

PRACTICAL SOLUTIONS TO Address Opioid Abuse and Misuse

Today, our country is grappling with an epidemic that permeates every community in America and involves all corners of the supply chain. Many steps already have been taken to reverse the prevalence of abuse and misuse of opioids. In 2016, the Centers for Disease Control and Prevention issued guidelines that called on providers to voluntarily limit their first opioid prescriptions for acute pain to a three-day supply or less. Several states and major health organizations, including the Centers for Medicare and Medicaid Services, have since implemented opioid limits and dosing requirements aligned with these guidelines. Insurers, health systems and pharmacy benefit managers are combing their data to identify and educate prescribers whose prescribing practices lie outside current guidelines. Federal institutions, including the White House, the Food and Drug Administration (FDA), the Drug Enforcement Administration (DEA) and Congress are focusing on this issue. Recognizing that each player in our diverse healthcare system has a role, wholesale distributors are committed to working collaboratively to tackle this complex national crisis.

The Healthcare Distribution Alliance's (HDA) primary mission is to support the operation of the safest — as well as the most secure and efficient — supply chain in the world. To this end, pharmaceutical distributors continue to work closely with supply chain partners and numerous regulatory agencies, most notably with the DEA, the FDA as well as regulatory authorities in every state. While distributors do not manufacture, prescribe, dispense or drive demand for medicines, HDA and its members recognize our role and responsibility in advancing meaningful initiatives to address the serious, complex issues raised by the opioid abuse crisis.

As logistics companies, wholesale distributors have invested heavily in information technology systems to help better identify suspicious orders based on their own individual customer experience and ordering patterns. They also employ team members to track and monitor pharmacy orders and continue to support efforts designed to improve coordination and communication between the industry and the DEA as well as other state and federal authorities.

More must be done in order to enhance and improve our collective response to addiction and abuse of opioids. HDA supports and encourages the following initiatives:

Enhancing Coordination, Data Sharing and Monitoring



- **Creating a Universal Suspicious Orders Database**
DEA recently announced that it is developing an online system through which registrants will be able to report suspicious orders, as well as advanced analytical tools for scrutinizing this data. HDA recommends that DEA allow state regulators and state and local law enforcement officials to access this suspicious orders database and these analytical tools, effectively creating a Universal Suspicious Orders Database.

A data management system, including standardized online reporting, that is operated by DEA but also accessible to DEA's state and local partners, will help federal and state entities identify trends that indicate that a pharmacy or other dispenser should no longer be permitted to handle controlled substances. This database would significantly advance states' ability to analyze and act on important public health issues, including opioid overuse and abuse. State boards of pharmacy often lack the resources to establish the sophisticated data analytics that DEA's database will provide. Additionally, providing state regulators with access to DEA's Universal Suspicious Orders Database will help prevent the inconsistent imposition of state rules for suspicious order reporting that conflict with DEA's requirements and guidance.
- **Expanding Access to ARCOS Data**
HDA recommends that DEA provide wholesale distributors with aggregated and blinded purchasing data from the ARCOS* database. If provided by DEA in aggregate form without identifying competitor distributors, this data could allow wholesale distributors to consider a customer's orders in the context of overall distributions of ARCOS-reportable drugs to that entity.

Distributors must report its dispositions (including sales) of all substances in Schedules I and II, and narcotic substances in Schedule III, on at least a quarterly basis. In the past, DEA Diversion Control Division officials have indicated that the agency would need to amend its regulations to disclose this information. Because this information would improve industry's efficiency in preventing diversion and oversupply of controlled substances, HDA recommends that DEA take the regulatory actions necessary to begin sharing this data.

This additional information may assist a distributor in determining whether orders are suspicious and whether the distributor should distribute controlled substances to that entity. In previously asking DEA to share ARCOS data, HDA has explained to DEA that such data could:

- Help indicate the specific drugs that distributor registrants should watch most carefully;
- Help in the increasingly difficult effort to detect trends and patterns; and,
- Help in assessing orders placed by individual practitioners, which are much less frequent than retail pharmacies or large healthcare entities (e.g., hospitals) and therefore more difficult to analyze for trends.

This data would not only help fill a significant gap in the data available to and analyzed by distributors, but also would provide much-needed context to the information that DEA has recently made available on the number of distributors that supply each downstream customer. DEA's recent decision to allow distributors to see the number of distributors that supply each downstream customer reveals one aspect of much-needed insight, specifically at the individual pharmacy level, but as Attorney General Jeff Sessions recently noted, "better information means better decisions."

- **Combating Illegal Imports**

HDA has always been committed to a safe and secure supply chain and is actively working to implement the Drug Supply Chain Security Act's directive to enable the tracing of prescription medications through the supply chain. For those reasons, HDA supports FDA's efforts to combat illegal imports of unapproved

drugs, including its careful coordination with other federal authorities and its communication with the public about the dangers of these imported drugs.

American patients can be placed in harm's way due to the presence of substandard, falsely labeled, falsified and counterfeit medicines in other countries, in part through purchases made from illegal internet drug sellers, who often hide the true origin of products. FDA's activities in preventing this illicit importation, using longstanding authorities and those more recently provided in the Food and Drug Administration Safety and Innovation Act of 2012, are critically important in preventing overdose deaths as well as other adverse health outcomes.

While HDA applauds FDA's recent successes, we also encourage Congress and the Executive Branch to continue to identify and address potential gaps. As the President's Commission on Combating Drug Addiction and the Opioid Crisis [recently reported](#):

The ability to easily purchase drugs like fentanyl online, which are subsequently shipped in a manner and at volumes that make them hard to detect, demonstrates a new pathway for these potent drugs to enter the domestic supply chain. This change carries enormous implications for the law enforcement and justice communities, and requires a framework of relationships, laws and regulations, and procedures to deal with an environment of drug trafficking and use the nation is just beginning to see.

To the extent that changes to federal law can improve the ability of other federal agencies to intercept such products before they cause harm to Americans, HDA supports such initiatives.

Educating Patients, Families and Caregivers



- **Increasing Patient Information About Safe Use of Opioids and Drug Disposal**

Distributors are committed to working with our pharmacy colleagues to provide education materials to patients. With [recent data](#) suggesting that more than 40 percent of those who misuse opioids first

* The Automation of Reports and Consolidated Orders System (ARCOS) is the automated system developed by the DEA to monitor selected controlled substances, including controlled opioids. ARCOS enables the government to maintain a current and historical record of inventories and transactions in those controlled substances from manufacture, through distribution, to the pharmacy or other practitioner that will dispense the drug to a patient.

obtained them from a friend or relative, we believe we can have a meaningful impact by informing patients and caregivers about how to prevent misuse before it happens.

HDA supports national take-back days and other methods of appropriate disposal. It is also critical that patients, family members and caregivers know how to swiftly and properly dispose of unused opioid medications. Over the past several years, pharmacies and healthcare providers have begun to collect unwanted medications. While these programs have increased, and the DEA continues to hold nationwide drug take-back days in partnership with state and local law enforcement, many families still may not find an immediately convenient disposal site. Other strategies can help to fill this gap such as take back kiosks in pharmacies or law enforcement locations, drug take-back envelopes and drug deactivating pouches that can be used at home to neutralize drugs, making them unavailable for future use or misuse. By informing patients about all of their options for disposing of unwanted drugs, we can reduce the number of opioids available for abuse and misuse.

- **Increasing Patient Education Related to Partial Filling of Prescriptions**

HDA also endorses efforts of pharmacists to use professional judgement to “partial fill” opioid prescriptions and/or to inform patients about their ability to request a “partial fill” of their opioid prescription. Partial fill provisions allow pharmacists to dispense part of the prescription on one day and, if the patient or prescriber asks, the remaining prescription in a few days. Partial fill provisions mitigate the likelihood that a patient would have more medication than he or she needs, but still can receive the entire amount if necessary. This also provides the pharmacist and patients with additional opportunities to interact, allowing the patient to ask any new questions and the pharmacist to provide advice and to detect signs of misuse.

Using Data and Technology to Prevent Diversion and Abuse

- **Enhancing Prescription Drug Monitoring Programs**

All 50 states and the District of Columbia have authorized the operation of a Prescription Drug

Monitoring Program (PDMP). Yet, a [2015 report from the Johns Hopkins Bloomberg School of Public Health](#) found that prescribers check PDMP data only 14 percent of the time before prescribing opioids. The most effective PDMPs are those that have been incorporated into the regular prescribing and dispensing of doctors and pharmacists, respectively. HDA believes that more widespread adoption should be encouraged. To the extent that prescribers would benefit from continuing education in accessing, interpreting and applying PDMP data, HDA supports such training. Improvements in PDMPs that allow for easier interpretation of patient data, better alignment with electronic health records and streamlining of data updates also could increase usage and utility.

Distributors also support improving the connectivity of PDMP databases across state lines and between prescribing and dispensing locations. Increasingly connected and easily accessible information will immeasurably assist prescribers and pharmacists in identifying patients involved in drug abuse and misuse, even if they travel to different states to fill prescriptions, prevent those patients from attaining dangerous drugs and help move them into appropriate treatment programs. In addition, HDA supports efforts to provide pharmacists with tools to identify potential instances of fraud or opioid misuse to protect patient safety.

- **Facilitating Electronic Prescribing for Controlled Substances, Including Opioids**

Greater use of securely designed electronic prescribing protocols for controlled substances (EPCS) can help limit counterfeit prescriptions and can enhance PDMP data. Currently, nearly 90 percent of retail pharmacies are equipped to receive electronic prescriptions, but only 20 percent of prescribers can issue electronic prescriptions for controlled substances, meaning that the overwhelming majority of controlled substance prescriptions are still issued using paper prescription pads. EPCS can be an important tool in stemming opioid misuse and abuse by helping to reduce prescription fraud and protecting against “doctor shopping.”

Because EPCS is regulated by the DEA, HDA encourages the agency to take the steps necessary to address prescribers’ concerns about the administrative burden and time constraints involved in using this secure electronic means of prescribing.

By streamlining EPCS processes and addressing physician work-flow concerns, the DEA could encourage adoption of this technological method of reducing prescription opioid abuse.

Ensuring Appropriate Access to Safe and Effective Treatments

- **Reviewing Production Quotas for Opioid Medicines**
HDA supports recent efforts by the DEA to gradually reduce production quotas for opioid medicines. The agency should work closely with healthcare providers and patient groups to assess and determine current needs and revisit annual production quotas accordingly.
- **Assessing Appropriate Prescribing Limits**
HDA supports appropriate guidelines and limitations of opioid prescribing to be determined by state medical boards and other entities that govern the practice of medicine.
- **Promoting Access to Naloxone**
Improving access to naloxone treatment can save lives and improve patients' health. As of May 2017, each state has removed some of the legal barriers that had hindered the timely administration of naloxone. Distributors strongly support expanding access to and coverage of this lifesaving treatment and encourage states to advance "overdose Good Samaritan" provisions that allow bystanders to summon emergency responders without fear of arrest or other negative legal consequences.

- **Reducing Barriers to Effective Alternative Pain Treatments**

Despite coverage requirements under the Mental Health Parity and Addiction Equity Act, many insurers may limit or restrict access to non-opioid treatments like physical therapy and acupuncture by imposing step therapy ("fail first") or prior authorization requirements. If we are to adequately treat pain while also reducing opioid usage, patients must have equal access to effective alternative treatments. HDA encourages insurers to amend their coverage and encourages states to enforce coverage parity requirements.

- **Increasing Federal Funding for Treatment**

HDA encourages Congress to appropriate additional federal funding to expand the treatment options for those suffering from opioid-use disorders. Additional resources for first responders and the addiction treatment providers that are on the front lines of the opioid abuse crisis, like the resources allocated through the Comprehensive Addiction and Recovery Act and the 21st Century Cures Act, are vital in allowing more patients to access treatment.

These practical solutions reflect a shared responsibility by all healthcare stakeholders to protect the health and safety of millions of Americans, marshal our collective resources, learn from the past, and look to the future to end this public health crisis.

About the Healthcare Distribution Alliance

The Healthcare Distribution Alliance (HDA) represents 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. The HDA Research Foundation, HDA's non-profit charitable foundation, serves the healthcare industry by providing research and education focused on priority healthcare supply chain issues. For more information, visit www.hda.org.