HDA
Healthcare Distribution Alliance

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The Rest of the Story: Facts about Pharmaceutical Distributors and the Opioid Crisis

As the country continues to face a serious problem with opioid addiction, elected officials, the media and the public continue to discuss and debate the cause and possible solutions to this problem. Unfortunately, these conversations often include a narrow, distorted view of the prescription drug supply chain and, in many cases, overstate pharmaceutical wholesale distributors' role in this serious public health issue. Many stakeholders in the supply chain — including physicians, pharmacists, manufacturers, distributors, federal and state regulators, law enforcement, and others — share responsibility for opioid abuse and misuse in our country. It is important to understand the role each stakeholder plays as we work to end the current opioid epidemic.

Fact: Distributors DO NOT manufacture opioids, license registrants, write prescriptions or dispense medicines.

Primary pharmaceutical distributors are solely responsible for the safe and efficient distribution of all medications, including controlled substances, from drug manufacturers to licensed pharmacies and other healthcare providers. Wholesale distributors are not "pill mills." Distributors fulfill orders only from entities licensed by the U.S. Drug Enforcement Administration (DEA) and state regulatory authorities. This fact is often ignored. To successfully identify and prevent prescription drug abuse and diversion, distributors strive to work closely with those responsible for prescribing, dispensing and regulating opioids.

Fact: Distributors CANNOT make medical determinations regarding patient care or provider prescribing.

Distributors have no access to patient information, nor are they qualified to question a licensed physician's recommended treatment plan for their patient, including prescriptions. Distributors must balance providing access to needed medications while taking all efforts to eliminate diversion of these same medications for inappropriate use.

A main tool to prevent abuse of prescription drugs is the prescription itself. The Centers for Disease Control and Prevention (CDC) recently released updated, evidence-based guidelines on prescribing opioids for chronic pain. This was a critical step to ensure safe and medically appropriate treatment plans for patients, and HDA is encouraged by recent reporting that doctors are beginning to change the way they approach pain management and the use of narcotics pain pills.

Fact: The DEA sets annual production quotas for opioids. Distributors report controlled substance orders that are filled and those that are deemed suspicious to the DEA, and have ROBUST controls in place to monitor distribution.

Distributors fulfill orders *only* from entities that are registered with the DEA and licensed by state regulatory authorities. Further, these orders are for prescriptions written by medical professionals licensed by state medical boards. A distributor only knows what it ships to a particular dispenser. It does not know what that particular dispenser may also be receiving from other wholesalers nor does it know the full scope, or total volume, of the medicine supply for a city, county or state.

Wholesalers devote millions of dollars to state-of-the-art, anti-diversion monitoring programs and processes. Distributors regularly report suspicious activity and — when appropriate — cut off the supply of products to customers when "red flags" of possible drug diversion or other illegal activity are observed.

Fact: A public-private partnership between distributors and the DEA could help IMPROVE distributors' monitoring systems.

The GAO in a June 2015 report concluded that "DEA communication with and guidance for its registrants are essential to help ensure that registrants take actions that prevent abuse and diversion but do not unnecessarily diminish patients' access to controlled substances for legitimate use because of their uncertainty about how to appropriately meet their CSA roles and responsibilities."

Targeted, rapid response against opioid abuse and diversion is a challenge and requires a positive relationship between distributors and the DEA. The DEA can assist distributors in their efforts by responding to compliance questions around patient safety monitoring and enforcement. In addition, by sharing data and information there will be additional opportunities to identify and curb misuse, overuse and abuse of prescription opioids.

Fact: Recognizing the need for robust information sharing, Congress passed bipartisan legislation that represented a change in COMMUNICATION and enforcement across all parties.

In 2016, Congress enacted the *Ensuring Patient Access and Effective Drug Enforcement Act* (S. 483/Public Law 114-145) — without dissent — marking a dramatic change in information sharing and collaboration among distributors, and other registrants, and the DEA. This law does not "decrease" DEA's enforcement against distributors; it supports real-time communication between all parties in order to counter the constantly evolving methods of drug diversion.

- Under the new law, the DEA remains fully empowered to take quick action against a DEA registrant (i.e., prescribing physician, pharmacist, distributor, manufacturer) if there is "a substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance will occur…."
- In circumstances where there is a lack of regulatory clarity around a DEA registrant's roles and responsibilities, a corrective action plan provides a registrant 30 days to adequately address the DEA's concerns and to avoid having their registration revoked, which could have significant ramifications for the supply chain and patients.
- In April 2017, HHS is legislatively required to present a report on the nation's response to the opioid epidemic.

Fact: Distributors are strongly COMMITTED to finding systemic solutions to the challenges that contributed to the opioid epidemic.

Distributors are strongly committed to addressing the barriers and challenges that contributed to the opioid epidemic. They, like all actors in the system, recognize that the opioid epidemic was a systemic failure and that improvements are needed across the board. Distributors stand ready to work with all players across the system — physicians, pharmacists, manufacturers, federal and state regulators, law enforcement, and others — to identify and stop rogue actors who intentionally undermine patient safety and the public health.