



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 Health
Hearing on:
“Examining the Federal Government’s
Response to the Prescription Drug Abuse
Crisis”
June 14, 2013
9:30 a.m.
2123 Rayburn House Office Building

National Association of Chain Drug Stores (NACDS)
1776 Wilson Blvd, Suite 200
Arlington, VA 22209
703-549-3001
www.nacds.org

Introduction

The National Association of Chain Drug Stores (NACDS) thanks the Subcommittee on Health for the opportunity to submit a statement for the hearing on “Examining the Federal Government’s Response to the Prescription Drug Abuse Crisis.” NACDS and the chain pharmacy industry are committed to partnering with federal and state agencies, law enforcement agencies, policymakers, and others to work on viable strategies to prevent prescription drug abuse. Our members are engaged daily in activities with the goal of preventing drug abuse.

NACDS represents traditional drug stores, supermarkets, and mass merchants with pharmacies – from regional chains with four stores to national companies. Chains operate more than 41,000 pharmacies and employ more than 3.8 million employees, including 132,000 pharmacists. They fill over 2.7 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 over \$1 trillion 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 \$1.81 trillion, equal to 12 percent of GDP. For more information about NACDS, visit www.NACDS.org.

NACDS and the chain pharmacy industry share the Subcommittee’s concerns with the problem of prescription drug abuse. We believe that there are a variety of ways to help

curb prescription drug abuse, and chain pharmacies actively work on many initiatives to reduce this problem.

Background

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 are all 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 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, 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.

In addition to developing, implementing, and maintaining our own policies and procedures, we support numerous other initiatives to mitigate and reduce prescription drug abuse. 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 that are authorized by law enforcement.

The Role of FDA

Six 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 is a REMS 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.

In addition, FDA recently implemented a REMS for another class of drugs with elevated abuse potential: transmucosal immediate-release fentanyl (TIRF) products. 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 TIRF products.

As we pursue solutions to the problem of prescription drug abuse, 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.

Controlled Prescription Monitoring Programs

NACDS and chain pharmacies support controlled substance prescription monitoring programs to help combat prescription drug abuse. Currently, about 44 states have operational monitoring programs and another five states are in various stages of program implementation. Recognizing the important 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 abuse. 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.

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 abuse. 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 commented on DEA’s proposed regulations to allow consumers to properly dispose of unused, unwanted prescription drugs, and look forward to DEA’s final rule.

The Role of 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.

Pharmacies understand that controlled substances are subject to abuse by a minority of individuals who improperly obtain controlled substance prescriptions from physicians and other prescribers. Pharmacies must treat medical conditions and ease patients’ pain while simultaneously guarding against the abuse of controlled substances. The key is to

guard against abuse while still achieving our primary goal of assisting patients who need pharmacy services.

DEA regulations provide that physicians and other prescribers are responsible for ensuring that prescriptions for controlled substances are issued for legitimate medical purposes within the prescribers’ usual course of professional practice. According to DEA regulations, the responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment is not a prescription within the meaning and intent of section 309 of the CSA (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, is subject to the penalties provided for violations of the CSA.

In the recent past, it is our understanding that DEA has been taking a harder look at the problem of prescription drug abuse in the U.S. DEA has placed increased scrutiny on both wholesale distributors and pharmacies. Since the mid-2000’s, DEA has taken action against wholesale distributors that it deems are inappropriately distributing controlled substances to pharmacies, including shutting down a number of their wholesale distribution centers. More recently, DEA has focused its attention on chain pharmacies, shutting down such chain pharmacy distribution centers that it deems are distributing controlled substances inappropriately, as well as shutting down a number of chain pharmacies that it believes are dispensing medications to patients inappropriately.

In addition, DEA has been visiting states nationwide and providing day-long presentations to pharmacists to apprise them of DEA’s expectations.

Better Focusing Government Resources

Unfortunately, DEA’s enforcement actions are causing problems with patients’ ability to access much needed prescription pain medications. To better focus government resources on solving the problem of prescription drug abuse, NACDS urges Congress to create a commission or advisory group to bring together all stakeholders to address the problems of prescription drug diversion and abuse. The activities and recommendations of the advisory group should be broad in scope; however the recommendations should include specific direction for federal agencies to carry out. Most importantly, there should be an agreement from all participants to support this collaborative result.

The appropriate participants include key government agencies, patient groups, pharmacy groups, prescriber and other provider groups, prescription drug wholesaler groups, pharmaceutical companies, public policy experts, state attorneys general, and law enforcement officials including groups representing local law enforcement.

The policy areas that should be reviewed include:

- Improving controlled substance monitoring programs to avoid duplication and provide access to all relevant stakeholders
- Shutting down illegal Internet prescription drug sites
- Shutting down “pill mills”

- Facilitating proper disposal of prescription drugs through take-back programs
- Identifying hot spots of prescription drug abuse
- Better collaboration among federal agencies, especially FDA and DEA, on drug abuse issues to suggest guidelines for DEA action
- More resources for law enforcement
- Better education of providers, patients, parents and youth
- Development of abuse-resistant products
- Recommendations for reducing robberies, burglaries, and cargo theft
- The recommendations should be broken down by state and federal recommendations with respect to what is appropriate federally versus the individual states

We believe that bringing together stakeholders to address the problems of prescription drug abuse in this manner would provide better solutions than have been developed to date. Improved collaboration and coordination among federal agencies and other stakeholders would benefit all, including the patient, whose access to critical medication must be preserved in order for any potential solution to be successful.

Conclusion

NACDS thanks the Subcommittee for consideration of our comments on efforts to address the problem of drug abuse. We are committed to the health and welfare of our patients, as well as all Americans, including ensuring that they can still access critical pain medications while we tackle the problem of prescription drug abuse.