NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

Statement

Of

The National Association of Chain Drug Stores

For

United States House of Representatives
Committee on Energy and Commerce
Subcommittee on Health

Hearing
on:

"Examining Legislative Proposals to Combat our Nation's Drug Abuse Crisis"

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The National Association of Chain Drug Stores (NACDS) thanks Chairman Pitts, Ranking Member Green, and members of the Energy and Commerce Subcommittee on Health for the opportunity to submit a statement for the hearing on Examining Legislative Proposals to Combat our Nation's Drug Abuse Crisis. 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. Since our members operate pharmacies in almost every community in the U.S., we support policies and initiatives to combat the prescription drug abuse problem nationwide. We believe that holistic approaches must be implemented at the federal level.

NACDS represents traditional drug stores and supermarkets and mass merchants with pharmacies. Chains operate more than 40,000 pharmacies, and NACDS' chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ more than 3.2 million individuals, including 179,000 pharmacists. They fill over 2.9 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 850 supplier partners and over 60 international members representing 22 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 and abuse and are collectively known as "controlled substances." The CSA creates a closed system of distribution for controlled substances; the Drug Enforcement Administration (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 throughout every step along the way. Some of those initiatives could include conducting background checks before hiring personnel who have access to prescription drugs, training employees on 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 NACDS-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 and utilize 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 and some will conduct drug testing, including random, for cause, and pre-employment testing.

Chain pharmacies are committed to ensuring that prescription drugs remain under tight control for the purposes of providing care to their patients, and are not diverted for nefarious purposes. Our members' efforts are evidence of this commitment.

Legislative Initiatives

NACDS shares the goals of policymakers to curb the incidence of fraud and abuse and appreciates the work that has been done over the last year, such as with the 21st Century

Cures Initiative. NACDS believes that any potential programs aimed at "locking-in" a beneficiary to a certain pharmacy or pharmacies - such as the one included in the 21st Century Cures Initiative - must ensure that legitimate beneficiary access to needed medications is not impeded. Policies to reduce overutilization must maintain access to prescription medications by the beneficiaries who need them most.

While the use of a single pharmacy could decrease incidents of fraud, waste and abuse as well as provide the potential for better care coordination, a lock-in provision may actually be a barrier to care as supply chain issues exist around these medications which are beyond the pharmacy's control. Also, patients often legitimately see multiple doctors representing different specialties in different locations. In addition, there are instances due to location and /or services offered (e.g. compounded or specialty drugs) that a single pharmacy may not meet all the needs of a specific patient.

In order to protect legitimate patient access while combating prescription drug abuse and diversion, mechanisms must be included in any legislation that would allow a pharmacy, in consultation with the prescriber, to fill legitimate prescriptions without needlessly delaying treatment for beneficiaries. This includes ensuring that back-up systems are in place which would allow a beneficiary to obtain needed medication in the event their "locked-in" pharmacy is unable to supply the medication. Without this, the potential for harm from unnecessary delay in obtaining medication is possible.

Additionally, NACDS believes a beneficiary should be able to select a pharmacy location, or number of locations that are under common ownership and that electronically share a real time, online database. The ability to share real-time data will ensure that beneficiaries are only obtaining the necessary prescriptions while protecting beneficiary access and health.

The Role of DEA

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 that is not issued 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 any 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

[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

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.

The Role of FDA

In 2007, Congress passed the Food and Drug Administration Amendments Act of 2007 (FDAAA), which provided FDA the authority to impose risk management plans on

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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).

prescription drugs; this program is 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 extended release and long-acting opioid products ("ER/LA 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 ER/LA 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 ER/LA 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 2011, FDA announced a REMS for another class of drugs with elevated abuse potential: transmucosal immediate-release fentanyl (TIRF) products. NACDS and other industry stakeholders worked closely with FDA to design and implement this REMS. We are appreciative of this collaborative effort spearheaded by FDA, and believe such a collaborative effort should serve as a model for similar programs to address prescription drug abuse.

The GAO Report

Numerous groups and state and federal entities are working to reduce the problem of prescription diversion and abuse. Unfortunately, in their efforts to combat prescription drug abuse, federal agencies have not been effectively coordinating their efforts to assure access to prescription controlled substances for patients who legitimately need these medications. In GAO's recent report that examines shortages of prescription drugs that contain controlled substances, GAO found that DEA and FDA have not established a sufficiently collaborative relationship to ensure an adequate supply of controlled substance medications.[4] GAO found that the barriers to coordination prevent DEA and FDA from preventing or alleviating shortages[5]. Although critical to their efforts, a memorandum of understanding (MOU) between the two agencies has not been updated in *40 years*.[6]

Specific to DEA, GAO found that:

- DEA does not meet its requirements due to lack of internal controls for data reliability, performance measures, and performance monitoring,[7]
- Insufficient internal DEA controls lead to errors in its data system,[8]
- DEA has not met required time frames for more than a decade,[9] and
- DEA is not prepared to respond to future prescription drug shortages.[10]

[4] "Drug Shortages: Better Management of the Quota Process for Controlled Substances Needed; Coordination between DEA and FDA Should Be Improved;" Government Accountability Office; February 2015; pp. 43-51.
[5] Ibid.
[6] Ibid., at 46.
[7] Ibid., at 29.
[8] Ibid., at 47.
[9] Ibid.

Considering the patient harm that occurs due to prescription drug shortages, the concerns identified by GAO about lack of federal agency coordination, and serious DEA deficiencies, we believe that Congress should act. Federal agencies must come together behind a comprehensive approach and pursue drug abuse prevention policies that are strategically designed to target enforcement efforts while still maintaining access to prescription controlled substances for patients who legitimately need these medications.

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 supported H.R. 471, the "Ensuring Patient Access and Effective Drug Enforcement Act of 2015," which passed in the House in April. This legislation would promote cooperation among key government agencies, such as DEA and FDA, to jointly identify obstacles to legitimate patient access to controlled substances, issues with diversion of controlled substances, and how collaboration between law enforcement agencies and healthcare stakeholders can benefit patients and prevent diversion and abuse of controlled substances.

H.R. 471 also facilitates open dialogue on issues related to prescription drug diversion and abuse by directing key federal agencies to consult with patient groups; pharmacies; drug manufacturers; common or contract carriers and warehousemen; hospitals,

[10] Ibid.

physicians, and other healthcare providers; state attorneys general; federal, state, local, and tribal law enforcement agencies; health insurance providers and entities that provide pharmacy benefit management services on behalf of a health insurance provider; and wholesale drug distributors.

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.

Additional DEA Recommendations

Although the GAO report focuses on the quota process for prescription drugs, we have a number of additional concerns about DEA processes and functions that should brought to light. 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.

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. 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.

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 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.

Conclusion

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