

Testimony of Elizabeth Gallenagh, Senior Vice President, Government Affairs and General Counsel for the Healthcare Distribution Alliance (HDA).

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Good morning, Chairman Burgess, Ranking Member Green and members of the Committee. Thank you for the opportunity to participate in today's hearing. I am Liz Gallenagh, Senior Vice President, Government Affairs and General Counsel for the Healthcare Distribution Alliance (HDA). HDA is the national trade organization representing 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. HDA's members include 35 national, regional and specialty primary distribution companies who are not just distributors, but are technology innovators, information management experts, security specialists and efficiency professionals. Their expertise streamlines the supply chain to ensure safety and efficiency, while also achieving cost savings for our nation's healthcare system.

Role in the Supply Chain

The U.S. healthcare supply chain is complex, and the nation's primary pharmaceutical distributors play a vital role within it. Each day hundreds of thousands of healthcare provider locations must receive needed medicines and other healthcare products from thousands of manufacturers. These manufacturers and providers are served predominantly by HDA's primary distributors, who operate out of about 176 warehouses and purchase directly from authorized manufacturers — a relatively small, but highly efficient and effective network. In fact, most pharmaceutical sales in the U.S. flow through primary distributors (95.7%).¹

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

Every day HDA members work around the clock to safely and efficiently ship 15 million healthcare products (medicines, medical supplies, durable medical equipment, et al.) to pharmacies, hospitals and other healthcare providers to keep their shelves stocked with the medications and products they need to treat and serve their patients.

Distributors are unlike any other supply chain participants — their core business is not manufacturing, and they do not prescribe medicines or dispense to patients. Their key role is to serve as a conduit for medicines to travel from manufacturer to patient while making sure the supply chain is fully secure and as efficient as possible.

HDA distributor members focus significant resources on the safety and security of the supply chain, and their secure supply chain efforts may in fact be the most important service distributors provide to the overall pharmaceutical delivery system. With this committee's support several years ago, HDA strongly advocated for the enactment of the Drug Supply Chain Security Act (DSCSA), Title II of the Drug Quality Security Act, which sets a framework for unit level traceability of medicines by 2023. Today, HDA members are in the midst of Phase I implementation efforts and work to collaborate with FDA, state regulatory authorities and trading partners to build the systems and processes necessary to achieve unit-level traceability of prescription drugs by 2023, as outlined in the law.

Relationship with Provider Customers

On a daily basis, pharmacies, hospitals and other healthcare providers place orders with HDA distributor members for the medicines, supplies and equipment they need to serve their patients. Without pharmaceutical distributors, pharmacies and providers would have to carry weeks of inventory and undertake the time-consuming process of placing individual orders with each and every manufacturer for products needed by the healthcare provider on a daily basis. By working with full-line distributors, providers can maintain just-in-time inventories, saving pharmacies and hospitals the expense and staff necessary to carry extensive

inventories or have large storage facilities, both of which would add significantly to their cost of operations.

While distributors provide many services to the pharmacy provider community, the core services are supply chain related — providing on-time and complete shipment of ordered drugs in a safe and efficient manner. In addition, they often provide financial credit, pharmacy management systems and in-store retail support, among many other services.

Traditional distributors serve a broad array of provider types — mostly retail and hospital settings, including chain pharmacy warehouses, mass merchandisers and food chains, and chain pharmacies (42%); hospitals, HMOs, clinics and nursing homes (22.7%); independent pharmacies (15.7%); mail order (16.4%). Specialty distributors (and specialty subsidiaries) serve other provider settings such as physician offices, home care, specialty pharmacy and some retail pharmacy.²

Relationship with Manufacturer Suppliers

The work of primary distributors also enables manufacturers to concentrate on developing and producing needed medicines without the added expense and logistical challenges of determining how to get those medicines to the providers and patients across the U.S. However, pharmaceutical distribution has evolved over the last decade from simply managing warehouses and shipping goods. While HDA members are primarily supply chain logistics and operations experts, this is no longer an industry focused solely on moving products from point A to point B. Rather, pharmaceutical distributors 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 ultimately to patients. Some examples of these core services include: receiving orders and shipping pharmaceutical products in a safe, efficient manner; inventory handling and inventory management, providing manufacturers with data about where (and in which settings) their products are utilized; verifying downstream customer eligibility to purchase products at pricing

² HDA Research Foundation, *88th Edition HDA Factbook: The Facts, Figures and Trends in Healthcare (2017-2018)*, 2017.

established under various programs or contracts between such customers and given manufacturers; and processing relevant chargebacks to manufacturers.

In exchange for the variety of distribution and logistics services that primary distributors provide to manufacturers, they charge manufacturers what are referred to as “bona fide service fees” for the provision of these services. These fees, which are not passed on to the customer, represent a fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement. This model reduces demand volatility — aligning order patterns more closely to actual patient demand and, eliminating artificial demand spikes, allowing for a supply chain that operates more smoothly and predictably.

It should also be noted that without HDA members, each manufacturer would have to ensure that more than 200,000 pharmacy and provider settings receive the medications they need when they need them, employing substantial financial, logistical and staff resources to provide medicines and supplies to hundreds of thousands of dispensing sites. Because distributors provide these logistical, inventory and other service support which manufacturers and pharmacies would otherwise have to perform themselves, the pharmaceutical supply chain is more efficient, reliable and secure, and patients are able to get the medicines they need in a timely fashion, saving our healthcare system approximately \$42 billion each year.³

Primary Wholesale Distributors’ Role in Drug Pricing⁴

The primary pharmaceutical distribution industry is a very high-volume, yet very low-profit margin industry, with the industry margin just over one percent on average in 2016. In fact, overall profitability for the primary distribution sector shows little notable change over the

³ The Center for Healthcare Supply Chain Research, The Role of Distributors in the U.S. Healthcare Industry, 2011.

⁴ HDA’s antitrust policy strictly prohibits any discussions which constitute or imply an agreement or understanding between or among its members concerning: 1) prices, discounts, or terms or conditions of sale; 2) profits, profit margins or cost data; 3) market shares, sales territories or markets;; 4) allocation of customers or territories; 5) selection, rejection or termination of customers or suppliers; 6) restricting the territory or markets in which a company may resell products; 7) restricting the customers to whom a company may sell; or 8) any matter which is inconsistent with the proposition that each members company of HDA must exercise its independent business judgment in pricing its services or products, dealing with its customers and suppliers and choosing the markets in which it will compete.

past several years, even during recent market volatility.⁵ Moreover, in a recent 2017 study, the Berkeley Research Group concluded that the pharmaceutical wholesale distributor profit on overall branded drug costs was just under one percent.⁶

Traditional pharmaceutical wholesale distributors purchase pharmaceuticals from manufacturers based on the Wholesale Acquisition Cost (“WAC”), a publicly available figure reported for each pharmaceutical product by the manufacturer to various compendia such as Medi-Span and RedBook, which publish such prices. WAC represents the manufacturer’s list price, and does not include rebates, prompt payment, or other adjustments in price resulting from proprietary negotiations between the manufacturer and wholesaler, downstream payer groups or other customers. Manufacturers (pharmaceutical, biologic, generic, etc.) set the WAC price for their products. Wholesale distributors are not privy to how such WAC pricing decisions are made. Wholesale distributors typically purchase pharmaceuticals from manufacturers based on WAC and they also charge manufacturers distribution fees related to their services, as previously discussed.

Wholesale distributors typically sell branded drugs to downstream customers based on WACs established solely by pharmaceutical manufacturers. Wholesale distributors might also sell generic drugs to downstream customers based on WACs established solely by pharmaceutical manufacturers and published in the various pricing compendia or they may price generic drugs sold to downstream customers in response to the market, which includes supply of competing generic drug and considers the WACs for such generic drug products and competitors to such drug products. As such, wholesale distributors do not control the price of pharmaceuticals rather the price of pharmaceuticals is dictated by published WAC or other list prices determined solely by manufacturers of such products and other market forces, including the WACs of generic drugs that compete with a given generic drug product.

⁵ Data obtained from Annual *HDMA/HDA Factbook*, compiled and compared across multiple years.

⁶ 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.

Conclusion

As I noted earlier, primary pharmaceutical distributors have evolved from providing basic inventory management and distribution to now offering a suite of services supporting many different operations of both manufacturers and healthcare providers. Ultimately, these services result in benefits to patients and consumers and have made the U.S. pharmaceutical supply chain one of the safest and most efficient in the world.

Traditional pharmaceutical wholesale distributors' goal in the pharmaceutical supply chain is a simple one: add efficiency, security and timely delivery of products so providers can concentrate on patient care and ensure their patients have regular access to the medications they need. Historically, HDA distributor members have effectively achieved this goal and have had a positive effect on the supply chain and patients while taking costs out of the pharmaceutical supply chain and having minimal impact on the overall cost of drugs.

Thank you. I am happy to answer any questions you may have.