NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

Statement

Of

The National Association of Chain Drug Stores

For

U.S. House of Representatives
Committee on Energy and Commerce
Subcommittee on Health

Hearing on:

"Improving Predictability and Transparency in DEA and FDA Regulation"

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The National Association of Chain Drug Stores (NACDS) thanks Chairman Pitts, Ranking Member Pallone, and Members of the Subcommittee on Health for the opportunity to share our perspectives on "Improving Predictability and Transparency in DEA and FDA Regulation." Together, DEA and FDA are responsible for approving and regulating prescription medications that may be subject to diversion and abuse. NACDS and the chain pharmacy industry are committed to partnering with federal and state agencies, law enforcement personnel, policymakers, and others to work on viable strategies to prevent prescription drug diversion and abuse. Our members are engaged daily in activities aimed at preventing drug diversion and abuse.

NACDS represents traditional drug stores and supermarkets and mass merchants with pharmacies. Chains operate more than 40,000 pharmacies, and NACDS' 125 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ more than 3.8 million individuals, including 175,000 pharmacists. They fill over 2.7 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 800 supplier partners and nearly 40 international members representing 13 countries. For more information, visit www.NACDS.org.

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 and are collectively 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 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 member prescription drug distribution centers right down to the point of dispensing to the patient. Our members 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, maintaining electronic inventories of controlled substances, and conducting random audits. Our members work closely with law enforcement to see that perpetrators of crimes relating to controlled substances are brought to justice.

Specifically, at the pharmacy level, examples of the member initiatives 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, pharmacy and chain distribution centers are required to be highly secured with physical barriers, heavy duty safes, secure cages, and complex alarm systems. Some pharmacy chains also utilize cameras and closed-circuit television surveillance 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 testing.

In addition to developing, implementing, and maintaining the requisite policies and procedures, our members 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

Seven years ago, Congress passed the Food and Drug Administration Amendments Act of 2007 (FDAAA), which provided 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.

The Role of DEA and Improving DEA Transparency

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 regulatory and law enforcement bodies to curb prescription drug abuse and mitigate drug diversion.

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 also 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.

Community pharmacists are front-line healthcare providers and are one of the most accessible members of a healthcare team. As such, the CSA requires pharmacists to take on diverse and sometimes conflicting roles. On the one hand, pharmacists have a strong ethical duty to serve the medical needs of their patients in providing neighborhood care. On the other hand, community pharmacists are also required to be evaluators of the

legitimate medical use of controlled substances.[1] As briefly mentioned above, the CSA requires that a pharmacist, prior to dispensing any controlled substance, make the following determinations—whether the prescription complies with all legal and regulatory requirements, and whether the prescription has been issued for a "legitimate medical purpose" "by a prescriber acting in the usual course of his or her practice."[2] The former obligation is called "corresponding responsibility," and if the two elements are not met, the prescription is not valid. DEA interprets a pharmacist's corresponding responsibility "as prohibiting a pharmacist from filling a prescription for a controlled substance when he either 'knows or has reason to know that the prescription was not written for a legitimate medical purpose.'"[3]

Pharmacies fully 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 strive to 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's enforcement activities include conducting inspections of the entities that are subject to its regulatory oversight. Although such enforcement activities are essential to its mission, DEA has been criticized for an alleged lack of transparency in its inspection and other enforcement actions, and even inconsistency among the actions of its numerous field offices. Such opaqueness and inconsistency impose challenges on the compliance efforts of DEA registrants.

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[1] In order for a prescription for a controlled substance to be valid, federal law (21 C.F.R § 1306.04(a)) requires that the prescription be issued for a legitimate medical purpose by a prescriber acting in the usual course of his or her practice. The rule places a ***corresponding responsibility*** upon the dispensing pharmacist to establish the validity of the prescription by ensuring the prescription is written for a legitimate medical purpose.

[2] 21 C.F.R. 1306.04(a).

[3] *East Main Street Pharmacy,* 75 FR 66149, 66163 (Oct. 27, 2010).

To help address the problems of DEA opaqueness and inconsistency, we support efforts to promote accountability and transparency with respect to DEA's inspection and enforcement programs. In fact, the following recommendations drawn from FDA transparency and oversight and enforcement initiatives could serve as a model for DEA:

1. Development of a Comprehensive DEA Investigation Program, Corresponding Inspector Manual & Compliance Policy Guides: Specifically, DEA would set forth guidance for its oversight of regulated facilities inspections that provide clear and firm direction. A common set of standards for industry sectors to comply with, and for DEA inspectors to apply in their inspections would provide an essential foundation for effective oversight.

2. Accountability & Consistency among Field Offices: DEA would ensure the uniformity and effectiveness of its inspection program and oversight over field offices. DEA would provide public training for inspectors, and develop an audit process to ensure that inspections are carried out consistently across field offices.

3. Transparency & Communication - DEA Inspection Observations: DEA would provide substantive and timely feedback to inspected regulated facilities regarding agency observations and facility compliance. Specifically, DEA would provide regulated facilities with substantive written feedback upon completion of an inspection when an investigator(s) has observed any conditions that in their judgment may constitute violations of the CSA and implementing regulations. Without receiving such information, it is difficult, if not impossible, for regulated facilities to implement requisite facility and process improvements and take corrective actions where necessary.

4. Public Disclosure - Oversight of Inspections: An important mechanism of accountability is public disclosure of information. Disclosure of final inspection reports of regulated facilities would provide the public with a rationale for DEA enforcement actions and the industry with transparency into agency decision-

making, allowing them to make more informed actions to enhance facility compliance.

5. Ombudsman Office: An ombudsman office would address complaints and assist in resolving disputes between companies and DEA regarding interactions with the Agency on inspections and compliance issues.

We believe these recommendations would greatly increase predictability and transparency in DEA regulation. The adoption of such recommendations would greatly enhance the compliance efforts of DEA registrants, thus leading to more effective DEA regulation and oversight. Enhanced compliance efforts by DEA registrants and more effective DEA regulation and oversight would have highly beneficial impacts on efforts to combat prescription drug diversion and abuse.

A related challenge for pharmacies is whether the DEA registration number of a prescriber is valid and/or valid for the class of medication that has been prescribed. We support efforts to enhance the verification of prescriber data provided by DEA. It would be most helpful if DEA could provide reliable, consistent, and clear data that serves as the ultimate source for the status of a prescriber. Ideally, this database would include information about the status of the prescriber's license from the state issuing authority, such as the state medical board. Moreover, we request that there be a mechanism for DEA to provide clear guidelines on the expiration of prescribers' DEA registrations. This is currently a protracted process and it can be unclear to pharmacy personnel whether a lapsed prescriber registration (such as due to a late renewal) is still valid or, in fact, expired and invalid.

Better Focusing Resources

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.

Additionally, we are hearing that DEA and other enforcement actions may be imposing arbitrary limits on the distribution and dispensing of prescription pain medications, causing problems with patients' ability to access much needed prescription pain medications. Different groups are pointing fingers at each other as the source of the problems of prescription drug abuse and for legitimate patients having difficulty accessing their prescription pain medications. Pointing fingers of blame is not a helpful exercise and usually causes more harm than good, especially when lives are at stake. NACDS and chain pharmacies avoid assigning blame for the complex prescription drug abuse issues that we all need to address.

Since NACDS and our members are focusing our energies on real, workable solutions that will address the problem of prescription drug abuse while also ensuring that legitimate patients are able to receive their prescription pain medications, we are pleased to support H.R. 4069, the "Ensuring Patient Access and Effective Drug Enforcement Act of 2013." By establishing the "Combating Prescription Drug Abuse Working Group," this legislation would better focus government resources on solving the problems of prescription drug abuse and ensuring that legitimate patients are not harmed.

We believe that bringing together stakeholders to address the problems associated with 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 legitimate access to medication must be preserved in order for any potential solution to be successful.

NACDS is committed to efforts to curb prescription drug abuse and ensure patient access to prescription medications. We know that for some patients, access to necessary prescription drugs to control their chronic pain may be limited due to efforts to thwart prescription drug abuse. Even in the news media, we see coverage about the effects of prescription drug abuse, but the patient access challenges are conspicuously missing. However, the pharmacy trade publication, *Drug Store News*, has created a microsite on its website to raise awareness about patients living with chronic pain. The site focuses on the challenges that real patients face if unable to access prescription pain medications due to laws or regulations designed to curb prescription drug abuse. In collaboration with the U.S. Pain Foundation, *Drug Store News* conducted a series of interviews, including an audio segment with a patient who has been living with chronic pain for 20 years. In addition, profiles of four patients living with chronic pain are included on the microsite.

Electronic Prescribing and Prescription Monitoring Programs

Since DEA issued regulations to allow for the electronic prescribing of controlled substance (EPCS) prescription medications, NACDS has aggressively pursued state legislation and regulations to allow all controlled substances to be prescribed electronically. We believe that EPCS will mitigate forgeries associated with written and oral prescriptions, and provide a deterrent effect for prescribers. Most importantly, EPCS holds promise to create a robust database of real-time information that could be used by industry stakeholders and enforcement officials that may assist with the proactive identification of drug abuse. Now that most states allow EPCS, we urge the states to require that all controlled substance prescriptions be issued electronically.

On a parallel track, NACDS and chain pharmacies support controlled substance prescription drug monitoring programs to help combat prescription drug abuse. Currently, 48 states have operational monitoring programs and one more is in the 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 on a weekly or daily basis depending on the particular state's program requirements. This information includes data 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 identifying, deterring, or preventing drug diversion and abuse. They 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 support these programs and believe they have greater potential. To this end, we have developed a number of recommendations to improve them. Since prescriber access to the information in prescription monitoring programs can be challenging to obtain (and, in some states, is not even permitted under a particular state's laws,) we support initiatives to facilitate and mandate prescriber use of the program data. These programs contain a wealth of data that could assist prescribers in making determinations about whether to issue a prescription for an addictive medication.

All pharmacies and relevant pharmacy personnel should have access to prescription monitoring program data, both at the corporate and the retail pharmacy level. Pharmacy access to this data helps inform whether a prescription has been issued for a legitimate medical purpose. Certain tasks with respect to accessing the data should be allowed to be delegated to supportive personnel, such as pharmacy technicians. To streamline access for pharmacists and other pharmacy personnel, prescription drug monitoring data should be integrated into pharmacy management systems as part of the prescription claims adjudication process.

Unfortunately, many state programs are not connected with each other. Connected state prescription monitoring programs would allow prescribers to access patient data from other states which is critically important in any metropolitan area that extends across state lines. Consequently, we support efforts to standardize and interconnect all states' prescription drug monitoring programs.

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 operates 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 have 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.

Conclusion

NACDS thanks the Subcommittee for consideration of our comments. We look forward to working with policy makers and stakeholders on these important issues.