

Florida Controlled Substances Standards Committee

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Good afternoon. My name is Gary Cacciatore and I am Vice President of Regulatory Affairs and Associate Chief Regulatory Counsel for Cardinal Health. I also serve as Chair of The Florida Drug Wholesale Distributor Advisory Council for the Florida Department of Business and Professional Regulation, but I am here today representing Cardinal Health and not the Advisory Council or DBPR. I also want to make it clear that any testimony or comments I provide today may not necessarily represent the views of all wholesale drug distributors.

Even with that caveat, I believe my position with Cardinal Health and my experience in this area will be beneficial to the committee and I hope I can offer a clearer understanding of the drug distributor's role in the fight against prescription diversion and what our legal and regulatory obligations are.

Let me start out by saying that prior to my work as an attorney, I was a pharmacist and I am still a licensed pharmacist in the state of Florida. So I appreciate the complexity of this issue and the difficulty pharmacists face in trying to meet their responsibilities under the "corresponding responsibility" doctrine while still ensuring that legitimate patients have access to the medications they need.

I think it's important to understand from the outset that distributors do not prescribe nor do we dispense drugs directly to patients. While wholesale distributors do not prescribe or dispense drugs directly to patients, we share a common goal with drug manufacturers, doctors, pharmacists, policymakers, regulators and law enforcement officials to help ensure a safe supply of medicines, while keeping prescription painkillers out of the hands of people who may use them for purposes other than which they are intended. In the fight against prescription drug abuse, the distribution industry brings expertise in information technology, security and logistics, and diversion prevention, which helps law enforcement locate and prosecute those criminals who attempt to divert prescription drugs from the legitimate supply chain.

Distributors registered with the DEA are required by regulation to verify that customers to whom they ship controlled substances are properly registered with the DEA. Distributors are also required to detect suspicious orders for controlled substances and inform the DEA of suspicious orders. Suspicious orders are defined as "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."

In addition, the DEA has directed letters to all distributors stating that if a distributor determines that an order is suspicious, "the order may not be shipped and this suspicion must be reported to the local DEA Field Division Office." The DEA further advised distributors that routinely filling suspicious orders without first ascertaining that the orders will not be diverted is "failing to maintain effective controls against diversion" which could lead to the loss of the distributor's DEA registration. In accordance with the DEA's letters to distributors, Cardinal Health closely monitors orders for controlled substances,

refuses to fill suspicious orders, and takes appropriate steps to determine whether the drugs we distribute are being diverted. Time does not permit me to explain every aspect of our order monitoring system. The major component of our system designed to detect suspicious orders includes placing individualized limits on each controlled substance drug family (e.g. oxycodone, hydrocodone, etc...) that we distribute to a customer. Additionally, we have limits on particular drug strengths within a drug family (e.g., limits on the amount of oxycodone 15 and 30 mg products). We also have established metrics to evaluate ordering patterns across multiple drug families (e.g., evaluating purchases of all narcotic analgesics). We consider the drug combinations that the DEA has identified as being widely diverted such as oxycodone, alprazolam and carisoprodol. These factors and many others play a role in our decisions to service customers and in setting limits on the distributions of controlled substances.

It is important to point out that the limits or thresholds that we put on customers' ability to purchase controlled substances are not random or arbitrary. We have complex and sophisticated statistical methodologies that we use in determining thresholds for customers and these thresholds are customized for each customer and by drug family. At Cardinal Health, our system relies on prescription volume, so the more accurate information we have on a pharmacy's total prescription volume and other information that we request, the more accurate our thresholds will be.

While we understand that many pharmacies will have an above average utilization of controlled substances, our statistical methodology ensures that the volume of controlled substances we distribute to a customer is consistent with the legitimate dispensing of controlled substances based on our knowledge of the customer's business. Some customers may have a legitimate need for controlled substances that deviate from predicted statistical values. In these cases, customers must provide **verifiable** compelling reasons to justify a higher utilization of controlled substances. The key in these cases is communication between pharmacies and their wholesalers. Wholesalers need to understand why a pharmacy's ordering pattern is changing and in particular why a pharmacy needs to increase their purchase of controlled substances. For example, if a pharmacy signs a new contract to service a nursing home or hospice facility which will result in an increase demand for certain controlled substances, the pharmacy needs to communicate that information to their wholesaler in advance of that increased demand.

Another thing that will assist with ensuring pharmacies have adequate inventory to meet their patients' medical needs is, to the extent possible, pharmacies should try to purchase most of their prescription drugs from a single wholesaler. Doing so allows the wholesaler to obtain a more accurate view of the pharmacy's purchases and dispensing needs so that the wholesaler can compare the pharmacy's controlled substance purchases to their non-controlled purchases, another factor DEA has stated that wholesalers should be aware of when determining whether a pharmacy's orders are suspicious.

DEA has also emphasized that distributors must perform "due diligence" in "knowing their customers" in order to have a meaningful suspicious order monitoring program. Our Quality and Regulatory group for this area consists of over 35 people and this team works to learn about our customers through a variety of means. We learn about our customers through data and statistical analysis. We also learn about our customers by requesting and obtaining information from them. Additionally, we conduct site visits at many of our customers' locations. These site visits are conducted by our Quality and Regulatory Affairs Investigators, our Distribution Center Compliance Officers, third-party compliance consultants, and our sales force. These site visits are conducted to determine if there are observable "red flags" or warning signs of diversion at the pharmacy. During some site visits, information will be obtained from the pharmacy if needed. Knowing our customers is an important factor that helps us to establish reasonable

and appropriate limits for controlled substances that we will distribute to each customer. We expect our customers to cooperate with us in these matters since our activities are designed to meet our legal obligations and the DEA's expectations.

At Cardinal Health we also have been working hard to help our customers meet their obligations to prevent the diversion of controlled substances. We have put together many educational pieces that describe the pharmacist's role under the "corresponding responsibility" doctrine as well as checklists and a list of red flags that pharmacists should be aware of. I have brought samples of some of those documents today. In addition, we also send expert speakers to pharmacy groups to address pharmacists on these topics. In the past 18 months, we have done presentations at ten different state and national pharmacy meetings on these topics.

Cardinal Health also participates in broad coalitions to address the prescription drug abuse problem such as the Anti-Diversion Industry Working Group which, in conjunction with the National Association of Boards of Pharmacy, produced an educational video for pharmacists to help them identify the warning signs of prescription drug abuse. We have also been an active participant in the National Association of Boards of Pharmacy's Stakeholders Coalition which recently released a consensus document on the Challenges and "Red Flags" Warning Signs Related to Prescribing and Dispensing Controlled Substances. Cardinal Health is a founding member of the Alliance to Prevent the Abuse of Medicines (APAM) a non-profit partnership of key stakeholders in the prescription drug supply chain that have joined together to develop and offer policy solutions to address prescription drug abuse. In addition, since 2009, the Cardinal Health Foundation has invested over \$4 million nationwide in partnerships and grants to leverage awareness, education and prevention efforts in the fight against prescription drug abuse. In summary, wholesale distributors play a critical role in ensuring patients have access to prescription drugs by providing millions of prescription drug products, including controlled substances to pharmacies, hospitals, clinics and other locations on a daily basis. Our goal is to ensure that our customers have the products they need to meet their patients' medical needs, but we also take steps to prevent the diversion of controlled substances and are required to have systems to identify and report suspicious orders to the DEA.

The best way for pharmacies ensure that they have the products they need is to maintain regular communication with their wholesaler regarding any changes in the pharmacy's practices or services that will require increased orders of controlled substances and by meeting their obligations to ensure that the products they dispense are being used for legitimate medical purposes.

Thank you.