

Testimony

of the

**American
Pharmacists
Association**

**To Do No Harm: Strategies for
Preventing Prescription Drug Abuse**

**Submitted to the
Government Reform Committee's
Subcommittee on Criminal Justice, Drug
Policy and Human Resources**

**United State House of Representatives
February 9, 2004**



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**Investigative Hearing on
To Do No Harm: Strategies for Preventing Prescription Drug Abuse**

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Good afternoon, Mr. Chairman and Members of the Committee. I am Theresa Wells Tolle, a pharmacist and owner of Bay Street Pharmacy in Sebastian, Florida. I am here today representing the American Pharmacists Association (APhA). APhA, founded in 1852 as the American Pharmaceutical Association, represents more than 50,000 practicing pharmacists, pharmaceutical scientists, student pharmacists, and pharmacy technicians. APhA is the first-established and largest national association of pharmacists in the United States.

APhA welcomes the opportunity to present the pharmacist's perspective on the abuse of prescription drugs, including controlled substances. APhA and its members are committed to working with Congress, the Food and Drug Administration (FDA), the Drug Enforcement Administration (DEA), other health care providers, and patients to find the appropriate balance between appropriate medication use and measures to curb the abuse and diversion of prescription drugs. As the medication experts on the health care team, and the health professionals dedicated to partnering with patients to improve medication use, we appreciate the opportunity to discuss the importance of striking a balance between providing effective, legitimate, appropriate health care and preventing prescription drug abuse and diversion.

The Pharmacist's Role in Improving Medication Use: Limiting Diversion & Abuse

Prescription medications are safe and effective when used appropriately, but they can be deadly when used incorrectly. My colleague pharmacists and I are the health care providers who work most closely with patients to make certain patient use of medications is appropriate. Prescription drug abuse is one type of medication misuse — misuse that we try to prevent. Pharmacists work collaboratively with prescribers and other health care providers to prevent the diversion of prescription medications and to identify incidents of abuse or addiction. As part of this process,

pharmacists assess the appropriateness of every prescription order they review or dispense. I watch for individuals who attempt to fill fraudulent prescriptions, visit multiple prescribers, or present prescriptions for unusually large quantities of medication. Every day, pharmacists assess the validity of prescriptions, watching for errors in the content or format of the communications. However, it is not always easy to determine if a prescription is legitimate – no simple algorithm determines appropriate use. And importantly, I cannot view every patient as a potential drug abuser without compromising my responsibilities as a health care professional.

Identifying potential drug abusers is an area where collaborations with regulatory agencies makes sense. For example, the Florida Department of Health recently barred one of Florida's most prolific Medicaid prescribers from issuing any more prescriptions for controlled substances. Having either the Florida Board of Medicine or the Florida Department of Health provide this information to the pharmacist community would help educate pharmacists about potentially illegitimate prescriptions. Another area of collaboration between regulatory authorities and pharmacists is occurring now in my practice. The narcotics detective of our local Sheriff's Department now informs pharmacists about a potential drug abuser as well as when a local prescriber's prescription blanks have been stolen. These efforts help pharmacists determine whether a prescription is legitimate. In both of these examples, the regulatory authorities are helping pharmacists by providing them information. However, in both examples, the pharmacist has the final say in whether or not the prescription is for legitimate purposes — a determination they must make for every prescription presented to them.

Developing Appropriate Interventions

APhA fully supports efforts to examine possible strategies to reduce the abuse and diversion of prescription medications without restricting access to drugs for patients with legitimate medical need. In October 2001, APhA, in collaboration with 20 other health care organizations and the DEA, released a joint consensus statement on the need to prevent abuse of prescription medications while ensuring that they remain available for patients in need. Focusing on the subset of medications known as opiate analgesics, the groups recognized that for many patients, opiate analgesics are the only treatment option to provide effective and significant pain relief. However, a narrow focus on the abuse potential of a drug could erroneously lead to the

conclusion that these medications should be avoided when medically indicated—generating a sense of fear rather than respect for their legitimate purpose.¹

APhA generally supports the FDA’s and the DEA’s efforts to ensure that legitimate users of prescription medications maintain the ability to continue using these products, while reducing their diversion and abuse. Although APhA agrees that some action is necessary to address the diversion and abuse of prescription medications, we know that some well-intentioned interventions can actually create new problems. We caution, for example, against efforts to restrict the distribution of certain medications or arbitrarily limit health care providers’ ability to prescribe or dispense appropriate medications. With every barrier erected to limit diversion, the potential for those barriers to diminish appropriate prescribing increases exponentially. Restrictions in the drug distribution process can disrupt patient care by delaying access to medication therapy, disrupt existing patient-pharmacist-prescriber relationships, and potentially create an increase in the cost of medications. Also, any additional stigma attached to the drugs will have a significant chilling effect on health care providers’ willingness to prescribe and dispense appropriate medication and patients’ interest in using the medications. Decreasing the number of patients using a medication may be seen as a “success” in managing risk. But this “success” is tempered by the accompanying “failure” of patients with legitimate need to access the same medication.

Measures to curb abuse and addiction should be attempted, but measures that simply increase providers’ paperwork or restrict access to one troublesome product will not solve the problem. Those suffering from chemical dependency will find another way to obtain the product or find another product to achieve the same effect. These individuals need help to treat their substance abuse and addiction. Efforts to limit abuse and diversion should be developed in collaboration with health professionals and consumers, and designed for maximum benefit and minimum intrusion. State-level tracking systems, when well-constructed, can provide this benefit. Well-constructed programs provide prescribers and pharmacists with relevant, timely information

¹ A Joint Statement From 21 Health Organizations and the Drug Enforcement Administration. *“Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act.”* Oct. 2001.

about dispensed medications. But such databases targeting abuse and diversion should not be confused with clinical programs to more broadly improve medication use.

These examples demonstrate the need for collaboration when developing interventions to limit prescription drug abuse and diversion. While it may sound trite, every action has a reaction — in this situation, some reaction that is positive, some reaction that is not. In 1982, for example, the state of Texas implemented a triplicate prescription law for controlled substances. A subsequent study of a 1200-bed teaching hospital found a 60% decrease in prescriptions for Schedule II controlled substances from 1981 to 1982.² This shows that simply increasing recordkeeping requirements discouraged use of these medications. It is highly unlikely that 60% of these prescriptions were unnecessary. And in a survey conducted by New York State’s Public Health Council, 71% of physicians surveyed reported that they do not prescribe the most effective pain medication for cancer patients if the prescriptions require a special state-monitored prescription form for controlled substances—even when the medication is legal and medically indicated for a patient.³

We respect the desire to heighten regulation in this area, and cautiously support such efforts. Federal enforcement agencies, such as the DEA, should continue to be a law enforcement agency fighting the illegal diversion of drugs. But the DEA should not be turned into a medical oversight body – a task for which it is unsuited. Providing a government agency the explicit authority to question the intent of any physician or medical practitioner who authorized the use of a medication for a patient could increase doctors’ reluctance to prescribe drugs resulting in more patients suffering, especially at the end of life. Drug therapy should be managed by healthcare professionals – physicians, nurses, and pharmacists – not by federal law enforcement officers. The very threat of regulatory intervention and oversight – and the fear of having their intentions misconstrued – could dissuade physicians from using aggressive efforts that are often needed to use medications effectively.

² Sigler K, Guernsey B, et al. Effect of a Triplicate Prescription Law on Prescribing of Schedule II Drugs. *American Journal of Hospital Pharmacy* 41 (1984), 108-111.

³ New York State Public Health Council, Report to the Commissioner of Health, *Breaking Down the Barriers to Effective Pain Management: Recommendations to Improve the Assessment and Treatment of Pain in New York State*, January 1988.

Furthermore, non-medical enforcers will face substantial problems in distinguishing between legitimate medical use of prescription medications. Drawing the line is not easy for healthcare professionals with years of experience. It certainly will not be easy for law enforcement officers with no medical training. For example, many patients can tolerate and indeed require extremely high doses of controlled substances to relieve their pain and other symptoms. Health professionals have concerns with regulators making this distinction, and many do not feel secure that they will be protected if they aggressively manage pain with opioids.

Manufacturer-Level Efforts

APhA understands that one strategy to reduce the abuse and diversion of prescription medications has already been initiated by drug manufacturers. These efforts include reformulating products to reduce the potential for abuse. Certain additions to the medication can limit abusers who crush and inject the drug from obtaining the desired “high.” APhA supports these product development efforts to reduce the potential for abuse of drug products and we encourage Congress and the FDA to work with manufacturers to accelerate the development and approval of reformulated versions. Reformulated versions continue to provide patients with effective pain management, while removing the stimulus for illegal abuse, and importantly for pharmacists, lessen the potential for pharmacy robberies related to prescription drug abuse.

Conclusion

It is important that patients do not lose access to valuable and effective medications because of a failure to prevent medication misuse. Any solutions must not have a chilling impact on effective drug therapy management. The solution requires the education of health care professionals, law enforcement personnel, and the public on the use and abuse of prescription medications.

Thank you for your consideration of the views of the nation’s pharmacists. APhA looks forward to working with the Committee to develop a safer and more effective system of providing prescription medications to all Americans.