

Statement from
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Subcommittee on Commerce,
Manufacturing, and Trade

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Good morning Chairwoman Bono Mack, Ranking Member Butterfield and Members of the Energy and Commerce Subcommittee on Commerce, Manufacturing and Trade. I am John Gray, President and CEO of the Healthcare Distribution Management Association (HDMA). Thank you for the opportunity to inform the Subcommittee's efforts regarding the critically important issue of prescription drug abuse and diversion.

HDMA is the national association representing America's primary pharmaceutical distributors – the vital link between manufacturers, pharmacies and healthcare providers.

Our industry's primary mission is to operate the safest and most secure and efficient supply chain in the world. As part of this mission, the pharmaceutical distribution industry is committed to addressing the serious national problem of prescription drug abuse and to being part of the solution.

HDMA's members have not only statutory and regulatory responsibilities to detect and prevent diversion of controlled prescription drugs, but undertake such efforts as responsible members of society.

The remedies for prescription drug abuse are not the same as those involving illegal drugs handled by criminals. Prescription drugs are

approved by the government (many of which are manufactured under stringent controls and pursuant to active ingredient quotas set by DEA), intended to improve the lives of patients and are distributed by fully licensed distribution companies.

To address the issue of prescription drug abuse, distributors have developed complex systems to help prevent the diversion of medicines and to comply with the Drug Enforcement Administration's (DEA) expanded expectations for suspicious order monitoring and reporting.

To aid in the development and implementation of these systems, in 2008 HDMA and its member companies developed Industry Compliance Guidelines (ICGs) to support distribution industry practices on the evaluation of customer orders for controlled substances and the reporting of "suspicious" orders to the DEA. The ICGs were vetted with the DEA in advance of their publication.

The guidelines emphasize the concept of "Know Your Customer" – that is, obtaining and reviewing thorough background information about a prospective healthcare provider prior to doing business. Therefore, in many cases, potential problems can be avoided even before an order is placed.

Obviously, because of antitrust concerns, individual distributors must make their own decisions regarding their business practices. Individual

distributors take proactive steps to prevent controlled substances from entering into the wrong hands. An individual distributor may place limits on the amount of controlled substances that a provider may purchase, and may cease to do business with a provider who has engaged in what appears to be suspicious ordering.

Because of the advanced systems now in place and the industry's proactive efforts, the DEA reported last year that between 2006 and 2011 distributors stopped shipping controlled substances to more than 1,500 customers that could have posed an unreasonable risk of diversion.

Let me add, it is critical that the anti-diversion efforts of our industry as well as the enforcement actions of the DEA always carefully balance the need to cut off supply to any customer engaged in diversion while not limiting access to appropriately prescribed and dispensed medicines for seriously ill patients or potentially putting legitimate pharmacies out of business.

Despite the efforts of our industry, we find ourselves in a conundrum. Pharmaceutical distributors do not manufacture controlled substances. We do not license pharmacies or healthcare providers. We do not write prescriptions for patients. We do not "dispense" products to patients. We do not see the prescription a patient presents at a pharmacy for filling. A single

pharmaceutical distributor does not know, and has no way of knowing, if a pharmacy customer is purchasing prescription drugs from other distributors.

However, the DEA receives information from each distributor that sells controlled substances to a particular pharmacy or prescriber. The agency also sets annual allowable production quotas for manufacturers of controlled substances.

Distributors are often held accountable, with incomplete information, for diversion from parts of the supply chain they do not control. To comply with DEA's expectations, distributors are being asked to judge the diagnosis, intent, medical knowledge and experience of doctors and pharmacists. Furthermore, the DEA's emphasis on volumes and national averages to determine suspicious orders oversimplifies the problem for Schedule II controlled prescription drugs. The analysis of a single pharmacy's controlled substance ordering patterns is far more complex and includes critical factors such as pharmacy size; patient demographics; and proximity to hospital and surgery centers, nursing homes, cancer clinics and hospice providers.

Today, each distributor essentially must operate in an information silo:

- Unaware that a new pharmacy customer may have been cut off by another distributor who had concern about potential diversion at that pharmacy; or,
- Unaware that an existing pharmacy customer is ordering controlled substances from multiple distributors; or,
- Unaware that a specific pharmacy may be dispensing controlled substances for a physician who is writing prescriptions for patients when there is no legitimate medical need.

In an effort to break down the silo walls, HDMA has asked the DEA to provide clarification and guidance on the agency's expanded expectations of an anti-diversion program for wholesale distributors, and sought greater information sharing between the agency and our industry. In face-to-face meetings as well as in written communications with the agency, our questions have ranged from seeking a better understanding of distributors' responsibilities for controlled substances suspicious orders monitoring and reporting, to improved understanding of DEA's perspective on the relationships between prescribers, pharmacies and distributors.

Throughout these communications, HDMA and its members also have asked DEA to provide aggregated and blinded data from the Automation of Reports and Consolidated Orders System (ARCOS) that could be used to further assess product orders or to provide other supportive information. A distributor does not have the independent ability to determine whether a pharmacy or physician customer is ordering from multiple distributors – only DEA possesses that information. Our members report orders for controlled substances to DEA but do not have access to the aggregated data.

To conclude, there are three themes that I would like for the Subcommittee to take away from my testimony today.

First, there is a need for the DEA to acknowledge that prescription drugs are different from illegal drugs and, therefore, a completely different mindset is required to fix the problem.

Second, anti-diversion efforts led by our industry and the DEA need to balance the responsibility to take action to prevent the diversion of prescription drugs to illegitimate use while avoiding disruptions and shortages for patients with real medical needs. We ask for proportionate enforcement by the DEA for distributors who have implemented necessary anti-diversion controls.

Third, the more information that is shared between DEA and distributors, and across the supply chain, the more effective our anti-diversion efforts will be.

HDMA strongly believes that the healthcare industry as a whole, the government and all supply chain stakeholders – doctors, pharmacists, distributors, and manufacturers – must work collaboratively to effectively detect and fight prescription drug abuse and diversion. We all share the same goal: to ensure a sufficient, safe supply of medicines for legitimate patients while keeping these same drugs out of the hands of individuals who will abuse them.

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