

**Healthcare Distribution Alliance (HDA)
Testimony
Connecticut Healthcare Cabinet
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Matthew J. DiLoreto, Vice President of State Government Affairs**

Introduction:

Good Morning. Thank you for the opportunity to participate in today's discussion. My name is Matthew DiLoreto and I am the Vice President of State Government Affairs for the Healthcare Distribution Alliance (HDA). HDA is based in Arlington, Virginia and represents the nation's primary pharmaceutical distributors. My role at HDA is to oversee the organization's state government affairs efforts, nationwide.

HDA members are the vital link between the pharmaceutical manufacturers and more than 200,000 pharmacies, hospitals, long-term care facilities, clinics and other healthcare provider settings. Since 1876, HDA has operated with the goal of helping our members navigate regulations and industry innovations to get the right medicines to the right patients, at the right time, safely and efficiently. Since the early days of the industry, distributor services have evolved into a technologically sophisticated, highly regulated distribution operation that provides healthcare settings with at least daily access to virtually any necessary drug or healthcare related product. However, the core function of the industry remains a simple one that must be remembered when any discussion surrounding the supply chain occurs – distributors purchase products (medications) from manufacturers, safely store them in warehousing facilities, fill pharmacy customer orders and ultimately ship them to the provider for dispensing to patients. The wholesale distributor industry is achieving this goal, and doing so successfully.

Prior to my role at HDA I held the position of Senior Director of Government Affairs at the National Community Pharmacists Association (NCPA) overseeing the national state government affairs efforts for the independent community pharmacy industry. Before that, I represented the Pennsylvania Pharmacists Association (PPA) in Harrisburg, Pennsylvania. I mention this background to summarize the fact that my entire government affairs career has focused on the pharmacy industry – and this remains an industry which one continues to learn something new about each day. HDA commends this panel for taking the necessary steps to educate itself on an extremely complex and often confusing supply chain. Bringing all members of the supply chain to the table for an open discussion is vital to ensure that appropriate policies are implemented.

Today I will provide an overview of how the primary wholesale distributor industry fits into the overall pharmaceutical supply chain. HDA represents 34 member companies ranging from large publicly traded corporations to smaller, independent distributors which often are regional in nature or focus on a specific customer base, such as the independent pharmacy. Each company and their business model is unique. Antitrust laws constrain HDA and its members from sharing information about individual business models and customer arrangements with each other or the organization. I must be clear that HDA cannot speak to the individual services specific companies may provide, the pricing involving such services, or to the contractual relationships such companies may have with other supply chain members. And frankly, as an HDA staffer, I simply do not have access to such information. Any questions about such specifics would need to be raised with individual companies. However, I hope the information I cover today will achieve this panel's objectives.

Role in the Supply Chain:

The U.S. healthcare supply chain is very complex, with over 200,000 provider ship-to locations (pharmacies, hospitals, long-term care facilities, etc.) which must be served in an efficient and secure manner, on a daily basis. These providers are served predominantly by 34 HDA primary distributors who operate out of approximately 203 warehouses across the nation. Our members purchase directly from authorized manufacturers --- a relatively small, but highly efficient and effective network. There is a public perception that pharmacies contact a manufacturer, order their needed products and ultimately dispense them to a patient. This is an inaccurate assumption. Due to the number of drug products currently on the market, and the number of worldwide manufacturer locations, this would be an extremely burdensome and next to impossible task from a logistics and administrative standpoint. Most pharmaceutical sales flow through wholesale distributors (93.79%), while less than 6% of pharmaceutical goods revenue flows directly from manufacturers to customersⁱ. In 2015, the top 25% of wholesalers purchased products from over 1,300 manufactures/suppliers eachⁱⁱ. Put simply, wholesale distributors stock product from many authorized manufacturers, and provide their customers with a “one stop shop” to acquire virtually any drug product, both prescription and over the counter, as well as medical devices and supplies. The service that wholesalers provide prevents their customers from having to invest in the infrastructure required to safely and efficiently store and manage massive quantities of products and medications. Instead, wholesalers provide such customers with daily access to such needed products.

Every day HDA members work literally around the clock to safely and efficiently ship 15 million healthcare products to pharmacies, hospitals and other healthcare providers in order to keep their shelves stocked with the medications and products necessary to treat and serve their patients. Distributors are unlike any other supply chain participants – their core business is not engaged in manufacturing, they do not prescribe medicines or dispense to patients, and most importantly for this discussion they do not set the “list price” of any medications. Their key role is a simple one --- serve as a conduit for medicines to travel from manufacturer to patient while making sure the supply chain is fully secure, functional, and as efficient as possible. In simple terms, primary distributors purchase pharmaceutical products from brand and generic manufacturers. They store, handle, pick, pack and ship those products, delivering them to virtually every pharmacy setting in the country.

In addition to managing warehouses and shipping pharmaceutical goods, wholesale distributors provide a wide array of supporting services that enable the pharmaceutical supply chain to function and deliver

significant value to manufacturers and healthcare providers — and ultimately to patients and consumers as well. Without these companies, each manufacturer would be responsible for ensuring patients get the medicines they need when they need them, employing substantial financial, logistical and staff resources at the company level to provide medicines and supplies to hundreds of thousands of pharmacies, hospitals and other healthcare providers. Without wholesale distributors, the supply chain would be much less efficient, less reliable and less secure, which could hinder the ability of patients to get the medicines they need in a timely fashion and add significant costs to our healthcare system. Pharmacies, hospitals and other healthcare providers place orders with distributors on a daily basis for the medicines, supplies, equipment they need. Without pharmaceutical distributors, healthcare providers would have to undertake the time-consuming process of placing individual orders with each and every manufacturer of a drug needed by the healthcare provider on a daily basis. Full-line wholesale distributors allow providers to place one order and get every single product they need shipped to them the following day. This just-in-time delivery saves pharmacies and hospitals millions of dollars annually by not having to carry extensive inventories or have large storage facilities — both of which would add significantly to their cost of operations.

Wholesale distributors focus significant resources on the safety and security of the supply chain. By working directly with manufacturers, wholesale distributors are able to ensure that they are purchasing only legitimate, FDA-approved medicines and to prevent the introduction of counterfeit medicines into the supply chain. They also maintain secure facilities that are federally inspected and approved. In the case of a drug recall, wholesale distributors assist manufacturers by collecting and returning recalled product in the pharmaceutical supply chain to the applicable manufacturer.

Wholesale distributors also provide numerous services to independent and small chain pharmacies by providing workable credit terms and information technology support to assist in the ordering and inventory management needs of these businesses.

Relationship with Manufacturers and Providers:

HDA understands that a primary objective of this group is to determine a wholesale distributor's impact on the pharmacy providers and the patients they serve, and to understand how primary wholesale distributors impact the ultimate price of medication to a citizen.

As mentioned earlier, due to anti-trust constraints HDA is precluded from being privy to, or providing a venue for any discussion about prices and/or the components of prices among individual members. As members, may not discuss pricing, pricing formulas, policies or the terms of their purchase and sales contracts in any HDA sponsored venue, the organization is unable to provide any comments or answer questions about specific drug product prices, classes of product, or negotiations that take place between member companies and their suppliers and/or customers. Put simply, HDA is precluded from having any knowledge of these topics.

Wholesale distributors typically purchase pharmaceuticals from manufacturers based on Wholesale Acquisition Cost ("WAC"), a measure reported by pharmaceutical manufacturers to various compendia such as Medi-Span and RedBook, which publish such prices. WAC represents the manufacturer's list price, which does not include prompt pay or other discounts, rebates or reductions in price as reported by pharmaceutical manufacturers. Each WAC is specific to the drug, strength, dosage form, package size, and manufacturer. A manufacturer choosing to increase the published WAC for a product drives

drug price increases for brand and generic drugs alike. When the WAC of a product is increased by a manufacturer, wholesaler distributors pay more to purchase the product and in turn downstream customers pay more to wholesaler distributors for such product. I also encourage all panel members to reference an excellent article published in October 3, 2016 by USA Today entitled “How Prescription Drug Middlemen Make Their Money.” This article included a graphic that is provided to you in each of your packets, and as an attachment to this testimony. The graphic demonstrates that from the overall cost of a \$250 drug, the wholesaler retained a net profit of \$2.50 --- the smallest profit margin in the entire drug supply chain.

Generally, wholesale distributors carry the products that pharmacy customers order. However, it should be noted that nothing requires a pharmaceutical manufacturer to sell a given product to a wholesale distributor. A manufacturer may elect not to sell to a distributor and there are many business reasons why this might occur, such as an exclusive distributor arrangement or a Risk Evaluation and Mitigation Strategies (REMS) program the manufacturer participates in as a condition of its FDA-approval for a given drug.

The primary wholesale distribution industry is an extremely high volume, but very low profit margin industry. In a recent study (2017) released by the Berkeley Research Group, it was concluded that the wholesaler profit on overall branded drug costs was just under one percent ⁱⁱⁱ. In 2015, the net profit of HDA members was approximately 1.4 percent on average^{iv}.

Although the primary products distributed by wholesale distributors are medications, it should be noted that HDA members do manage a wide range of healthcare related products and services. Also, as mentioned throughout this presentation, distributors provide many secondary services to the pharmacy provider community, but the core services are supply chain related – providing on-time and complete shipment of ordered products in a safe and efficient manner.

Also, traditional primary wholesale distributors serve a broad array of provider types; mostly retail and hospital setting, including chain pharmacy warehouses, mass merchandisers and food chains, and chain pharmacies (42.5%); hospitals, HMOs, clinics and nursing homes (22.1%); independent pharmacies (16.8%); mail order (15.7%). Specialty distributors (and specialty subsidiaries) serve other provider settings such as physician offices, home care, specialty pharmacy, and some retail pharmacy^v.

Business Model:

In terms of industry structure, between 2004 and 2008, the compensation model for branded and specialty pharmaceuticals shifted from a “buy and hold” (also known as “forward buy”) model to a “fee for service” compensation model. With the buy and hold model distributor profits were driven primarily by price appreciation – when pharmaceutical manufacturers raised prices, distributors would capture gains on on-hand inventory that they were storing. However, since the industry shift to a service-fee model, manufacturers pay distributors a fee for distribution and other ancillary services.

In exchange for the variety of distribution and logistics services wholesaler distributors provide to manufacturers, they charge manufacturers what are referred to as “bona fide service fees” for the provision of these services. These fees represent a fair market value for a bona fide, itemized service performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement.

The fee for service model has reduced demand volatility – aligning order patterns more closely to actual patient demand and eliminating artificial demand spikes which, under the old model had more potential to occur when distributors would make large inventory purchases, hypothetically at a lower rate for this example, in advance of price increases. The overall system is now more transparent, with a supply chain that operates more smoothly and predictably.

As noted previously, without HDA members, each manufacturer would be responsible for ensuring that patients get the medicines they need when they need them, employing substantial financial, logistical and staff resources at the company level to provide medicines and supplies to hundreds of thousands of pharmacies, hospitals and other healthcare provider settings. The entire wholesale distributor business model is built upon efficient movement of product, due to strategically located distribution centers. The Manufacturer marketplace is not designed, or currently equipped to function in this manner.

Other Wholesaler Services:

As previously mentioned, some primary wholesale distributors have evolved their business portfolio from simply managing warehouses and shipping goods. These distributors may also provide a wide array of supporting services that enable the pharmaceutical supply chain to function efficiently and safely, delivering significant value to manufacturers and healthcare providers — and therefore ultimately to patients and consumers.

Manufacturers choose to create partnerships with distributors to distribute product on their behalf, and help ensure that product is available and accessible to providers. Primary distributors offer manufacturers and other customers an array of distribution and adjacent supporting services which facilitate the product's route to market, enable and support the pharmaceutical company's commercialization strategy, ensure a smoothly running supply chain and allow pharmacy providers to function more effectively and purchase more wisely. Some examples of these services include:

- Receiving orders and shipping pharmaceutical products in a safe, efficient manner
- Inventory handling and inventory management programs
- Marketplace product analysis
- Durable Medical Equipment
- Health IT Resources
- Electronic Health Records
- Suspicious Order Monitoring
- Contracting Service Consulting
- Providing independent and small chain pharmacies workable credit terms
- Provider information technology support / ordering and inventory management

Manage chargeback systems that allow contractual discounts negotiated by and between institutional payers, pharmacies and other downstream customers and manufacturers to be realized by the without

requiring the customer to have a “in-house” process for seeking refunds or rebates. (Note: Distributors facilitate this process, they do not set the terms between the parties, nor are they aware of specific contract details).

Each of these offered additional services are determined by the primary wholesale distributor and the contracting relationship with their customers. The largest distributors often have additional niche services including: Oncology Management, Compounding, Syringe Operation.

Supply Chain Security

And finally, I would like to focus on supply chain security. HDA distributor members focus significant resources on the safety and security of the supply chain. HDA has worked for many years at the state and federal level to raise standards for wholesaler licensure and strengthen the security of the supply chain. In 2013, Congress enacted the Drug Supply Chain Security Act (Title II of the DQSA), which sets a framework for unit level traceability of medicines by 2023 – a law we strongly supported.

Working directly with manufacturers, primary wholesale distributors are able to ensure that they are purchasing only legitimate, FDA-approved medicines and to prevent the introduction of counterfeit medicines into the supply chain. They also maintain secure facilities that are both state and federally inspected and approved. In the case of a drug recall, wholesale distributors play an integral role by assisting manufacturers by collecting and returning recalled product in the pharmaceutical supply chain to the applicable manufacturer.

Conclusion

In conclusion, HDA greatly appreciates the opportunity to be involved in this discussion. We feel that Connecticut is taking an extremely important step to understanding a complex issue by bringing all supply chain partners “to the table” to openly discuss their role and influence in medication delivery. Primary wholesale distributors goal in that pharmaceutical supply chain is a simple one: wholesalers add efficiency, security and timely delivery of products so that providers can concentrate on patient care, and so that patients can have regular access to the medications they need. Wholesalers effectively achieve this goal while having limited influence on the overall cost of drugs. We hope to continue to be a resource for this panel as you move forward with any policy recommendations that come from these discussions.

ⁱ 87th Edition HDMA Factbook (2016-2017), Table 1, p.32 Understanding Pharmaceutical Distribution Presentation 2017

ⁱⁱ HDA Research Foundation, 87th Edition Factbook: The Facts, Figures and Trends in Healthcare"

ⁱⁱⁱ The Pharmaceutical Supply Chain: Gross Drug Expenditures Realized by Stakeholders; 2017; Table 2

http://www.thinkbrg.com/media/publication/863_Vandervelde_PhRMA-January-2017_WEB-FINAL.pdf

^{iv} 87th Edition HDMA Factbook (2016-2017), Table 1, p.32 Understanding Pharmaceutical Distribution Presentation 2017

^v 87th Edition HDMA Factbook (2016-2017), Table 1, p.32 Understanding Pharmaceutical Distribution Presentation 2017

Primary Pharmaceutical Distributors

PROVIDING A SMART, SECURE AND SOPHISTICATED SUPPLY CHAIN

Healthcare distribution has never been just about delivery. It's about getting the right medicines to the right patients at the right time, safely and efficiently. Every day, primary pharmaceutical distributors sustain a complex supply chain, serving as a vital link in the healthcare system between manufacturers and healthcare providers. The Healthcare Distribution Alliance's (HDA) members work around the clock to help deliver more than 15 million prescription medicines and healthcare products each business day to over 200,000 pharmacies, hospitals, long-term care facilities and clinics across the country to keep their shelves stocked with the medications and products that patients need every day.



DID YOU KNOW?

**NEARLY 94 PERCENT OF
PRESCRIPTION MEDICATIONS
SOLD IN THE UNITED STATES**
are delivered by the nation's primary
pharmaceutical distributors.

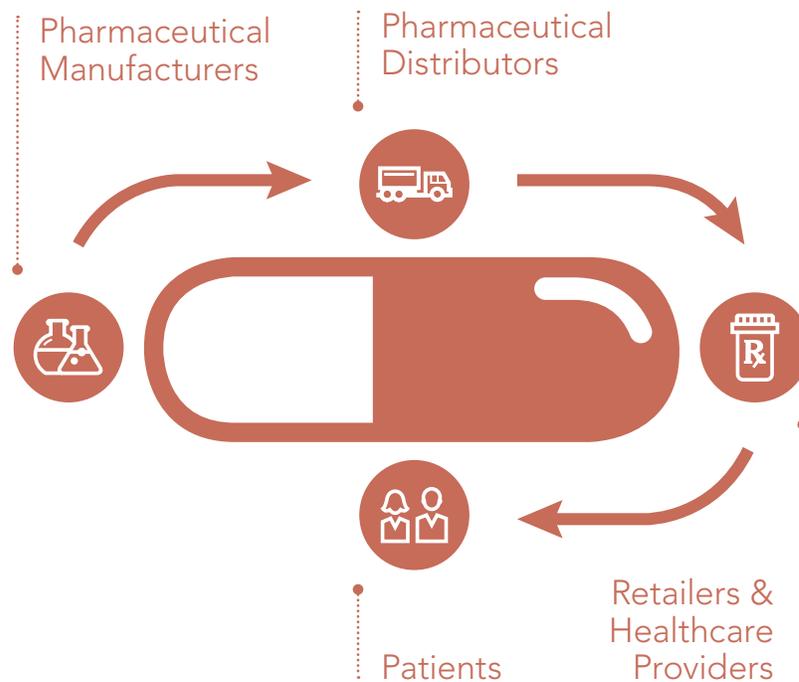
As the healthcare system rapidly changes, primary distributors are constantly envisioning new ways to move and secure the nation's medicines, all while protecting patient safety. HDA members are not simply distributors. They are technology innovators, information management experts, security specialists and efficiency professionals, whose expertise streamlines the supply chain to reduce costs and save the nation's healthcare system both time and money. With operations running around the clock, a typical distribution facility manages nearly 5,800 orders each day and can take orders made by 8:00 p.m. and deliver them to their end destination as soon as the next morning.

HOW IS IT DONE?

Primary distributors purchase prescription medicines and other medical products directly from manufacturers for storage in warehouses and distribution centers across the country. Healthcare providers place orders with distributors for the medicine and products they need, and the distributors process and deliver the orders daily. Without primary distributors acting as a vital link between manufacturers and healthcare providers to ensure patients get the medicines they need when they need them, manufacturers would spend a substantial amount of financial, logistical and staff resources on this task that could be used in other important areas. Thanks to distributors, the system is more efficient, reliable and secure.

NAVIGATING THE PHARMACEUTICAL PRODUCT PATH

Pharmaceuticals pass through a sophisticated, highly regulated supply chain working around the clock to safely and efficiently deliver medicines from manufacturers to thousands of pharmacies and healthcare providers — and ultimately, patients — across the country.



ABOUT THE HEALTHCARE DISTRIBUTION ALLIANCE

HDA represents primary pharmaceutical distributors — the vital link between the nation’s pharmaceutical manufacturers and more than 200,000 pharmacies, hospitals, long-term care facilities, clinics and others nationwide. Since 1876, HDA has helped members navigate regulations and innovations to get the right medicines to the right patients at the right time, safely and efficiently. The HDA Research Foundation, HDA’s nonprofit charitable foundation, serves the healthcare industry by providing research and education focused on priority healthcare supply chain issues.

The U.S. Pharmacy Distribution and Reimbursement System for Patient-Administered, Outpatient Prescription Drugs

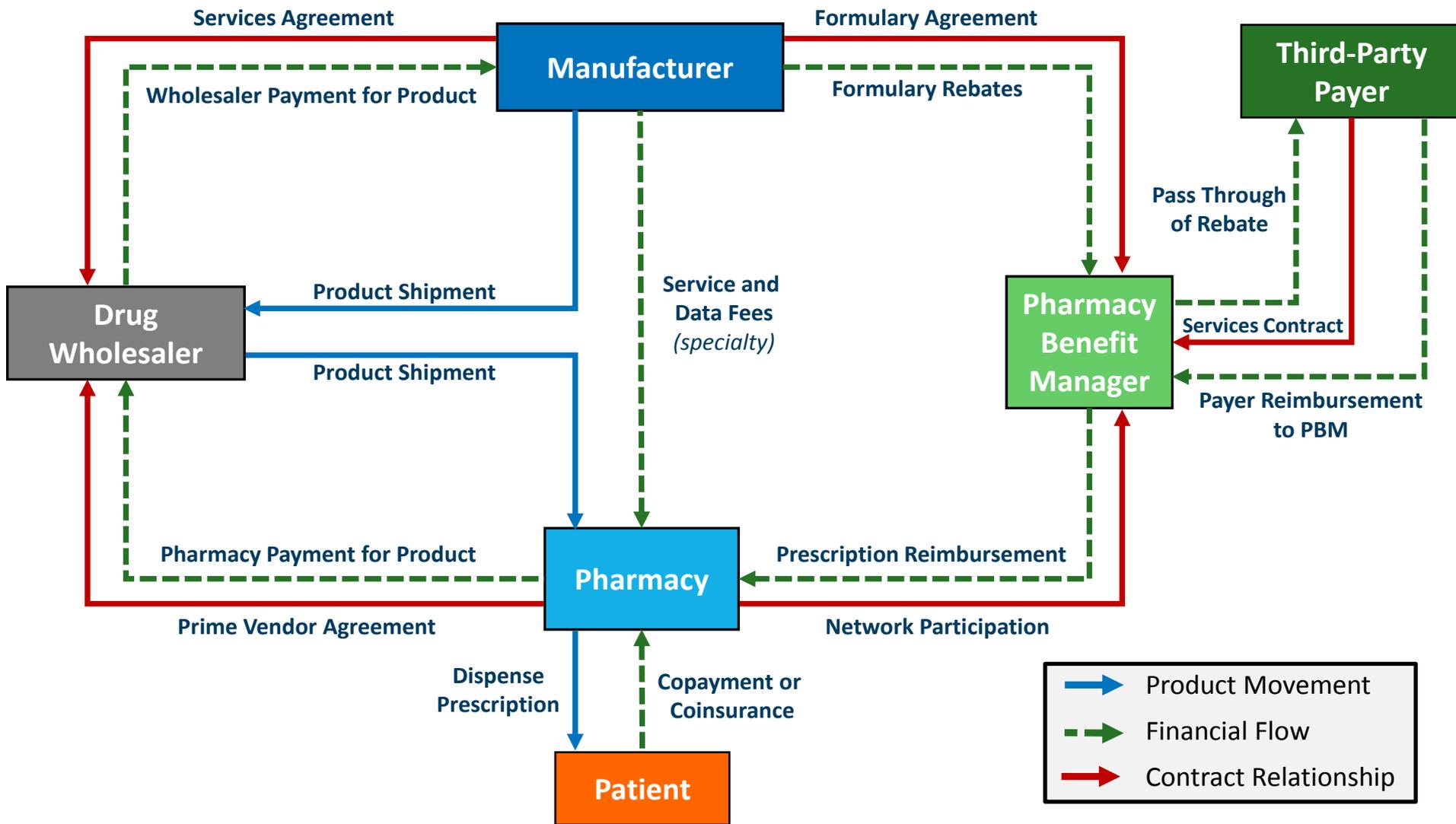
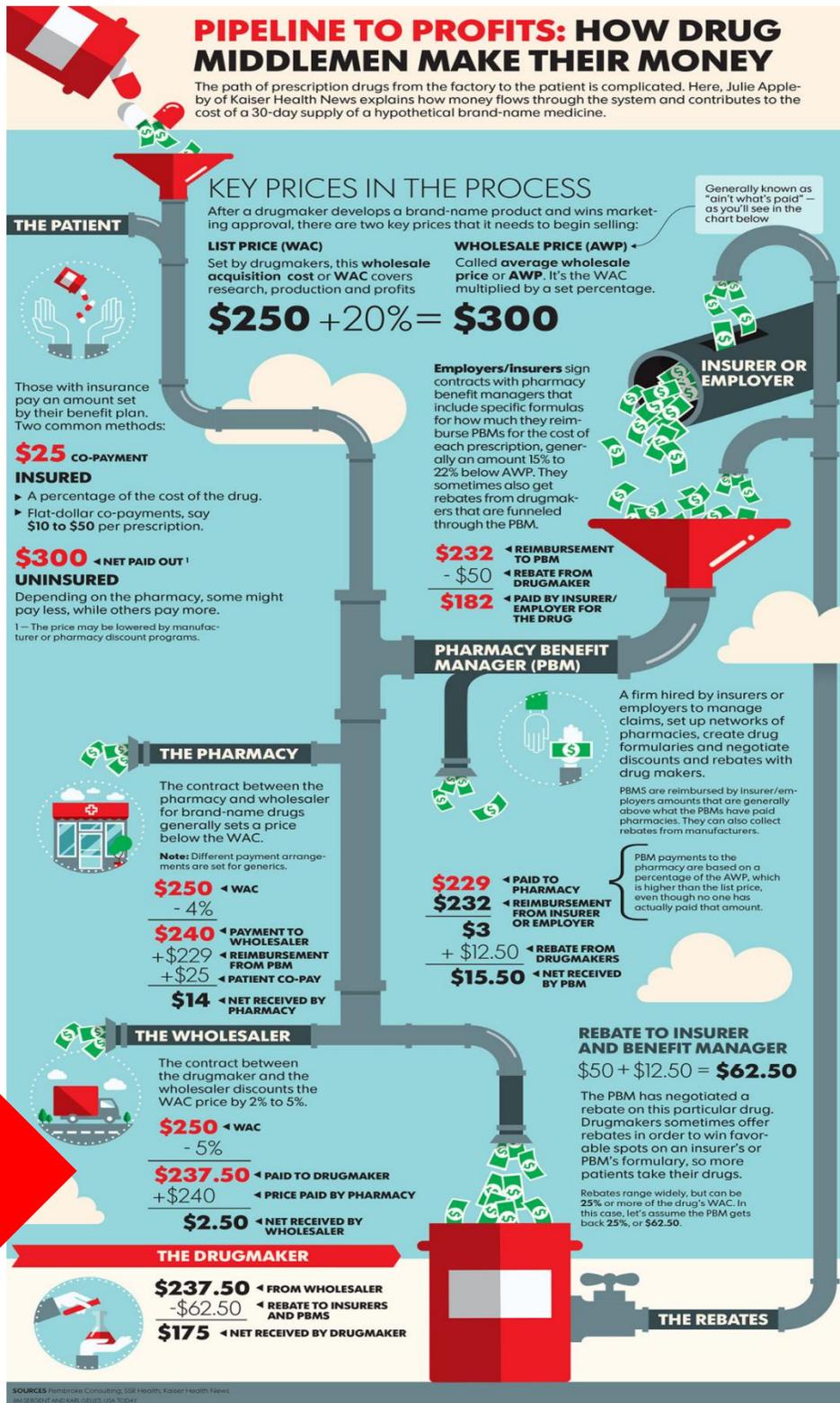


Chart illustrates flows for patient-administered, outpatient drugs. Please note that this chart is illustrative. It is not intended to be a complete representation of every type of financial, product flow, or contractual relationship in the marketplace.

Source: Fein, Adam. J., *The 2016 Economic Report on Retail, Mail and Specialty Pharmacies*, Drug Channels Institute, January 2016.

(Available at http://drugchannelsinstitute.com/products/industry_report/pharmacy/)



Wholesaler Pays
Manufacturer:
\$237.50

Pharmacy Pays
Wholesaler:
\$240

Wholesaler
Profit:
\$2.50

Fighting an Epidemic

COMBATING PRESCRIPTION DRUG ABUSE AND DIVERSION

Our nation's prescription drug abuse and diversion epidemic is a serious healthcare challenge that threatens both patient safety and the security of the healthcare supply chain. At the center of that supply chain, the Healthcare Distribution Alliance (HDA) and our primary pharmaceutical distributor members are committed to working collaboratively to bring stakeholders together to tackle this complex national crisis.



While distributors do not prescribe or dispense drugs directly to patients, they do share a common goal with doctors, manufacturers, pharmacists, law enforcement officials and policymakers: to ensure a safe supply of medicines. Among other safeguards, distributors are dedicated to keeping prescription painkillers out of the hands of people who may use them for purposes other than those for which they are intended. To help address this growing threat, HDA and its member companies support and employ a multilayered approach:

Pharmaceutical distributors work to ensure that healthcare providers receive the medically necessary medicines to treat their patients and improve public health.

- HDA is committed to our core mission of helping to protect patient safety and access to medicines, while creating efficiencies in the healthcare supply chain.
- We work with manufacturers, pharmacies, hospitals, nursing homes, clinics and other healthcare providers to provide the appropriate inventory levels of the medications and products that patients need every day.
- Our member distributors register with the DEA and follow rigorous statutory and regulatory requirements for the storage, handling and distribution of controlled substances. These sophisticated security systems and processes help safeguard the supply chain.

Pharmaceutical distributors coordinate with a range of supply chain partners, as well as federal and state regulatory agencies, to help prevent the diversion of prescription drugs.

- We work with supply chain stakeholders, including pharmaceutical manufacturers, hospitals, retail pharmacies and other healthcare providers, to share information and develop strategies to identify and help prevent abuse and diversion.
- We work collaboratively with law enforcement and regulators to combat bad actors who attempt to breach the security of the legitimate supply chain, coordinating with law enforcement and regulators to offer deep information technology, security and logistics expertise that helps locate and prosecute bad actors who attempt to misuse and divert prescription drugs from the legitimate supply chain.
- We take steps to "know our customers," including actively assessing and reviewing purchases from pharmacies and healthcare providers that order controlled substances to monitor and report to the DEA if a customer's controlled substances volume or pattern of ordering might signal inappropriate use of the

product. If inappropriate use is suspected, distributors work proactively with the DEA, local law enforcement and others to help in the investigation of potential diversion cases.

- We provide the DEA with additional data and reports to aid their efforts to seek out criminal behavior. Distributors communicate about any handling of selected controlled substances to the DEA's reporting system, Automation of Reports and Consolidated Orders System (ARCOS). This system monitors the flow of DEA controlled substances from their point of manufacture through commercial distribution channels to the point of sale at the dispensing/retail level.

Pharmaceutical distributors work to educate suppliers, customers and policymakers about our industry's efforts to help prevent prescription drug abuse and diversion.

- We are committed to being a part of the national dialogue on prescription drug abuse and will continue to participate in national, state and local forums to educate, raise awareness of and advance solutions to prescription drug abuse and diversion.
- HDA's collaborative efforts to mitigate this issue include work with the National Governors Association's Prescription Drug Abuse Project, The Partnership for Drug-Free Kids initiative "The Medicine Abuse Project," the Alliance to Prevent the Abuse of Medicines and the Community Anti-Drug Coalitions of America (CADCA).
- In 2014, 2015 and 2016 HDA also collaborated with Georgia Attorney General Sam Olens' "We're Not Gonna Take It" video contest with high school students, highlighting the risks of prescription drug abuse among teens. Through HDA's support, the winning videos were aired on TV stations throughout the state of Georgia.

For more than two years, HDA worked closely with members of Congress to help enact the Ensuring Patient Access and Effective Drug Enforcement Act of 2016 (PL 114-145, S. 483). Based on ideas initially conceived by HDA and its members, the law further strengthens the relationship between pharmaceutical supply chain stakeholders and the DEA, enhancing collaboration in the fight against prescription drug abuse. It was the first significant legislation passed in the 114th Congress to address this complex issue.

DID YOU KNOW?



CONTROLLED SUBSTANCES are drugs that are regulated by federal or state laws to help control addiction and abuse, other physical harm or illegal trafficking.

Certain controlled substances only can be prescribed by a physician. As mandated by the Controlled Substances Act, drugs and other substances that are considered "controlled substances" in the U.S. are divided into five different schedules. These schedules are based on the substance's potential for abuse and the likelihood that the drug will lead to dependence when abused, in contrast to non-controlled substances, which have a decreased chance of being abused by individuals.

Pharmaceutical Supply Chain Security

PROTECTING THE INTEGRITY OF A COMPLEX DELIVERY NETWORK

Primary pharmaceutical distributors are committed to ensuring a secure pathway for all medicines and healthcare products. We offer peace of mind to the millions of patients who depend on these products and help them feel confident that their medicines are safe and secure. In partnership with manufacturers, pharmacies, healthcare practitioners, law enforcement and regulators, distributors continuously monitor, protect and enhance the security of the nation's medicine supply.



As medicines move through the supply chain, distributors have procedures in place to safeguard products from theft and diversion. These include:

- Advanced physical security systems that feature surveillance cameras, alarms and perimeter controls;
- Established practices to safely store and transport medical products;
- Monitoring and reporting suspicious orders to the DEA to help mitigate the diversion of prescription medicines; and,
- Information-sharing programs with local law enforcement and supply chain security coalitions, such as the Pharmaceutical Cargo Security Coalition, to share best practices on securing of the nation's healthcare supplies.

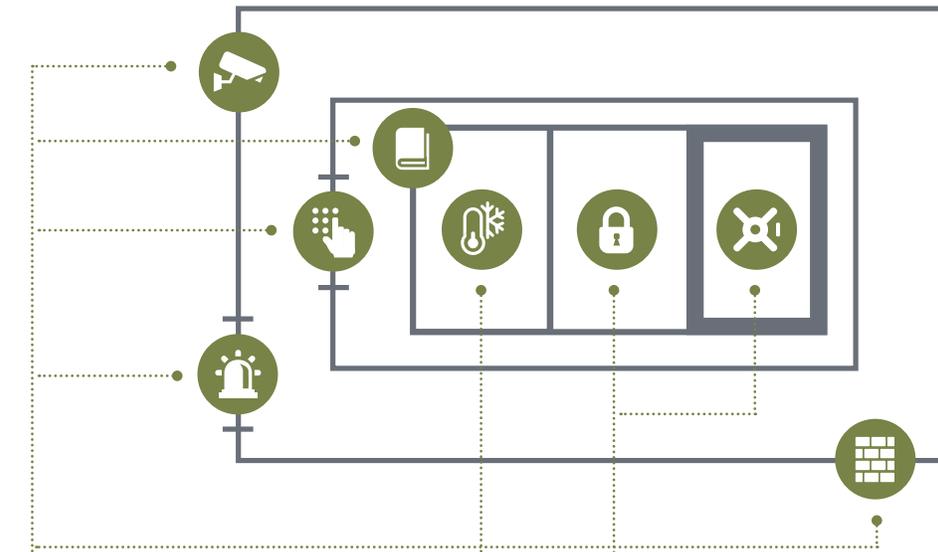
The Healthcare Distribution Alliance (HDA) is committed to partnering with its members, regulators and policymakers to ensure supply chain security by:

- Leading the effort to make the supply chain safer and more efficient by helping to secure a national framework to trace prescription medications in the supply chain through the 2013 enactment (and ongoing implementation) of the Drug Supply Chain Security Act;
- Strongly advocating for the enactment of The Safe Doses Act (PL 112-186), which expanded federal penalties for pharmaceutical cargo thefts; and,
- Supporting tough, rigorous and consistent standards for state licensing of pharmaceutical distributors that help ensure criminals do not infiltrate the supply chain and gain access to prescription medicines.

To help members navigate this complex issue, HDA also developed the "Supply Chain Security Guidelines," "Recommendations for Securing Pharmaceutical Storage Facilities" and "Security Guidelines: Protecting Last-Mile Pharmaceutical Shipments" to provide the steady guidance needed to meet this new challenge and adapt to the requirements of ensuring the safe and efficient distribution of prescription medicines.

A LOOK INSIDE: DISTRIBUTION FACILITIES

Pharmaceutical distribution facilities feature sophisticated security systems and technology to securely store prescription drugs using an integrated, multi-layered security approach. The FDA, DEA and individual states have regulations that outline comprehensive security specifications for the entire warehouse and operations.



Security specifications:

Special alarms and electronic security systems, door locks, perimeter security, limited employee access, employee screening, supervision of visitors and employees, and written policies and procedures for receipt, security, storage, inventory and distribution of pharmaceuticals.



Controlled substances:

Schedule III, IV and V controlled substances are in a secure, locked cage, which must meet security and construction criteria set by DEA, such as alarms, doors and cage size.

Schedule II controlled substances are kept in high-security vaults. The vaults' walls, floors and ceilings are required to be concrete and at least 8" thick and reinforced with steel rods. The DEA must review and approve all designs before construction and inspect and approve them after construction is complete.



Temperature control:

Medicines that require a certain temperature are stored within specialized, temperature-controlled containment devices and refrigerated storage areas.

Traceability: Transforming the Pharmaceutical Supply Chain

THE DRUG SUPPLY CHAIN SECURITY ACT

Leading the effort to make the supply chain safer and more efficient, in 2013 the Healthcare Distribution Alliance (HDA) helped secure a national framework to trace prescription medications through the enactment of the Drug Supply Chain Security Act (DSCSA). The law preempted a 50-state patchwork of pedigree requirements with one federal traceability solution for prescription medicines.



This groundbreaking law:

- **Clarified and consolidated supply chain regulations, increasing the efficiency and safety of the supply chain.** Beginning in January 2015, manufacturers and distributors were required to adhere to enhanced product tracing requirements, with pharmaceutical dispensers following later that year. Over the next 10 years, a single system of federal electronic, unit-level traceability requirements will be phased in to apply to the entire supply chain.
- **Strengthened distributor licensure standards across the United States.** Through the DSCSA, the FDA must issue new federal licensure standards. Once finalized, states have two years to adopt these standards. This approach is intended to create greater uniformity across states and enhance federal authority, while enabling states to maintain their authority to issue licenses and partner with FDA in enforcement efforts.
- **Established new processes for identifying suspicious and illegitimate products in the supply chain.** As required by the law, in June 2014, FDA released draft guidance to help supply chain trading partners more readily identify, quarantine and investigate suspect and illegitimate products. It also seeks to enhance the process for manufacturers, distributors and others to notify the agency of the existence of potentially dangerous products in the supply chain.

BRINGING THE INDUSTRY TOGETHER

The DSCSA implementation process has been one of the most collaborative efforts that pharmaceutical supply chain stakeholders and federal and state regulators have undertaken in recent history. Leveraging the deep knowledge and expertise HDA members bring to the pharmaceutical supply chain, HDA has helped form productive partnerships with industry stakeholder groups, customers and regulatory agencies — including the FDA and state Boards of Pharmacy — and has served as a forum for members and other professionals to address critical technology and compliance questions.

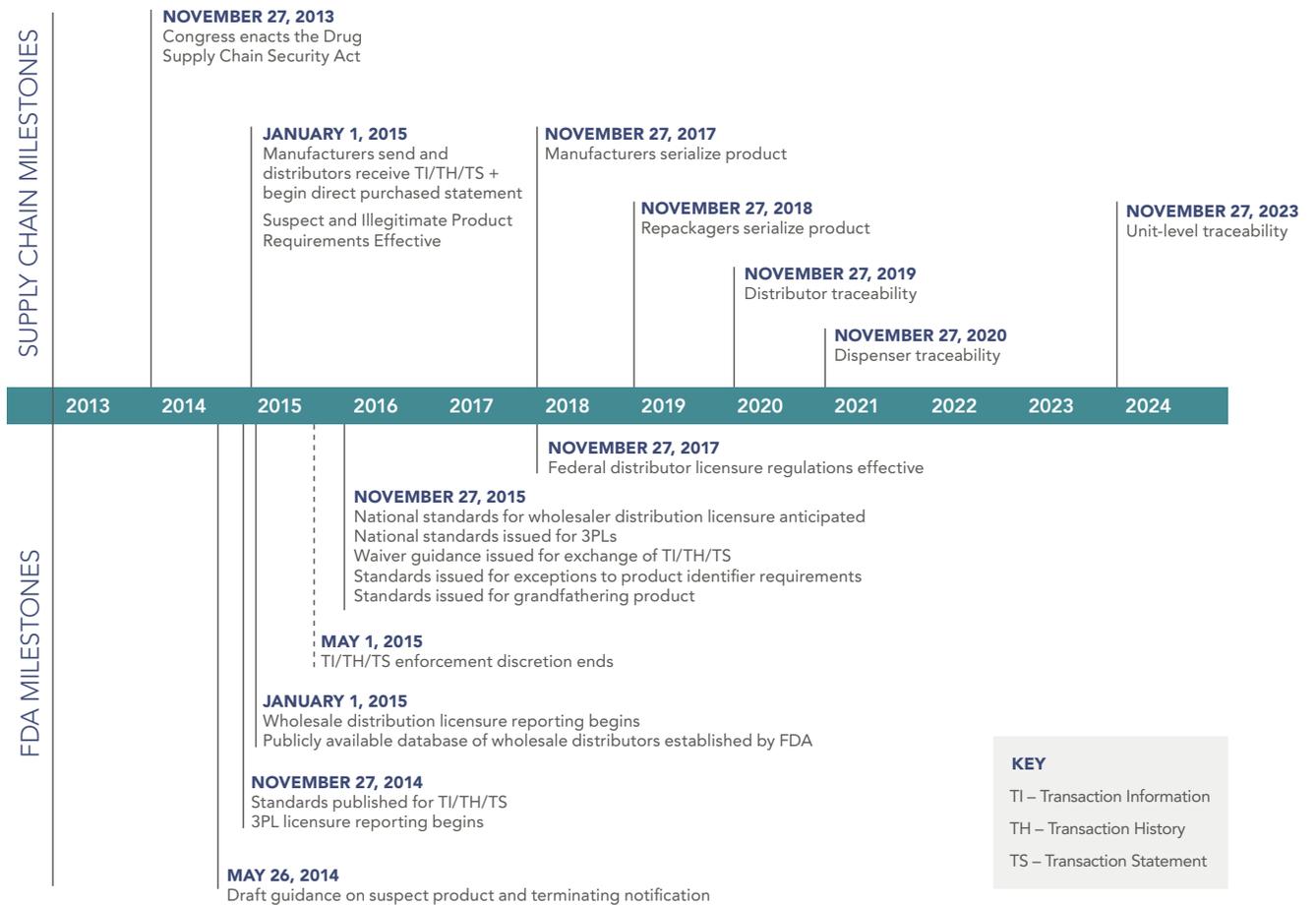
Throughout implementation, HDA has fostered knowledge and collaboration through educational programs, webinars, seminars, and product offerings, as well as a toolkit of supply chain materials touching on a range of topics, including:

- Updated Advance Ship Notice (ASN) EDI guidelines and new ASN exceptions guidelines;
- A series of typical transaction scenarios with related DSCSA data exchange applications;

- A bar code “quick start” guide updated in 2016;
- An updated “Standard Pharmaceutical Product Information” form that includes DSCSA-related elements; and,
- A list of answers to frequently asked questions about how the DSCSA applies to wholesale distribution operations and other law requirements.

Having successfully met past DSCSA implementation milestones, HDA is now coordinating with members and others to conduct pilot studies to understand the technologies and processes required to effectively and efficiently implement future DSCSA requirements. Specifically, to meet a 2019 deadline, HDA worked with EY (formerly Ernst & Young) to complete a pilot study for distributors and manufacturers to examine different methods of verifying product identifiers.

FEDERAL IMPLEMENTATION TIMELINE



For more information on the Drug Supply Chain Security Act, visit HDA’s Traceability Resource Page at [HDA.org/Issues/Pharmaceutical-Traceability](https://www.hda.org/Issues/Pharmaceutical-Traceability).