table 50.

Both the manufacturer and dispenser benefit greatly from the wholesale distributor saleable returns service offering as this process:

- Helps ensure product integrity and legitimacy;
- Improves product availability;
- Improves dispenser inventory productivity by facilitating the redeployment of excess inventory;
- Mitigates financial losses that would be otherwise incurred by the dispenser if the product could not be returned and becomes unsaleable;
- Is automated, efficient and cost-effective;
- Avoids unnecessary logistical and administrative costs; and,
- Reduces the volume of waste generated by the supply chain.

UNSALEABLE RETURNS

Figure 6: Unsaleable Prescription and Non-Prescription Pharmaceutical Return Metrics

Annual $ Volume	Annual Units	% Sales ($)
$6 BN-$8 BN[1]	**60-80 million**[2]	**1.5% to 2%**[3]

Sources:
1. Calculation: * [US Prescription Market (Figure 3)] *[% Sales ($)] * [Unsaleable portion of returns to manufacturer].
(Center for Healthcare Supply Chain Research, *2011–2012 HDMA Factbook*, Table 82, excluding recall, mis-ship and overstock returns)].
2. Calculation: [Annual $ Volume]/[Average unit cost of unsaleable product (Kindler & Crimmins proprietary information)].
3. Rate based on interviews and project team experience Calculation: [% Sales ($)] * [US Prescription Market (Figure 3)] * [Unsaleable portion of returns to manufacturer (Center for Healthcare Supply Chain Research, *2011–2012 HDMA Factbook*, Table 82, excluding recall, mis-ship, and overstock returns)].

Dispensers and wholesale distributors need a reverse distribution process to remove unsaleable products from the supply chain in an effective, reliable and secure manner. Unsaleable returns are processed in accordance with business rules established between trading partners and manufacturer return policies.[22] This helps to ensure the proper dispositioning of product and to identify products that may be eligible for reimbursement.

22- Business rules contain the basic information needed to handle returns and includes return valuation methodology, processing and invoicing frequency and returned goods policy exceptions, if any.

Most manufacturer return policies typically contain the following elements[23]:

- Return procedures;
- Payment methods;
- Definitions of credit value based on return entity;
- Product credit eligibility requirements, including:
    - Expiration/dating parameters;
    - Treatment of partial vs. full containers;
    - Product packaging requirements (e.g., returned in original manufacturer container, repackaged, or pharmacy vial);
    - Lot number and expiration date parameters; and,
- Policies specific to particular drugs and exceptions to general eligibility requirements.

Reverse logistics providers play a critical role by managing and applying numerous and varied manufacturer return policies, assessing whether credit may be due from the manufacturer and managing the proper dispositioning of products. Additionally, a few states[24] have statutes, regulations or policies that may conflict with manufacturers' returned goods policies, further adding costs and complexity to the credit eligibility determination process.

Reverse logistics providers have made significant investments to develop systems that manage and administer thousands of data records and policies for their clients. Data elements managed by reverse logistics providers may include:

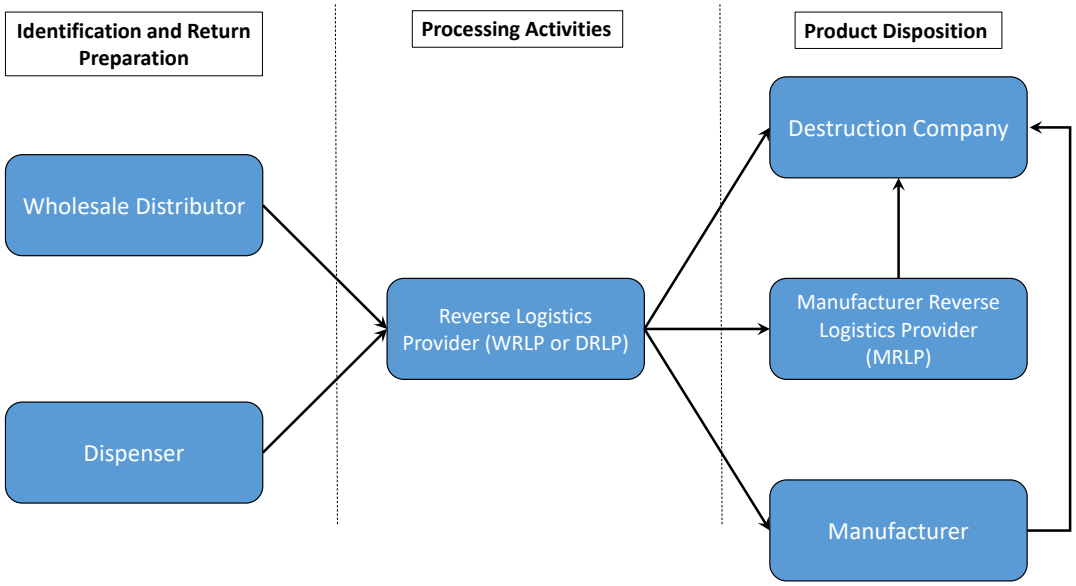
- Product detail (NDC, package size, package quantity, descriptions, etc.);
- Dispenser and wholesale distributor location information and customer identifiers;
- Dispenser and wholesale distributor DEA registration numbers and state licensure numbers;
- Wholesale distributor customer and vendor numbers unique to each wholesale distributor and/or dispenser;
- Manufacturer product notifications including product divestitures, returned goods policies and recalled products;
- NDC-specific product valuation by client; and,
- Client-specific exceptions for returned goods policies and pricing by NDC.

The unsaleable return processes detailed in the following sections include a description of the activities and processes used by each of the stakeholders. The physical flow of unsaleable prescription pharmaceutical products is illustrated in Figure 7. In addition to the physical flow of product, a large amount of information is passed between trading partners throughout the return process. This information flow is illustrated in Figure 8.

23- Based on research team's industry experience.

24- Specifically, Georgia, North Carolina and Mississippi.

Figure 7: Unsaleable Prescription Pharmaceutical Product Physical Flow



PRESCRIPTION PHARMACEUTICAL IDENTIFICATION AND RETURN PREPARATION

Dispensers (and, in some instances, reverse logistics provider field representatives) identify unsaleable product by visually inspecting on-hand inventory.[25] Dispensers pull inventory and initiate returns based on internal policies and schedules. Because numerous retail prescriptions are filled for a 90-day supply, many dispensers consider products with fewer than 90 days remaining prior to the product expiration date (referred to as "dating") as being unsaleable. Once inventory is identified as unsaleable, it is removed from the shelf and prepared and packaged for return to the reverse logistics provider (Figure 7).

Many dispensers prepare an inventory listing of the products being returned using an online return system portal developed and provided by the Wholesale Distributor's Reverse Logistics Provider (WRLP) or the Dispenser's Reverse Logistics Provider (DRLP). This inventory listing may be provided electronically to the reverse logistics provider as an advanced ship notification. Some larger retail chains use internally developed inventory management and return processing systems that may be integrated with their reverse logistics provider.

Wholesale distributors also pull inventory and initiate returns based on internal policies and schedules.[26] Due to various customer agreements, wholesale distributors generally pull product from saleable inventory six months prior to expiration and move it to the reclamation area. This is typically a separate and segregated area in the facility designated to hold potential product returns. In addition to creating this inventory list, product returns from dispensers deemed to be unsaleable[27] are prepared and packaged for shipment to the reverse logistics provider. Wholesale distributors generally provide their reverse logistics provider with an advanced shipment notification representing the unsaleable products removed from inventory.

25- There are other inventory service companies that offer similar services to assist the dispenser with identifying and preparing unsaleable product for return; these companies may be referred to as "shelf sweepers." However, they do not meet the definition of a reverse logistics provider for the purposes of this report.

26- A very small percentage of wholesale distributor unsaleable product returns may be shipped directly to the manufacturer or their reverse logistics provider.

27- As discussed previously in footnote 22, a small of all returns to wholesale distributors are unsaleable.

Damaged products represent a very small percent of the amount of total unsaleable products generated by both the wholesale distributor and dispenser.[28] For wholesale distributors, products may be damaged during the normal distribution process or while in transit to dispensers. For dispensers, some product may be damaged upon receipt or while it is being held in the pharmacy.

Industry wide, approximately 80 percent of the units returned to reverse logistics providers originate from dispensers, while the remaining 20 percent is from wholesale distributors.[29] This ratio may vary significantly among reverse logistics providers based on their individual client mix.

PROCESSING ACTIVITIES

Receiving

In general, unsaleable product is shipped to the WRLP or DRLP for handling and inspection. Upon receipt at the facility, controlled substances are segregated in accordance with regulatory and business process requirements. Schedule II products are transferred into the Schedule II vault for holding pending further processing and Schedule III-V products are moved to a secured inventory holding area (sometimes referred to as the "cage") comparable to wholesale distributor security practices for forward distribution.

Usually, product returns are separated and stored by client while being held for further processing. Product generally is processed based on a mutually-agreed upon schedule between the client and reverse logistics provider or on a first-in, first-out basis.

Product Count and Inspection

All products are identified, counted and undergo a physical inspection to determine product condition. As processing occurs, product may be segregated by wholesale distributor, dispenser, manufacturer and/or disposition. Specific data elements captured during this initial handling may include:

- Returning entity;
- Quantity, lot and expiration date by NDC;
- Unsealed or partial containers;
- Product packaging (original, repackaged or prescription vial);
- Product in original packaging with a patient prescription label affixed to it[30]; and,
- Product eligible for manufacturer credit.

Controlled substance returns are processed in a separate and secure area and follow the processing activities similar to those of non-controlled substances. Schedule II products are reconciled to the DEA Form 222 submitted by the returning wholesale distributor or dispenser. Generally, discrepancies between DEA Form 222 and physical product received are communicated to the returning entity for research and resolution. Additionally, any significant discrepancy between the quantity reported as returned (via the inventory listing or packing list) and the actual quantity counted by the reverse logistics provider must be reported to the DEA using Form 106.[31]

28- Center for Healthcare Supply Chain Research, *2011–2012 HDMA Factbook: The Facts, Figures and Trends in Healthcare* (Arlington, Center for Healthcare Supply Chain Research, 2011), Table 82.

29- 2017 survey of reverse logistics providers.

30- Prescription filled but not sold to/picked up by the patient and has never left pharmacy.

31- U.S. Drug Enforcement Administration, "Theft or Loss of Controlled Substances- DEA Form 106," https://www.deadiversion.usdoj.gov/21cfr_reports/theft/.

Credit Eligibility

Generally, credit eligibility is initially determined based on the information captured as the unsaleable product is processed by the DRLP or WRLP at their warehouse facility. Dispensers and wholesale distributors generally require their DRLP or WRLP to provide them with a preliminary estimate of the value of the unsaleable products that meet manufacturers' returned goods policies and may be eligible for credit. This is commonly referred to as Estimated Return Value (ERV). ERV is based on the quantities of credit eligible product physically counted by the reverse logistics provider and the estimated unit cost. [32] It is used by dispensers and wholesale distributors for inventory accounting and accounts receivable administration (Figure 8).

Sometimes product is returned too soon to be eligible for manufacturer credit. For example, dispenser and wholesale distributor inventory management practices may result in product being identified and returned as unsaleable before it is eligible for credit per the manufacturer dating parameters. If all other manufacturer product eligibility criteria are met during the initial processing, the product may be segregated and held by the DRLP or WRLP for future processing once the product falls within the manufacturer's dating eligibility requirements. This in-date inventory may also be referred to as "aging" or, more historically, as "morgue" inventory.

The percentage of unsaleable products eligible for credit varies greatly and is influenced by product mix, inventory management, automation and reverse distribution practices.[33] While wholesale distributors have a higher percentage of unsaleable product returns determined to be eligible for manufacturer credit (most such returns are unopened and unused), only 55 percent to 80 percent[34] of unsaleable dispenser returns may be eligible for credit (many such returns are opened or partial containers). Typically, even fewer unsaleable returns that originate from hospitals and long-term care facilities are eligible for credit.

Invoicing to Manufacturer

At the conclusion of the established processing schedule, an invoice (also referred to as return claim or debit memo) is generated by the WRLP or DRLP on behalf of the wholesale distributor or dispenser to the manufacturer that has financial responsibility for providing credit for the unsaleable product return. For nearly all dispensers and most wholesale distributors, these invoices are reported to manufacturers (or their reverse logistics provider) by their own reverse logistics provider (Figure 8, Step 3 or 4). Common invoice data elements include invoice number, invoice date, client name, client address, client DEA number (for controlled substances as required by DEA), NDC, product description, lot number, expiration date, product quantity and product return valuation. The product valuation process is managed by the WRLP or DRLP based on business rules established with their wholesale distributor or dispenser clients, including the unit cost or price file.

Product Disposition

Product disposition is determined by a manufacturer's return goods policy. In many instances, a manufacturer authorizes the WRLP or DRLP to arrange to have the product destroyed once the credit evaluation process, in-date inventory holding and other requirements are completed and further processing is no longer needed. Since most reverse logistics providers are not licensed destruction

32- Estimated unit cost may be based on manufacturer policy or the business rules established by wholesale distributor or dispenser.

33- Additional information can be found in the previously referenced HDMA (now HDA) report, *Understanding the Drivers of Expired Pharmaceutical Returns.*

34- 2017 survey of reverse logistics providers and Kindler & Crimmins proprietary information.

companies, this process is subcontracted to properly licensed destruction companies. Otherwise, the products must be sorted and held for return to the manufacturer or the manufacturer's reverse logistics provider (MRLP) (Figure 7) as many manufacturers wish to have direct control over the final accounting and dispositioning of their product.

Destruction

Product disposal processes and reporting requirements vary based on the type of pharmaceutical product authorized to be destroyed (for example, whether they are non-controlled substances, controlled substances or hazardous).

Reverse logistics providers pack and prepare non-controlled pharmaceutical products in accordance with applicable DOT regulations. Shipments to an appropriately licensed destruction company are regularly scheduled and coordinated by the reverse logistics provider. Upon receipt of shipment at the final destination, the destruction company verifies and destroys the product, and provides confirmation reporting to the reverse logistics provider. This reporting may be shared with manufacturers, wholesale distributors or dispensers.

In addition to the procedures described above and in accordance with DEA regulations, the destruction of controlled pharmaceutical products requires additional labor, security and documentation to help guard against diversion. DEA regulations require that two reverse logistics provider employees accompany shipments to the licensed destruction facility.[35] Additionally, the DEA requires the completion of a Form 41, which contains an inventory of the destroyed controlled substances, the method of destruction, the name of the destruction company and signatures of two employees witnessing the destruction.

Products identified as hazardous may require additional segregation to help ensure disposition to the appropriate waste stream, according to federal and state hazardous waste categories. An approved hazardous waste provider may be used to visit the reverse logistics provider's facility to segregate and/or verify waste streams. After product is segregated by waste stream, the reverse logistics provider or approved waste handler will coordinate the transportation to an approved hazardous waste facility.

Return to Manufacturer or the Manufacturer's Reverse Logistics Provider

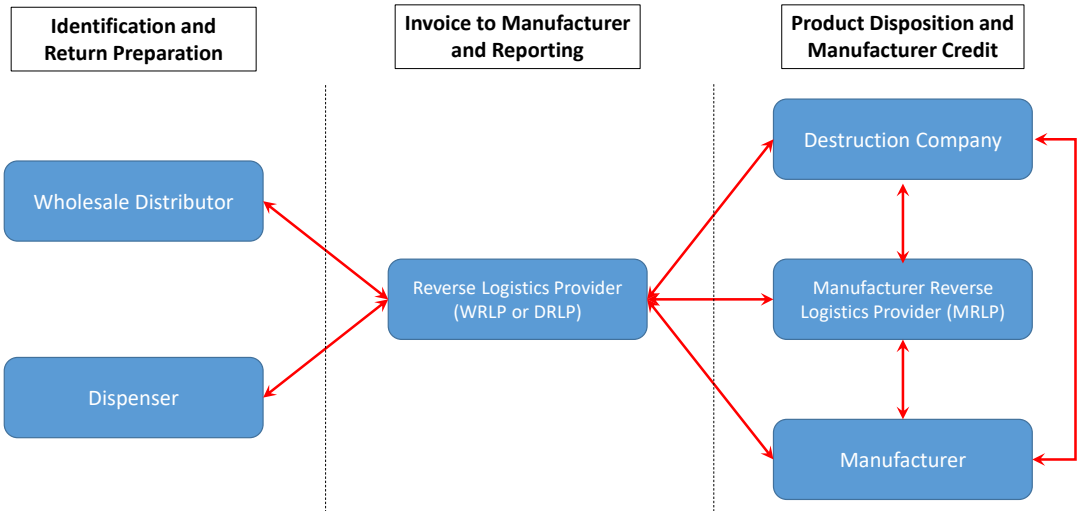
The manufacturer's returned goods policy may direct the WRLP or DRLP to request an RA from the manufacturer or the MRLP. Additionally, if the return shipment will contain Schedule II products, the WRLP or DRLP may need to request a completed DEA Form 222 from the manufacturer or the MRLP.

The WRLP or DRLP prepares and coordinates the product return shipment that includes a packing list or debit memo that contains an inventory of all products. If the return shipment contains Schedule II products, a completed Form 222 must be included with the shipment.

Upon receipt by the manufacturer or the MRLP, product is handled and generally will follow many of the steps previously performed by the original reverse logistics provider. The return will be inspected, recounted, reconciled to the RA (if required), stored and handled for final disposition following the procedures outlined in the "Destruction" section (Figure 7).

35- See 21 C.F.R. § 1317.95.

Figure 8: Unsaleable Pharmaceutical Product Information Flow



Reporting

As part of the returns process, reverse logistics providers generate and compile large volumes of data and produce a variety of analytical information and reporting for all stakeholders. Usually, this information is available electronically[36] and also may be available through online portals or websites developed by the reverse logistics provider. This self-service capability may enable clients to access data, perform research and prepare customized reporting.

The information provided to the wholesale distributors and dispensers may include return processing product detail, ERV, product not eligible for credit, manufacturer invoice and disposition details, including certificates of destruction, DEA Form 41 information and shipment tracking. This information may be used by multiple business groups, including inventory management, procurement, operations, accounting and quality assurance/audit. (Figure 8).

Manufacturers receive similar processing information from reverse logistics providers after the product has been received and processed (Figure 8). Product detail information is captured and transmitted to manufacturers in a mutually agreed upon electronic format and frequency. The manufacturer generally uploads this information into their financial system, which is used as the basis for the final manufacturer credit as discussed in the following section. The reporting information may be used by multiple business groups, including customer service, supply chain/customer operations, trade sales, accounting and quality assurance/audit. Figure 8 illustrates the flow of unsaleable product (or pharmaceutical) information.

36- Electronic formats may include standard EDI 180, Excel, CSV, text, etc.

MANUFACTURER CREDIT

The manufacturer (or the MRLP using business rules provided by the manufacturer) is responsible for making the final determination of the actual amount of credit due for all product returns. The evaluation is based on their returned goods policy, client agreements, legal requirements and the processing data provided by the reverse logistics providers (or warehouse management systems for those manufacturers processing their own returns; Figure 8). The credit amount may be based on the original acquisition cost, current or contract cost, or the cost minus a discount. Manufacturers may calculate the credit value internally or request their reverse logistics provider to perform this function.

Credit information is accumulated into a credit memo document, the formatting, content and delivery of which varies greatly by manufacturer. The credit memo detail may contain data elements similar to those included on the return invoice, however, it may omit products determined to be ineligible for credit. Since the Electronic Data Interchange (EDI) credit memo report format (EDI 812) is not widely used to transmit product information electronically among all trading partners, the credit memo is usually provided in a paper-based or PDF format and may be mailed or emailed.

For product returns initiated by the wholesale distributor, the final step in the credit process occurs when the manufacturer credit is issued directly to the wholesale distributor, and that credit is usually posted as an offset against future payments to the manufacturer.

For returns initiated by the dispenser, the credit amount and flow is based on the purchasing relationship between the manufacturer and the dispenser. If the dispenser has a direct purchasing relationship with the manufacturer, the total amount of the manufacturer's credit flows directly to the dispenser, and the dispenser applies the credit as an offset against future payments to the manufacturer. In some instances, the manufacturer's credit will be in the form of a check.

More typically, dispensers do not have a direct purchasing relationship with the manufacturer. In these instances, there are several different methods dispensers use to manage the unsaleable return credit process. Although the mechanics of each program vary, the dispenser will generally employ either the wholesale distributor or the reverse logistics provider to facilitate the credit and collection process. The actual credit amount issued to the dispenser is based on contractual arrangements between the dispenser and wholesale distributor and potentially the reverse logistics provider. Regardless of the program type, the physical flow of the product return process is the same.

NON-PRESCRIPTION (OVER-THE-COUNTER OR "OTC") PRODUCTS

Non-prescription (OTC) pharmaceutical product returns follow a similar flow. Some retail chain pharmacy dispensers and wholesale distributors, however, may contract with reverse logistics providers that use separate processing facilities for handling prescription and non-prescription returns. In some instances, the OTC product handled in these other facilities may be donated to charitable organizations at the direction the manufacturer. A chart comparing prescription and OTC unsaleable return processes can be found in Figure A4 of the Appendix.

THE VALUE OF THE UNSALEABLE RETURN PROCESS

Despite efforts by wholesale distributors and dispensers to manage inventory levels, inevitably, some inventory will become unsaleable and require a process to manage products at the end of their commercial life and remove them from the pharmaceutical supply chain safely and securely. Reverse logistics providers play a critical role in the supply chain by managing unsaleable product returns on behalf of wholesale distributors, dispensers and manufacturers.

The returns process:

- Provides a safe, secure and reliable method for removing unsaleable inventory and helps ensure that product is properly dispositioned;
- Provides expertise to manage and administer many manufacturers' returned goods policies with frequent policy changes;
- Identifies product that is eligible for manufacturer credit and assists with the credit and collection process (thereby mitigating financial risks for downstream trading partners);
- Removes costs from the supply chain by providing a more efficient and cost-effective return and disposition process;
- Minimizes the environmental impact of returns by helping to ensure all pharmaceutical waste is handled in an environmentally sound manner;
- Creates a standardized, centralized, controlled processing environment in a highly regulated pharmaceutical supply chain;
- Provides access to valuable data and analytics, which can be used by all stakeholders to proactively reduce unsaleable returns volume; and,
- Creates specialized providers for returns processing, which enables stakeholders to focus instead on core competencies, such as product manufacturing, distribution and patient care.

RETURNS IN A RECALL

Under the Federal Food, Drug and Cosmetic Act (FD&C Act), all pharmaceuticals must be safe and effective under their labeled conditions for use before they may be marketed in the U.S. The FDA and the manufacturer continually monitor products for any reports of problems with product quality, safety or efficacy. When a product violates the FD&C Act and the violation is serious enough that FDA would consider initiating a legal action, the product may be recalled from the market.[37] Products are recalled for many reasons, including labeling errors, contamination, product impurities or if a product fails to meet manufacturing specifications. Recalls are intended "to protect the public health and well-being from products that present a risk of injury or gross deception or are otherwise defective."[38] Pharmaceutical manufacturers may discover a product problem and voluntarily initiate a recall.[39] FDA may request that a firm initiate a recall when it has determined that a product presents a risk of illness, injury or gross

37- FDA provides guidance recall procedures in 21 C.F.R. Part 7, Subpart C; 21 C.F.R. § 7.3(g) (definition of recall).

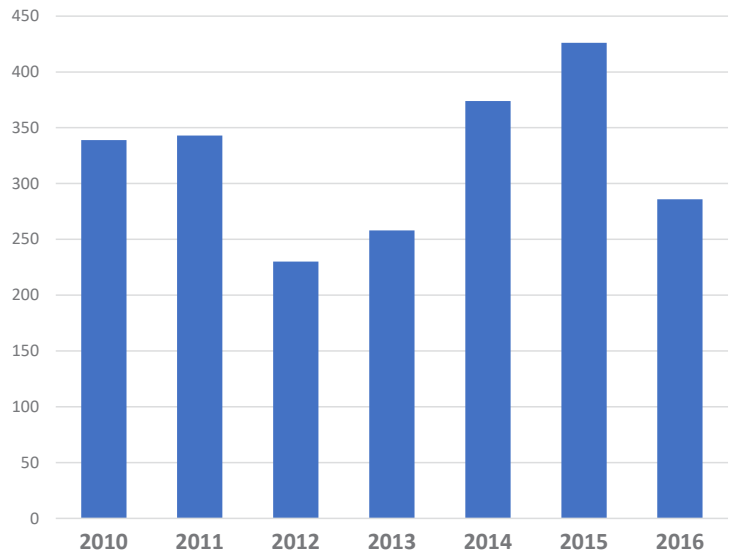
38- 21 C.F.R. § 7.40(a).

39- 21 C.F.R. § 7.46 (procedures for firm-initiated recall).

deception; the firm has not initiated a recall; and FDA action is necessary to protect public health and welfare.[40] The severity of the health risk will determine the type of recall and how far into the distribution chain it goes, including down to the wholesaler, dispenser or even patient level.

Both prescription and non-prescription pharmaceutical products can be recalled. The frequency of recalls varies significantly by year and the associated return volume also may vary substantially. For example, the annual number of recalled events attributed to prescription products had increased by 85 percent between 2012 and 2015, before decreasing in 2016 (Figure 9).

Figure 9: Number of Prescription Pharmaceutical Recall Events 2010–2016



Sources:
2010: Center for Healthcare Supply Chain Research, *2011–2012 HDMA Factbook,* Table 83.
2011–2012: Center for Healthcare Supply Chain Research, *2013–2014 HDMA Factbook: The Facts Figures & Trends in Healthcare,* Table 51.
2013–2015: HDA Research Foundation, *87th Edition HDA Factbook,* Table 52.
2016: HDA Research Foundation, *88th Edition HDA Factbook,* Table 51.

As part of the product recall process, manufacturers are responsible for providing the FDA with information about the product being recalled, the reason for the recall, a hazard assessment, the expected volume of recalled product, the distribution pattern and the recall strategy. The recall strategy also includes customer disposition instructions for the recalled product, how the return process will work and information about the recall's effectiveness that will be reported back to FDA in periodic status reports.[41]

Typically, manufacturers establish contractual arrangements with the MRLP or another reverse logistics provider (recall provider) to assist with prescription drug recalls (Figure 10). The reverse logistics provider may perform such services as distributing the multiple manufacturer recall notifications, receiving the returned product, processing the product, conducting follow-up communications with the wholesale distributors and/or dispensers affected by the product recall, and reporting information about the recall to FDA, including the number of products returned and the quantity of products accounted for.

40- 21 C.F.R. § 7.45 (procedures for FDA-requested recall). Most recalls are voluntary. FDA's authority to mandate a recall is limited. See, e.g., § 423 of the FD&C Act, 21 U.S.C. § 350l (mandatory recall authority for misbranded or adulterated foods where the use of or exposure to such article will cause serious adverse health consequences or death to humans or animals).

41- See FDA "Guidance for Industry: Product Recalls, Including Removal and Corrections", last modified 8/22/14, https://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129259.htm. See also 21 C.F.R. § 7.53 regarding submission and content of recall status reports to FDA.

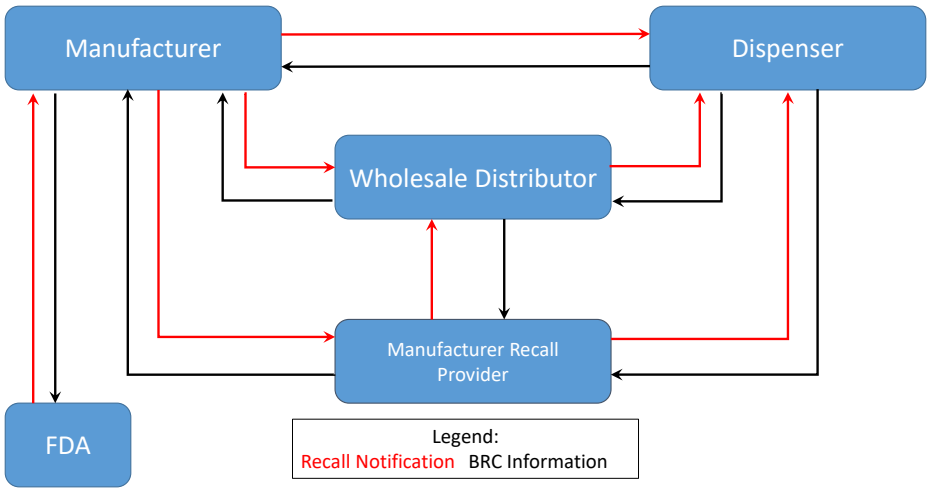
RECALL ADMINISTRATION

Recall Notification

The recalling party, usually the manufacturer, is responsible for notifying the supply chain stakeholders and possibly the public about a product recall. As part of the notification process, the recalling party will issue a "Recall Notification Letter" to various stakeholders described below. Generally, this recall communication comprises specific information about the product and the recall event,[42] including:

- How to identify the product subject to the recall;
- A description of the problem leading to the recall;
- The depth of the recall (i.e., who, within the supply chain, is requested to return the product):
  - Wholesale distributor or direct purchaser;
  - Dispenser or another indirect purchaser; or,
  - Consumer/patient level;
- Instructions on obtaining an RA and where to ship the product; and,
- A Business Response Card (BRC), which the recipient completes and returns to the manufacturer or recall provider.

Figure 10: Manufacturer Recall Notification and Business Response Card Flow



The manufacturer is required to notify their wholesale distributors and other direct purchasers of a recall. Depending on the depth of the recall, the manufacturer may require a sub-recall notification to entities that may have purchased product directly from the wholesale distributor. Manufacturers may request the wholesale distributor to communicate the sub-recall notification to dispensers or may request a list of customers potentially impacted by the recall from the wholesale distributor. The manufacturer may use the sales history to conduct the recall notification, outsource the notification to their recall provider or a combination of all methods. In the rare occurrence of a recall impacting patients or consumers, the dispenser must notify their customers or patients that may have purchased or been previously dispensed the affected product. As noted above, the manufacturer may arrange to have its MRLP conduct any or all of the above steps on the manufacturer's behalf.

42- 21 C.F.R. § 7.49.

Business Response Card

The Business Response Card (BRC) is a critical component of the recall notification packet. Upon receiving the recall communication, the recipient should review its inventory. The recipient then indicates on the BRC how much recalled product it has, if any, and returns the BRC to the recalling party or the recall provider acting on its behalf. The BRC provides the manufacturer and recall provider an early notification of the potential amount of recalled product in the market that is expected to be returned for proper processing and disposition.

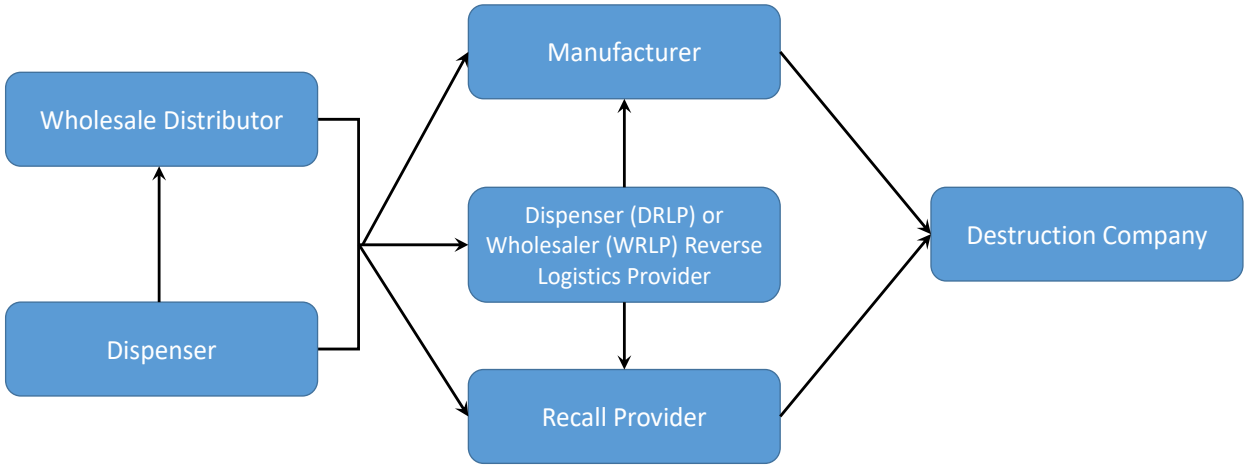
The manufacturer or recall provider is responsible for obtaining responses from dispensers and wholesale distributors achieving a sufficient positive response rate for the manufacturer and FDA monitoring the recall event. Therefore, the manufacturer or recall provider may initiate multiple communications by U.S. mail, a parcel carrier, fax and phone calls to the non-respondents. The communication methods and follow up conducted by the manufacturer or recall provider on the BRC is included in the recall strategy developed by the manufacturer and reviewed by FDA in order to support achievement of an acceptable response rate.

The recall provider must make this information readily available and coordinate with the manufacturer's quality assurance groups overseeing the overall recall event to facilitate the manufacturer's interactions with the FDA.

RECALL PRODUCT FLOW

The physical movement of recalled product from wholesale distributors and dispensers to final disposition varies widely in the industry and is depicted in Figure 11. The product being processed by the reverse logistics providers for recalls is similar to unsaleable product returns in terms of the data elements captured and reported. However, the shipment of recalled products to the manufacturer or their recall provider may originate from more locations than unsaleable product returns.

Figure 11: Recall Product Flow



Upon receipt of the recall notification letter, the wholesale distributor or dispenser will begin executing the recall by inspecting their inventory, quarantining the impacted products, completing and returning the BRC and initiating the return if product is on hand.[43]

43- Wholesale distributors and dispensers also may share the recall notification letter information with their reverse logistics provider.

While wholesale distributors generally follow the manufacturer return instruction as detailed in the recall notification letter, dispensers may follow the manufacturer instructions or respond in other ways. They may return product to the wholesale distributor, or may opt to return the product to the DRLP for consolidation and processing. The wholesale distributor also may employ the WRLP for product sent to them by dispensers after the initial recall event. The DRLP or WRLP will then process the recalled product according to the recall instructions provided by the manufacturer. Ultimately, the recalled product must be shipped, received and processed by the manufacturer or MRLP. The consolidation of recalled product at a DRLP or WRLP may result in fewer recalled product shipments to the manufacturer or recall provider than if they had been shipped from each individual dispenser or wholesale distributor location. This consolidation may streamline recall processing, dispositioning and credit issuance. This seemingly minor difference in handling by the dispenser and wholesale distributor may impact the flow of information and the return credit process.

After processing, the recalled product may be segregated by recall event and held in a secured area by the manufacturer or recall provider. It may be necessary for product to be held for an extended period of time as the manufacturer and FDA manage and evaluate the overall recall event prior to determining appropriate final disposition (Figure 11).

Upon the satisfactory completion of all recall activity, including monitoring the quantity of product recovered and verifying final product disposition, the FDA will formally close the recall event, often in a response to a written request from the recalling firm.[44] The reporting and information flows for recalled product returns are very similar to the processes already discussed in the "Unsaleable Returns" section, including Figure 7.

MANUFACTURER RECALL CREDIT

The manufacturer recall credit issuance process generally follows the unsaleable credit process. However, the recall return process usually results in a significantly larger number of individual returns and corresponding manufacturer credit memos or checks.

THE VALUE OF THE RECALL RETURN PROCESS

Reverse logistics providers play a critical role in the recall process, and the value they provide is, in many cases, identical to that of the unsaleable process value previously illustrated. Additionally, reverse logistics providers:

- Offer a comprehensive, tested solution to the manufacturer managing a recall event, including notification, BRC response administration, product processing and reporting;
- Facilitate the product flow from wholesale distributor and dispensers that may consolidate product; and,
- Leverage existing infrastructure that is able to handle the influx of significant and unpredictable product volume.

44- 21 C.F.R. § 7.55 (termination of a recall).

CONSUMER PRESCRIPTION DISPOSAL

Drug take-back programs, events and solutions — implemented by both the public and commercial sectors — are designed to provide a safe and secure method for consumers to dispose of unused or unwanted prescriptions. Historically, consumers disposed of unused pharmaceutical products using methods that created environmental concerns when pharmaceutical ingredients were sent into the water supply. Additionally, the need to minimize pharmaceutical diversion created an incentive to find alternative solutions for safe and secure disposal.

Grants have been made available to non-profit and public service groups to develop and test programs and to educate the public on the issues surrounding improperly disposed pharmaceuticals. One such non-profit group, the Product Stewardship Institute (PSI),[45] educates stakeholders and works to identify alternative business models that provide for a more comprehensive and sustainable disposal solution.

In addition to the DEA, cities and counties may conduct periodic take-back days, through which the public can dispose of used or unwanted pharmaceutical products. Another solution offered includes the installation of permanent kiosks in police stations to accept pharmaceutical products with certain restrictions. A handful of cities and counties have passed legislation increasing public access to collection receptacles in retail pharmacies, hospitals and other healthcare facilities. The legislative actions generally require manufacturers to register in each jurisdiction, submit comprehensive stewardship plans that outline the program being implemented including periodic reporting and fund the operating expenses to support the take back program. Manufacturers have responded by creating a coalition to function as a single group and have contracted with an organization specifically created to administer the program and meet all statutory requirements.[46]

Commercial entities have developed solutions that are more heavily focused on responsible actions by consumers and dispensers. Some dispensers provide mail-back envelopes that consumers purchase to send their prescriptions directly to a waste disposal vendor. Others have purchased secured kiosks from reverse logistics providers or developed their own kiosk internally and offer these as disposal locations for their customers and patients. Products collected as part of these programs are not eligible for manufacturer credit, so reverse distribution processes focus on proper disposal.

45- Product Stewardship Institute (http://www.productstewardship.us/).

46- Med-Project (www.med-project.org) and Pharmaceutical Product Stewardship Work Group (http://members.ppswg.org/PPSWG_PORTAL/PublicHome.aspx?WebsiteKey=3c292ed3-6eb2-4ee4-92e3-a73aa66f5381&LoginRedirect=true&returnurl=%2f).

PROCESS ENHANCEMENT OPPORTUNITIES

Opportunities exist today for key stakeholders to enhance their current practices to reduce the quantity of returned products and bolster the efficiency and effectiveness of the reverse distribution supply chain.

DATA AND INFORMATION

Access to current and relevant industry-wide unsaleable returns volume information is very limited. An opportunity exists for trading partners to share more comprehensive returns data. This valuable information has the potential to be used for benchmarking, developing key metrics and identifying opportunities to remove duplicative or non-value-added costs.

INVENTORY MANAGEMENT

In addition to managing the physical inventory and disposal of unsaleable product returns, reverse logistics providers deliver valuable product analytics for all key stakeholders to help improve inventory management and unsaleable returns volume. A large percentage (20–25 percent) of dispenser inventory is non-productive and may be considered excess inventory. Manufacturers, wholesale distributors and dispensers could realize significant financial savings by collaboratively focusing on inventory management practices, improving inventory productivity and reducing unsaleable returns volume.

REDUNDANT HANDLING COSTS

Many unsaleable product returns are initially handled and counted at the source of the return (dispenser or wholesale distributor), by their reverse logistics provider (DRLP or WRLP) and by the manufacturer or the MRLP. In some instances, this potentially redundant handling may provide little additional value to the overall return process. Opportunities may exist to realize additional cost savings by eliminating these redundant processes and through the reduction of multiple handling that often occurs in the current processing environment. The estimated savings from the increased adoption of a streamlined processing model is estimated to be $15 million to $40 million annually.[47]

ELECTRONIC TRANSACTIONS AND COMMUNICATION

There is a low utilization of electronic data, which makes the debit memo and credit memo reconciliation process very challenging. The EDI 180 (debit memo) is widely used, however the EDI 812 (credit memo) adoption rate between trading partners is low. The electronic credit memo allows for the efficient completion of the product level credit reconciliation process. Increasing the use of EDI in returns management would increase the efficiency, improve the accuracy and enhance the overall reconciliation process.[48]

47- 2017 survey of reverse logistics providers and research team analysis.

48- HDA Guidelines can be found at https://www.hda.org/resources/edi-guidelines-for-180-and-812.

The saleable, unsaleable and recall return of Schedule II controlled substance products is currently a highly manual process, requiring the completion of a DEA Form 222. HDA has previously recommended that the DEA update the Controlled Substance Ordering System (CSOS) to allow wholesale distributors to submit orders electronically to dispensers for saleable returns and allow reverse logistics providers to submit orders to wholesale distributors and dispensers for unsaleable and recall returns.[49] Changing the automated CSOS process to allow for the handling of Schedule II products returns (which is widely adopted in forward distribution) will create a more automated and efficient process. This change will reduce costs and enhance shipping timeliness.

Manufacturer return-related communications most frequently include changes in a manufacturer's returned goods policies, product divestiture and asset purchase notifications, as well as product recall letters. The current communications process may not include all stakeholders, such as the reverse logistics providers. Refining manufacturer communications to include reverse logistics providers will help increase the accuracy of wholesale distributor and dispenser unsaleable product return debit memos, identify the correct manufacturer financially responsible for the return of the products and determine the correct disposition for the products.

Acquisition or purchase cost by lot number generally is not captured by wholesale distributors and dispensers. Therefore, the reverse logistics providers may use price files from the dispensers and wholesale distributors or may apply business rules that assign a value to each product that is used to generate the debit memo. Often this debit memo valuation differs from the actual price used by manufacturers to determine credit. Because of the variability in debit memo valuation and the lack of accessible acquisition or purchase cost information, many debit memos require reconciliation once the manufacturer credit information is provided. Enhancing the accuracy of the reverse logistics provider debit memo valuation process will benefit all stakeholders.

Increasing the use of electronic transactions and improving the overall communication process should reduce the overall cycle time required for the payment and reconciliation process.

49- August 14, 2017, letter from John M. Gray, President and CEO, HDA, to Robert Hinchman, Senior Counsel, Office of Legal Policy, U.S. Department of Justice.

CONCLUSION

There always will be a need for an efficient and cost-effective reverse distribution function to assist dispensers and wholesale distributors with managing excess inventory and providing a regulated, efficient process to safely and securely move (or remove) returned pharmaceutical products from the supply chain. Although there are clearly opportunities to reduce unnecessary and redundant costs, the current reverse distribution supply chain is effective. Annually, more than 120 million units with a product value of more than $13 billion flows through the reverse distribution process. However, the reverse distribution industry faces future uncertainty which may present challenges and obstacles.

Legislative and regulatory changes might negatively impact the wholesale distributor's ability to efficiently process saleable returns, and could have a detrimental impact by driving up the costs to administer the saleable return process. Changes to saleable returns processes likely would impact the volume of unsaleable returns. For example, the verification process and eventual unit-level traceability required by the DSCSA, will result in new business processes that could increase the number of unsaleable product returns. Even a small increase could add significant costs to the supply chain.

The absence of an efficient and cost-effective saleable return process likely would lead to increased levels of non-productive and excess inventory — which may ultimately result in higher levels of unsaleable product returns. Although it is not possible to quantify the potential impact on unsaleable returns volume with currently available data, a simple illustration of the economics underscores the potential incremental cost that might be incurred. Based on the current estimated annual unsaleable returns volume, even a modest 1 percent increase in return volume would be equivalent to $60 million to $80 million in additional annual product costs incurred by supply chain stakeholders (not including the additional costs associated with processing, handling and disposal).

While the implementation of unit-level traceability has presented significant challenges and changes to the industry, the use of standardized product identifiers, serialization of products and the possibility to link critical data elements may present opportunities to improve regulatory compliance and adherence. For example, stakeholders may be evaluating whether manufacturers will be able to identify, by individual product serial numbers, which wholesale distributors (or other entities) have received specific recalled product. It is hoped that this ability to better target recall efforts and associated communications will boost recall adherence and reduce unnecessary or additional labor costs.

There also may be business process improvement opportunities beyond regulatory compliance and adherence. A manufacturer that is able to maintain records linking individual, uniquely identified products with pricing information could create an infrastructure to more precisely account for the credit it ultimately issues for unsaleable returned products. Reverse logistics providers have the opportunity to use unique product identifiers to generate extensive data and information for manufacturers, but systems and processes will need to be designed properly so the information can be captured and presented in a useful and actionable format.

The impact of future regulatory or legislative changes may significantly impact future saleable and unsaleable product return models. Trading partners, regulatory entities and other stakeholders are encouraged to work together to ensure that new or amended requirements support and enhance the operation of the current model. This collaboration could help avoid business, statutory or regulatory disruptions that could impair the operation of the current model and the normal flow of product, which may have a dramatic and detrimental impact on the quantities and costs associated with the reverse distribution process.

APPENDIX

Figure A1: Dispenser Saleable Return Eligibility Requirements and Restrictions

COMMON PRODUCT ELIGIBILITY REQUIREMENTS AND RESTRICTIONS MAY INCLUDE:

ELIGIBLE FOR RETURN	NOT ELIGIBLE FOR RETURN	RETURN ELIGIBILITY MAY VARY BY WHOLESALE DISTRIBUTOR
Unopened, pristine condition	Opened or not in original container	Refrigerated product
Has minimum dating	Dispensed	Schedule II product
Purchased from wholesale distributor	Discontinued or no longer carried by wholesale distributor	
No markings or labels added to original package		

Figure A2: Forward and Reverse Distribution Comparison

Distribution Comparison

Forward		Reverse
Scheduled and predictable	ORDER PATTERN	Reactive and resource dependent
Ordered and shipped in standard buying and/or dispensing units (case, bottle, etc.)	PRODUCT QUANTITIES	May be returned in any quantity from standard unit to lowest individual unit (pill, syringe, etc.)
Standard and known-Manufacturer or 3PL, wholesale distributor, dispenser	CHAIN OF CUSTODY	May differ and include multiple reverse logistics companies
Utilization for product movement, inventory reports and transaction sets is very high	EDI	Utilization is generally low and electronic exchange of information varies widely in format and content
Agreed and contracted in advance	TERMS & CONDITIONS	Included in agreements, but are often translated and evaluated by a third party
Agreed upon prior to or at point of purchase, discrete, tracked by contracted parties	PRICE & REIMBURSEMENT	Saleable: Similar to forward distribution, easily verified Unsaleable: Frequently based on historical cost, often not available
Standardized discrepancy resolution process	PRICE/CREDIT DISCREPANICIES	Unsaleable credit discrepancy reconciliation is often a manual process
Order to delivery process can occur in less than 24 hours	TIMING	Process may occur several years after purchase
Usually resides in distribution/logistics area, but may vary by company	PROCESS MANAGEMENT	May reside in a variety of different functional areas
Integrated purchasing and warehouse management systems are common	SYSTEMS	Variety of proprietary systems, significant customization may be necessary

Figure A3: Saleable and Unsaleable Returns Comparison

Return Process Comparison

Saleable		Unsaleable
Often necessary for return process	ORIGINAL INVOICE	Generally not available and or necessary
Usually required before dispenser ships product back to wholesale distributor	RETURN AUTHORIZATION	Not generally needed for dispenser return to reverse logistics provider, may be required by manufacturer prior to shipment
Usually submitted electronically by dispenser to wholesale distributor	RETURN AUTHORIZATION REQUEST	Significant variability in request process for returns to manufacturer
Standard data elements defined by and agreed upon by trading partners	DATA EXCHANGE	Significant variability in data availability and means of exchange
Agreed and contracted in advance between dispenser and wholesale distributor	TERMS & CONDITIONS	May be included in agreements, but are often implemented and evaluated by a third party
Reimbursement rate is usually detailed in supply agreement	PRICE & REIMBURSEMENT	Correct reimbursement price is generally not able to be included on dispenser return invoice
Usually based on original invoice price less set fee, simplifies verification and reconciliation	PRICE/CREDIT DISCREPANICIES	Price discrepancies common due to variety of valuation methodologies
Identification of eligible product and return process can occur in less than 24 hours after initial receipt	IDENTIFICATION AND RETURN TIMING	Return process may occur several years after purchase due to expiration dating
Organizational structure clearly defined	PROCESS MANAGEMENT	Oversight may reside in a variety of different functional areas
Typically involves two: dispenser/ wholesale distributor or wholesale distributor/manufacturer	STAKEHOLDERS	Typically involves four: dispenser, wholesale distributor, reverse logistics provider and manufacturer

Figure A4: Prescription and OTC Return Comparison

Return Process Comparison

Prescription		Non-Prescription
Requires wholesale distributor approval	SALEABLE RETURN APPROVAL	Initiated by dispenser and can be impacted by merchandising decisions
Usually required by manufacturer prior to return to manufacturer or their reverse logistics provider	RETURN AUTHORIZATION	Usually not necessary
Usually subject to credit evaluation under manufacturer's return policy and ultimately incinerated	DISPOSITION	May be incinerated, disposed in landfill, donated or liquidated
Product handled in facilities meeting particular licensure/ registration requirements	RETURN PROCESSING FACILITY	May be handled in prescription return facilities, but may also be handled in less regulated facilities
Uncommon in national return policies, more common in recall returns	RETURN PROCESSING FEE	Industry guidelines exist and are an accepted industry practice
Uses actual or approximate acquisition or approximate price as determined by manufacturer	PRICE & REIMBURSEMENT	May be determined by wholesale distributor or dispenser using current cost or swell/adjustable rate allowance
Unsaleable credit discrepancy reconciliation is often manual and uses historical purchase price	PRICE/CREDIT DISCREPANICIES	Use current cost so there are fewer discrepancies
Issued by manufacturer with check or credit memo	UNSALEABLE CREDIT ISSUANCE	Deduction or manufacturer check or credit memo
Unusual	RETURN ALLOWANCE PROGRAMS	Extremely common as national policy
May be handled and independently counted by multiple companies	UNSALEABLE RETURN PROCESSING	Greater likelihood of single product count

GLOSSARY

Adjustable rate allowance: A monetary cap on the amount of credit a manufacturer will give to a distributor for unsaleable products; these caps may be adjusted, up or down, based on the manufacturer's own audit process and findings.

Branded pharmaceutical: A pharmaceutical marketed under a brand name.

Business Response Card (BRC): Included with a recall notification letter from the manufacturer notifying supply chain stakeholders of a recall event; a communication document that wholesale distributors and dispensers send to the manufacturer indicating their possession of the affected product in the notification letter.

Cage: A secured and segregated area in a warehouse facility to store products designated as Schedule III–V by DEA.

Controlled pharmaceutical: A pharmaceutical product that contains a controlled substance whose manufacture, possession or use is limited by the Controlled Substances Act. Pharmaceuticals and other substances that are considered controlled substances are classified into one of five categories:

- **Schedule I:** Pharmaceuticals with no currently accepted medical use and high potential for abuse;
- **Schedule II:** Pharmaceuticals with an accepted medial use and high potential for abuse; or,
- **Schedule III/IV/V:** Pharmaceuticals with an accepted medical use and lower potential for abuse.

Substances are placed in their respective schedules based on whether they have a currently accepted medical use in treatment in the United States, their relative abuse potential and likelihood of causing dependence when abused.

Controlled Substance Ordering System (CSOS): An electronic ordering system developed by the DEA and is used by wholesale distributors and dispensers for ordering Schedule II controlled pharmaceuticals; CSOS replaces the need for those placing schedule II product orders to manually submit the paper DEA 222 ordering form.

Credit memo: A document issued by the seller of goods or services detailing the amount owed to the original buyer for the product they are returning.

DEA: Drug Enforcement Administration; in the U.S., the DEA is the regulatory agency responsible for administration of the Controlled Substances Act.

DEA Form 106: The DEA form required to report a theft or significant loss of controlled substances.

DEA Form 222: The DEA form required to be completed when ordering or returning Schedule I or II controlled substances.

Direct purchasing account: A purchasing relationship in which the purchasing company sources product directly from the manufacturer.

DOT: Department of Transportation.

Electronic Data Interchange (EDI): Standardized electronic formats used in pharmaceutical distribution:

- **EDI 180:** Transaction set contains the return authorization and return notification; and,
- **EDI 812:** Transaction set containing electronic credit memo used to communicate the amount owed to the buyer.

EPA: Environmental Protection Agency.

FDA: Food and Drug Administration.

Generic pharmaceuticals: A prescription pharmaceutical that is equivalent to a brand name product in dosage form, strength, ingredients, route of administration, quality, performance and intended use.

Indirect purchasing account: A purchasing relationship in which the purchasing company sources product from a wholesale distributor and not directly from the manufacturer.

Invoice: A document containing a list of products; it often functions as the billing document for a return claim initiated by the returning entity or on behalf of the returning entity by reverse logistics providers that process returns and provided to manufacturers. May also be called "debit memo."

Loss of Exclusivity (LOE): The point at which a branded pharmaceutical's patents and any other marketing exclusivity expire and the product is faced with generic competition.

Mis-shipment: Product received differs from product ordered — can be quantity or item discrepancy. Also referred to as "mis-pick." Product the recipient does not want to keep is usually addressed through saleable return process.

National Drug Code (NDC): A universal product identifier for OTC and prescription pharmaceuticals in the U.S. The NDC is a three-segment,10-digit number that includes a labeler code (assigned by the FDA), as well as a self-assigned product code and a package code. In the U.S. the NDC is included on the prescription pharmaceutical package inserts and also usually visible on OTC and prescription pharmaceutical outer packages.

Non-controlled pharmaceutical: Prescription and non-prescription products that are not listed as controlled substances under or pursuant to the Controlled Substance Act.

Outsourcing: A practice used by companies to transfer portions of work or a process to an outside company; in reverse logistics, credit evaluation and other processes are often outsourced to third party companies that are called reverse logistics providers.

Price File: An electronic record containing the value to be assigned to specific products.

Primary wholesale distributor: Companies that purchase prescription and non-prescription pharmaceutical products directly from manufacturers, store inventory in their distribution facilities and sell and distribute those products to healthcare providers.

Processing: A business term used to describe the operational activities performed by the reverse logistics provider within their returns facility; activities include the receiving, counting and physical inspection of products.

Product identifier: A standardized graphic affixed by a manufacturer or repackager on individual prescription drug packages and homogenous cases that includes, in both human-readable form and on a machine-readable data carrier that conforms to the standards developed by a widely recognized international standards development organization, a unique standardized numerical identifier and the product's lot number and expiration date.

Recall: Per 21 C.F.R. § 7.3(g), a recall is a firm's removal or correction of a marketed product that the FDA considers to be in violation of the laws it administers and against which the agency would initiate legal action (e.g., seizure). Recall does not include a market withdrawal or a stock recovery.

Recall event: The activities related to a specific recall.

Return Authorization: The process of receiving advance approval to return products to the manufacturer or wholesale distributor.

Reverse logistics providers (RLP): Companies that receive unwanted, unusable or outdated pharmaceutical products, including controlled substances, for the purpose of returning them to the manufacturer or the manufacturer's agent for credit, or where necessary, processing them for disposition and/or disposal; also referred to as "reverse distributors" or "return processors."

Saleable: Pharmaceutical and OTC products available for sale and eligible to be dispensed or sold to patients or customers.

Self-distributor: For purposes of this report, refers to a company entity that receives pharmaceutical product and re-distributes that product to distribution facilities or dispenser locations within that company (retail pharmacy distribution centers that distribute to their commonly-owned chain drug stores are the most common example).

Shelf life: The period of time from the date of manufacture that a pharmaceutical product is expected to remain safe, pure and potent, and within its FDA-approved product specifications (if any) while stored under defined conditions.

Shelf sweeper: A person, service or company (not DEA licensed) that assists the dispenser with administering and preparing for return of unsaleable pharmaceutical products according to the manufacturer's returned goods policy.

Short-dated products: Pharmaceuticals that can still be sold or dispensed, but have less dating until expiration than what is commonly acceptable within established business practices or agreements.

Swell allowance: A fixed percentage invoice deduction intended to cover the costs of products that may be unsuitable for use upon arrival at the purchaser; it may be applied to all products invoiced by the manufacturer and delivered to the dispenser or wholesale distributor's warehouse.

Third-party logistics company (3PL): A company that may be contracted by manufacturers to perform specific forward distribution functions, such as receiving and storing product, fulfilling orders and shipping to customers, and managing payments. They do not own the product being handled and shipped.

Unsaleable: Refers to pharmaceutical and OTC products that are no longer available for sale or dispensed to patients; typically, they are segregated from saleable products and eventually removed from the supply chain.

Vault: A highly-secured, self-contained unit to store Schedule II products.

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