



NATIONAL ASSOCIATION OF
CHAIN DRUG STORES

Statement
Of
The National Association
of Chain Drug Stores
For
U.S. House of Representatives
Energy and Commerce Committee
Subcommittee on Commerce,
Manufacturing, and Trade
Hearing on
Prescription Drug Diversion:
Combating the Scourge
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Introduction

The National Association of Chain Drug Stores (NACDS) thanks the Committee for the opportunity to submit a statement for the hearing on “Prescription Drug Diversion: Combating the Scourge.” NACDS and the chain pharmacy industry are committed to partnering with law enforcement agencies, policymakers, and others to work on viable strategies to prevent prescription drug diversion. Our members are engaged daily in activities with the goal of preventing drug diversion. In our testimony, we wish to highlight the following areas:

- The extensive federal and state regulatory regime with which pharmacies comply
- Federal regulation of pharmacies under the federal Controlled Substances Act and DEA’s regulations to implement it
- Chain pharmacies’ extensive initiatives to protect Americans from the dangers of prescription drug abuse and diversion
- Chain pharmacies’ support for the mission and efforts of DEA
- Chain pharmacies’ support for the mission and efforts of FDA
- Chain pharmacies’ support for other regulatory bodies
- Chain pharmacies’ support for Controlled Substance Monitoring Programs
- Our goal of shutting down illegitimate Internet drug sellers
- The need for proper disposal of unwanted prescription drugs

NACDS represents traditional drug stores, supermarkets, and mass merchants with pharmacies – from regional chains with four stores to national companies. Chains

operate more than 40,000 pharmacies and employ more than 3.5 million employees, including 130,000 pharmacists. They fill over 2.6 billion prescriptions annually, which is more than 72 percent of annual prescriptions in the United States. The total economic impact of all retail stores with pharmacies transcends their \$900 billion in annual sales. Every \$1 spent in these stores creates a ripple effect of \$1.81 in other industries, for a total economic impact of \$1.76 trillion, equal to 12 percent of GDP. For more information about NACDS, visit www.NACDS.org.

NACDS and the chain pharmacy industry share the Committee's concerns with the problem of prescription drug diversion. We believe that there are a variety of ways to help curb prescription drug diversion, and chain pharmacies actively work on many initiatives to reduce this problem.

Background

Chain pharmacies extensively train their personnel and have strict policies and procedures to prevent prescription drug diversion. Our members vigorously comply with state and federal laws and regulations. Pharmacies and pharmacy personnel are among the most highly regulated industries and professions.

To qualify as a pharmacist, an individual must successfully complete a rigorous six-year doctorate program. Upon successful completion, the Doctor of Pharmacy (Pharm.D.) degree is conferred. To then practice as a pharmacist, he or she must successfully pass a national board exam and a state exam for each state in which he or she wishes to practice.

Each pharmacist is licensed by the state board of pharmacy in which he or she practices and must complete mandatory continuing education in order to maintain that state license. The vast majority of states have mandatory training requirements for other pharmacy personnel that have access to prescription medications, and these pharmacy technicians are also registered or licensed by state pharmacy boards in almost every state. Each pharmacy location is individually licensed by the state board of pharmacy in which it is located and routinely inspected by board inspectors to ensure compliance with laws and regulations. Other state agencies have jurisdictional authority over pharmacies and pharmacy personnel depending on how the state executive branch is structured. These additional agencies include those that have specific authority over prescription drugs that are subject to diversion and abuse. These agencies also issue registrations and licenses and inspect pharmacies.

At the federal level, each individual pharmacy location is licensed by the federal Drug Enforcement Administration (DEA) and is subject to DEA inspection at any time. Pharmacies must also follow federal Food and Drug Administration (FDA) regulations for the prescription drugs they maintain and dispense.

The Federal Controlled Substances Act

First enacted in 1970, the federal Controlled Substances Act (CSA) regulates the manufacture, importation, possession, use, and distribution of prescription drugs that have a potential for diversion, addiction and abuse, known as “controlled substances.” The CSA creates a closed system of distribution for controlled substances; DEA often

refers to this as “cradle-to-grave” control over controlled substances. DEA has implemented a very tight and comprehensive regulatory regime pursuant to the CSA. States have followed this lead and have implemented similar, sometimes duplicative regimes. This matrix of regulation has created a multi-layered system of checks and balances to protect Americans from the dangers of prescription drug diversion and abuse. Pharmacists and other pharmacy personnel all are trained to understand and comply with this complex regulatory matrix.

Chain Pharmacy Initiatives

To comply with DEA’s “cradle to grave” regulatory regime, chain pharmacies have created a variety of extensive and robust loss prevention and internal security systems that are in place from our prescription drug distribution centers right down to the point of dispensing to the patient. We undertake initiatives to ensure that prescription drugs are accounted for in every step along the way. Some of those initiatives could include conducting background checks before hiring personnel who have access to prescription drugs, extensively training about controlled substance laws and regulations within 30 days of hire, and maintaining electronic inventories of controlled substances and conducting random audits. The tools we utilize to secure our facilities and operations can include camera surveillance, heavy duty safes, secure cages, and complex alarm systems. We work closely with law enforcement to see that perpetrators are brought to justice.

Specifically, at the pharmacy level, examples of the initiatives our members have undertaken include training pharmacy personnel on how to handle suspect prescription

drug orders, and exception reporting, in which exceptionally large or unusual orders of controlled substances will trigger an internal investigation. Chain pharmacies also may maintain perpetual inventories of controlled substances that are randomly audited by internal security personnel. Pursuant to DEA and state regulations, every pharmacy is highly secured with physical barriers and complex alarm systems. Some pharmacies also utilize cameras and closed-circuit television to ensure compliance with policies and procedures. Some pharmacies require employees to read and sign “codes of conduct,” which commits them to compliance. Some member pharmacies will conduct drug testing, including random, for cause, and pre-employment.

Chain pharmacies have zero tolerance for prescription drug diversion. Other steps pharmacies may take to minimize internal losses include: ensuring that invoices and bills are reconciled against actual inventory records, reviewing and mining system data to identify trends and potential suspicious activities, and providing toll-free anonymous tip phone lines for employees to report suspicious activities.

In addition to developing, implementing, and maintaining our own policies and procedures, we support numerous other initiatives to mitigate and reduce the scourge of prescription drug diversion. Chain pharmacies participate in state controlled substance prescription drug monitoring programs. NACDS and our member companies support policies that work to prevent illegitimate Internet drug sellers from selling or offering to sell drugs to U.S. consumers in violation of federal and state laws. We also support

efforts to provide patients with means for disposal of their unwanted medications in ways are authorized by law enforcement.

NACDS Supports DEA

DEA holds the primary authority to implement and enforce the CSA. NACDS and our members vigorously support the mission and efforts of DEA. We seek to work with DEA and other law enforcement bodies on a routine basis. NACDS and our members frequently dialogue with DEA officials about efforts to stem prescription drug diversion, both at DEA headquarters in Arlington, Virginia and throughout the nation, working with the officials at DEA's numerous field offices. We routinely schedule industry meetings a number of times every year to meet with both officials at DEA headquarters and field offices. NACDS staff and our chain pharmacy member representatives have personally met with officials from almost every domestic DEA field office within the past few years. In these meetings, which can last from one hour to almost a full day, we discuss prescription drug diversion trends and strategies to mitigate and reduce problems. We believe these meetings are essential to supporting DEA's mission to enforce the CSA and our responsibilities to protect the health and welfare of our patients.

NACDS Supports FDA

Almost five years ago, Congress passed the Food and Drug Administration Amendments Act of 2007 (FDAAA), which provided the FDA the authority to impose risk management plans on prescription drugs, known as Risk Evaluation and Mitigation Strategies (REMS). A REMS will be imposed if FDA finds that a REMS is necessary to

ensure that the benefits of a drug product outweigh the risks of the drug product. Among the numerous REMS that FDA has implemented, the agency announced that a REMS will be required for long-acting and extended release opioid products (“LA/ER opioid drugs”). These are pain relieving medications that have an elevated potential for abuse. The central component of this “Opioid REMS” is an education program for prescribers (e.g., physicians, nurse practitioners, physician assistants) so that LA/ER opioid drugs can be prescribed and used safely. NACDS agrees that prescribers should be properly educated about the risks and benefits of prescription drugs, including those that have elevated abuse potential like LA/ER opioid drugs. It is critical that all prescribers understand the nature of addiction and abuse before issuing prescriptions for these medications. NACDS supports FDA’s Opioid REMS.

Beyond LA/ER Opioids, FDA recently announced a REMS for another class of drugs with elevated abuse potential, transmucosal immediate-release fentanyl (TIRF) products. The TIRF REMS is scheduled to become effective in just over a week, on March 12. NACDS and other industry stakeholders have worked closely with FDA over the past few years to design and implement this REMS. We are appreciative of this collaborative effort spearheaded by FDA. If this REMS proves successful, we are hopeful that it could serve as a model for future REMS for products similar to the TIRF products.

As we pursue solutions to the problem of prescription drug diversion, it is critical that we do not place undue burdens on legitimate patients who require prescription medications. As FDA has recognized through the REMS program, the risks of medications must be

mitigated relative to their benefits. However, we cannot mitigate risks to the point that legitimate patients cannot receive medications' benefits. We believe that FDA has struck a proper balance thus far.

Additional Chain Pharmacy Support

In addition to our support of DEA and FDA, NACDS and our member pharmacies support the mission and activities of other, numerous federal and state agencies and law enforcement bodies. NACDS interacts routinely with other state and federal officials to devise strategies to protect Americans from the dangers of prescription drug diversion and abuse. We frequently meet and interact with the White House Office of National Drug Control Policy (ONDCP) to learn about national drug abuse trends and to collaborate on solutions. NACDS recently met with officials from the High Intensity Drug Trafficking Areas (HIDTA) program to develop potential solutions to stem armed robberies of pharmacies, a problem that recently spiked in a few areas of the country. HIDTA was created by Congress with the Anti-Drug Abuse Act of 1988 to provide assistance to federal, state, local, and tribal law enforcement agencies operating in areas determined to be critical drug-trafficking regions of the United States. Other examples include our work with state legislators and policymakers on controlled substance monitoring programs, described in more detail below. We support the work of the National Association of State Controlled Substance Authorities (NASCSA) as their members develop, implement and maintain these programs. We support the mission and objectives of the National Association of Boards of Pharmacy (NABP), and have worked with them on a number of initiatives over the years, including federal legislation to

combat illegal Internet sites that lure consumers into purchasing controlled substances without a prescription, also described below.

Controlled Prescription Monitoring Programs

NACDS and chain pharmacies support controlled substance prescription monitoring programs to help combat prescription drug diversion. Currently, about 40 states have operational monitoring programs and another seven states are in various stages of program implementation. Recognizing the role these programs have in helping to prevent drug abuse and diversion, chain pharmacies actively support these programs. Pharmacies submit information on the controlled substances they dispense monthly, weekly, and daily depending on the particular state's program requirements. This information includes information on the patient, prescribed drug dosage and quantity and the prescriber. This information allows the state to conduct confidential reviews to determine any patterns of potential abuse or diversion.

These monitoring programs offer many benefits to aid in curbing prescription drug diversion. For example, they aid in identifying, deterring, or preventing drug diversion and abuse. These programs encourage appropriate intervention to determine if a person may have a drug addiction, so that treatment may be facilitated. The programs also provide public information on trends in drug abuse and diversion.

NACDS and chain pharmacies support these programs as one of many strategies to help curb prescription drug abuse and diversion. We believe that these programs have proven

useful in preventing drug abuse and diversion at the prescriber, pharmacy and patient levels.

Target Illegitimate Internet Drug Sellers with the Chokepoint Approach

NACDS believes that an important strategy to stop drug diversion and abuse is addressing the problem of illegitimate Internet drug sellers. These illicit online drug sellers have websites that target U.S. consumers with ads to sell drugs often without any prescription required. They are almost without exception located outside of the U.S. yet have websites camouflaged to look like legitimate pharmacy websites. They operate in clear violation of U.S. state and federal laws and regulations that protect public health and safety. They sell drugs to consumers without the safety precautions of a legitimate prescriber-patient relationship, a valid prescription, and a licensed U.S. pharmacy.

These illegal Internet sites that profit from these illegitimate activities are often mistakenly referred to as Internet “pharmacies.” They are not pharmacies; they are *illegitimate Internet drug sellers*. They are not licensed as pharmacies by any U.S. jurisdiction, nor do they comply with any of the rigorous state and federal laws governing pharmacy licensure and the practice of pharmacy by pharmacists. Instead, these illegitimate Internet drug sellers are shipping unapproved, counterfeit, mislabeled, or adulterated products within or into the country.

We support targeting illegal Internet drug sellers through the *chokepoint approach*, rather than placing unwarranted burdens on legitimate, state licensed pharmacies that have

associated branded Internet websites. Under the chokepoint approach, entities such as domain name registrars that issue websites, financial entities that handle payment transactions, Internet Service Providers that show the illegitimate websites on the Internet, and common carriers that provide the mailing services would have authority to stop illicit transactions at their point of interaction with these bad actors.

Law Enforcement Authorized Programs for Return and Disposal of Unwanted

Prescription Drugs

Another important strategy to curb drug diversion and abuse is to provide consumers with appropriate means to return unwanted prescription drugs for disposal.

Finding a workable law enforcement authorized means for consumer disposal of unused and expired drug products is critical to reducing drug diversion. While varying policy options have been proposed, NACDS supports the following principles for proper return and disposal of consumers' unwanted medications. These include protecting patient health and safety by maintaining a physical separation between pharmacies and locations that take back consumers' unwanted drugs. For example, drug take-back events sponsored by DEA provide for such separation and avoid the potential for returned medications to re-enter the drug distribution supply chain. In addition, we support policies where consumers have a reliable and readily available means to return their unwanted medications such as mail-back envelope programs that are sanctioned by law enforcement or the DEA. The state of Maine has operated a DEA authorized drug mail-back program, funded through federal grants, where consumers are provided with pre-

paid mail back envelopes distributed at pharmacies and other locations, to mail in their unwanted medications. In addition, at various locations across the U.S. law enforcement partners with pharmacies to provide drug take-back events to give consumers means to return their unwanted medications. These programs help prevent teens and others from accessing and using prescription drugs in dangerous and potentially deadly ways. We look forward to DEA's upcoming regulations to allow consumers to properly dispose of unused, unwanted prescription drugs.

Conclusion

NACDS thanks the Committee for consideration of our comments on efforts to address the problem of drug diversion. We are committed to the health and welfare of our patients, as well as all Americans, including ensuring that they do not fall victim to prescription drug diversion and abuse.