

Written Testimony of

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Before the

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Concerning "Responding to the Prescription Drug Abuse Epidemic"

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Chairman Feinstein, Co-Chairman Grassley, and Members of the Caucus, my name is Joe Harmison and I am a pharmacist and owner of Harmison Pharmacies in Arlington, Texas, and past president of the National Community Pharmacists Association (NCPA). NCPA appreciates the opportunity to share the community pharmacy perspective regarding efforts to curb the prescription drug abuse epidemic and steps Congress might take to tackle this growing problem.

NCPA represents America's community pharmacists, including the owners of more than 23,000 community pharmacies, pharmacy franchises and chains. Together, they employ over 300,000 individuals including 62,400 pharmacists, and dispense nearly half of the nation's retail prescription medications.

Importance of Access to Effective Pain Treatments for Appropriate Patients

NCPA encourages community pharmacists to commit themselves to supporting national and local efforts to prevent the abuse of both prescription and non-prescription drugs, at the same time recognizing that policymakers should not diminish access to effective pain treatments for people who need them.

According to statistics from the Centers for Disease Control and Prevention, pain is a serious and costly public health issue, impacting 76.5 million Americans. Community pharmacists play an integral role in assuring that these patients have timely access to controlled substances and in the process provide vital counseling to ensure that these medications are not misused, abused or diverted.

The fact that nearly 70 percent of prescription drug abusers obtain unused prescription drugs from the family medicine cabinet or friends, should serve as a vital reminder that efforts to curb abuse and diversion must be focused in part on assuring appropriate quantities are dispensed in the first place, and that there is proper disposal of unused products. NCPA eagerly awaits regulations from the DEA that will pave the pathway for increased opportunities for patients to dispose of unused controlled substances. Many of our pharmacies serve as drop off points for patients for unused or unwanted medications – however, we cannot by law take back controlled substances.

Role of the Community Pharmacist and Prescribers in Efforts to Prevent Drug Abuse and Diversion

Community pharmacists recognize the importance of addressing the serious problem of prescription drug abuse. I am deeply saddened each time I hear about the victims of prescription drug abuse and offer my sincerest condolences to families of these needless tragedies. My role as a pharmacist is to ensure that patients have access to the optimal drug therapies as determined by their physician. Unfortunately, the impacts of prescription drug abuse are felt most sharply when there is a breakdown in a system that has been built to ensure the right patient gets the right medications at the right time. I believe that it is through enhanced systems and tools that pharmacists are best prepared to assist in efforts to curb prescription drug abuse.

Community pharmacists hold in high regard their corresponding responsibility, per the Controlled Substances Act, to exercise sound professional judgment when making a determination about the

legitimacy of a controlled substance prescription. We are proud of the fact that most independent community pharmacies have strong, long-lasting, face-to-face, personal relationships with their patients and the prescribers in their communities. This in fact serves as a deterrent to abuse because we know our prescribers and our patients, making it easier for us to detect a "doctor shopper" just looking for more controlled substances.

At the same we time, we support a more systems-based approach to controlling abuse and diversion. Everyone needs to be involved: patient, pharmacist, pharmacy benefit manager (PBM), wholesaler, manufacturer, and prescriber.

For example, there are proposals that would require prescribers to obtain additional education or certification on understanding addiction to and abuse of controlled substances and their appropriate and safe use by tying such education to the prescribers DEA registration number. NCPA supports such proposals and we think that fewer large quantities of pain medications should be prescribed and dispensed in the first place. We are particularly concerned about large quantities of controlled substances that are sent to patients from mail order pharmacies, and are often automatically refilled.

We support efforts that include appropriately structured FDA Risk Evaluation and Mitigation Strategies (REMS), prescription drug monitoring programs (PDMPs), and electronic prescribing, which can help to alleviate some of the problems with drug diversion once systems are in compliance with DEA requirements. In fact, NCPA played an active role in the "Enhancing Access to PDMPs Project", managed by the Office of the National Coordinator, and supports the goal of using health information technology to increase timely access to PDMP data.

Pharmacies believe that PDMPs can be more effective as they move toward real-time reporting systems and integration into pharmacy workflow processes. However, today's PDMP systems are not able to detect doctor shopping because of lags in data reporting, in addition to the dearth of prescribers who actually use the systems before a prescription is written. Having said this, community pharmacies are concerned that they would be put in the position of serving as "police man" once they check the database and see that a person has in fact had multiple prescriptions filled for controlled substances. There are cases where legitimate prescriptions would otherwise be blocked from dispensing based on PDMP data alone. The pharmacists' judgment in these situations must be protected.

Illegal Internet Pharmacies Continue to Contribute to Drug Abuse and Diversion

Purchasing prescription drugs without a prescription remains a viable option as illegitimate drug distributors continue to host Web sites that will ship drugs to anyone regardless of their need for the drug. Many of these Websites dispense medications without a valid prescription, as required by the Federal Food, Drug, and Cosmetic Act. Rogue, illegitimate drug trafficking operations are anathemas to legitimate independent community pharmacies. They are hazardous to patient safety, and create among both the general public and policymakers underserved negative impressions of pharmacists and the valuable practice of pharmacy.

As a solution to stop illegal internet pharmacies from distributing dangerous drugs, NCPA was a strong supporter of including The Online Pharmacy Safety Act (S. 2002¹ / H.R. 4095) in this year's reauthorization of the Prescription Drug User Fee Act (PDUFA). Although not included in PDUFA, NCPA will continue to support efforts leading to passage of this important legislation.

Proper PBM Edits Needed to Assist With Prevention of Diversion and Abuse

In addition to efforts to better educate prescribers, pharmacy benefit managers (PBMs) should be more accountable for monitoring patient use of controlled substances and preventing drug diversion. Even though many prescriptions that may be associated with efforts to divert are paid for in cash, there are many that go through the third party insurance adjudication process. And for those that are paid by cash I will ask for valid identification from these patients and will verify prescriber intent if I have any questions. However, this can oftentimes be difficult if the patient is presenting a prescription written by a large medical center or county hospital.

From the time the prescriber chooses a medication to the time that it is dispensed, PBMs should provide more information to health care professionals that can help us make better decisions, such as providing the complete patient medication profile, when or where other prescriptions for these products have been filled, and the identity of the prescriber. There might even be a way to connect PBM systems into PDMP systems to allow such information to be available to the prescriber and the pharmacist in real time.

PBMs should also be held accountable for the fact that they dispense large quantities of controlled substances through the mail. Oftentimes, certain medications that are prescribed will not work for a patient, the patient only needs a few doses, or the patient expires, which can mean these large quantities can go to waste. Having these large quantities of controlled substances sitting around patients' homes does not serve the public interest.

In sum, PBM's should provide more robust information to both pharmacists as well as prescribers, which is made more possible with the expanded use of electronic prescribing, but should not be the deciding factor in whether a prescription is ultimately dispensed or not.

The Unintended Patient Care Consequences of DEA's Increased Efforts to Block Diversion of Prescription Drugs

The DEA states that their increased efforts to block the diversion of prescription drugs to the black market by using many of the techniques it employs to combat illegal drug use have resulted in a substantial dismantling of "pill mills". NCPA appreciates these efforts as we believe that inappropriate prescribing is a primary culprit of the overall problem. However, NCPA has serious concerns with the fact that the DEA is now using the same tactics to prosecute the legitimate pharmaceutical supply chain, including increased inspections and fines against drug wholesalers, which ultimately leads to severe consequences for independent community pharmacies. These consequences include wholesalers cutting off all controlled substance supplies to certain legitimate independent pharmacies, with prescription orders of controlled substances going unfilled. Many independent pharmacies cannot obtain medications for their patients, and are fearful and reluctant to service legitimate patients in pain.

¹ NCPA is supportive of H.R. 4095 and the revised Senate bill (as a substitute) which incorporates various important changes made in the House.

The wholesalers are being targeted for failure to detect "suspicious" order volume from several pharmacy customers. For example, over the past five years, Cardinal has publicly stated they have cut supplies of controlled substances to more than 375 customers nationwide, including 180 pharmacies in Florida. Every one of these customers is an independent pharmacy and nearly 70 percent still have active DEA registration numbers. NCPA contends the fact that so many of these pharmacies still have their registrations means that more clarity is needed from the DEA as to what constitutes excessive orders.

Independent pharmacies that have had controlled substance orders halted by their wholesaler have relayed to NCPA that there is no consistent reasoning behind what constitutes excessive orders. Some wholesalers refer to reasons such as ratios of controlled to non-controlled substances, dosage units per month, specific spikes in volume, and dollar amount of orders.

These wholesaler actions have put many independent pharmacies in the untenable position of having to find a back-up wholesaler quickly, oftentimes while having to legally challenge their wholesaler decision to halt controlled substance deliveries. Unfortunately this is causing hardships for independent pharmacies that are primarily located in and serve more rural populations. There is a perception that independents are being targeted for reasons beyond their control such as a lack of ability to self-warehouse, perceived less stringent internal controls, and/or decreased legal capabilities, among others. The DEA must recognize that their actions on wholesalers are having detrimental impacts on legitimate small-business independent community pharmacy owners who are practicing pharmacy to the full extent authorized under the law.

Lastly, NCPA questions if the DEA and/or wholesalers take into account mail order pharmacies when determining which pharmacies to target to combat prescription drug abuse? Mail order pharmacies dispense large quantities of controlled substances to patients they do not have a personal relationship with. Nor do they have a relationship with the prescribers whose prescriptions they fill. Many of our pharmacies report that the majority of controlled substances that patients seek to return to pharmacies (which we cannot take back) are from mail order outlets that shipped excessive controlled substances to patients that did not need them simply because they were on 'automatic' shipment.

Preventing Pharmacy Crime

Equally important to preventing doctor shopping and drug diversion fueled by prescription drug abuse are stronger efforts to crack down on pharmacy crime. There were 686 armed robberies of pharmacies in 2010 and over 1,800 pharmacies nationwide have been robbed in recent years. In fact, armed robberies of pharmacies rose 81% between 2006 and 2010. Unfortunately, some of these incidents resulted in senseless deaths. The Caucus is probably already all too aware of the number of high profile pharmacy murders in the last two years, including two highly publicized pharmacy murders in New York.

Pharmacies, particularly, small, independent community pharmacies are sitting ducks for burglaries and armed robberies. Unlike chain drug stores, small, independent community pharmacies do not have the resources to hire security personnel or purchase expensive security systems or safes. Pharmacy crime has become such an epidemic that extraordinary preventive measures are now required, but such preventative measures are also extraordinarily expensive. For my pharmacy alone I have spent over twenty-thousand dollars to install security measures that are in response to three burglaries of my store.

Accordingly, NCPA recommends the following legislative initiatives to address the scourge of pharmacy crime across the United States:

- Provide tax incentives for pharmacies to adopt safety and crime prevention measures. More specifically, allow pharmacies to take an upfront deduction for purchases of security measures instead of spreading out the tax deduction over a period of years, as is now required.
- Pass legislation to shut down pill mills, which are encouraging addiction, creating a thriving black market for narcotic drugs and fueling desperate criminals to rob pharmacies. NCPA was pleased to note that DEA data illustrates a 97% decrease in oxycodone purchases by doctors in Florida from 2010 to 2011, following implementation of new state laws in 2011.
- Improve communication between federal and state law enforcement to better coordinate prosecution of pharmacy crime. NCPA is concerned that all too often the respective federal, state and local law enforcement agencies are unaware of what the other is doing.
- Hold Congressional oversight hearings on pharmacy crime to examine the scope of pharmacy crime problem, and the extent to which the federal government is enforcing existing laws against pharmacy crime, including the actions of the FBI, DEA and US Attorneys' offices.

In Conclusion

NCPA is committed to working with Members of Congress and state and local law enforcement officials to combat the abuse and diversion of prescription drugs and is committed to working towards sensible solutions. We need a system-wide approach and improved tools to address this issue. Thank you for your time and for the opportunity for us to share the viewpoints of independent community pharmacy.