



HEALTHCARE DISTRIBUTION MANAGEMENT ASSOCIATION

**Testimony before the
Senate Commerce, Science and Transportation Committee**

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Good morning Chairman Rockefeller, Ranking Member Hutchison and Members of the Senate Commerce Committee. I am John Gray, president and CEO of the Healthcare Distribution Management Association (HDMA). Thank you for the opportunity to provide an overview of the pharmaceutical distribution system with respect to the critically important issue of drug shortages.

We applaud the Committee's efforts to address the drug shortage issue and some of the resulting symptoms, including gray market diversion of products in short supply.

For the purposes of our discussion today I will reference a recent report from the Premier Healthcare Alliance that defines the gray market as a parallel market, "that is unofficial, unauthorized or unintended by the original manufacturer." Given that context, and to distinguish HDMA members from the gray market, I will share with you information about the primary pharmaceutical distribution industry.

HDMA is the national association representing America's primary healthcare distributors – the vital link between manufacturers and providers in our nation's healthcare system.

Approximately 90 percent of all pharmaceutical product sales in the United States flow through HDMA's 34 distributor members. Each business day, HDMA member companies ensure that more than nine million prescription medicines and healthcare products from more than 1,100 manufacturers are delivered safely and efficiently to nearly 200,000 healthcare providers including, pharmacies, hospitals, nursing homes, clinics and other healthcare entities. Our provider customers generally place orders for prescription medicines by 8 p.m. in the evening and receive deliveries from their distributors the next morning.

Wholesale distribution is defined as the “distribution of prescription drugs to persons other than a consumer or patient.” HDMA members are primary wholesalers, that is our members are predominantly Authorized Distributors of Record (ADRs), as designated by pharmaceutical manufacturers. Our members purchase the majority of product directly from pharmaceutical manufacturers and sell only to appropriately licensed healthcare providers and entities.

In 1988, the Prescription Drug Marketing Act (PDMA) was enacted to increase safeguards in the drug distribution system by preventing the introduction and retail sale of substandard, ineffective or counterfeit drugs. It also helped define the pharmaceutical distribution industry as we know it today. Our distributor members operate in accordance with the requirements set forth in the PDMA, as well as licensing rules and standards in all 50 states.

HDMA and its members are strong advocates for increased wholesaler licensure standards and a uniform federal pedigree system to enhance the safety and security of the pharmaceutical supply chain. In addition to fundamentally addressing counterfeit and diverted medicines, federal pedigree may be a useful tool in discouraging gray market activities associated with drug products in short supply.

Effectively addressing a drug shortage is a difficult and complex challenge for the entire healthcare community, in large part because a shortage typically appears with little or no warning and often requires significant resources to manage. HDMA member companies are working hard to improve communications within the supply chain and, where possible, to mitigate the impact of drug shortages. Distributors do not manufacture product and so can do little about the root causes of shortages. However, distributors do play an important role by helping to coordinate and share information about drug shortages when they arise.

Distributors are typically notified of a shortage by a manufacturer or provider partner. Once information is received, distributors communicate with their manufacturer partners about product availability to understand the scope and expected duration of any shortage. They then work as quickly as possible with their customers to fill orders, to the extent they are able, usually based upon each customer's historical purchasing patterns. If necessary, distributors work with customers and manufacturers to identify alternative product options.

HDMA, in collaboration with its distributor members, manufacturers and providers, recently completed voluntary industry guidelines on improving communication between supply chain partners in the event of a product shortage. We hope this effort, in conjunction with enhanced wholesale licensure standards and a uniform federal pedigree system, will contribute to the better management of product shortage issues in the future.

HDMA is committed to working with the Congress, all relevant regulatory agencies and the entire supply chain to develop collaborative solutions that mitigate the impact drug shortages have on the most important stakeholder: the patient.

I thank you again for the invitation to participate in this hearing and hope this overview was valuable to the Committee as it explores this important and timely topic.