



TESTIMONY OF

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GENERIC PHARMACEUTICAL ASSOCIATION

**HEARING ON “WARNING: THE GROWING DANGER OF
PRESCRIPTION DRUG DIVERSION”**

BEFORE THE
ENERGY AND COMMERCE SUBCOMMITTEE ON COMMERCE,
MANUFACTURING AND TRADE

U.S. HOUSE OF REPRESENTATIVES
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Good morning Chairwoman Bono Mack, Ranking Member Butterfield, and Members of the Energy and Commerce Subcommittee on Commerce, Manufacturing and Trade.

My name is John Coster, Senior Vice President of Government Affairs at the Generic Pharmaceutical Association (GPhA) and a licensed pharmacist. On behalf of GPhA and our member companies, thank you for calling this hearing and for the opportunity to testify on the very important subject of prescription drug diversion. We applaud your leadership on this issue.

Background on Generic Drug Industry

Let me begin by giving some background on the role of the generic drug industry in the U.S. About 75 percent of all prescriptions are filled with generic medications. Yet, generics account for only about 22 percent of total drug spending. We are proud that our industry helps make high-quality, safe, effective prescription medicines more affordable for millions of Americans while saving the health care system billions of dollars each year.

In fact, based on a 2010 analysis by IMS Health, the use of generic drugs saved the government and other purchasers of prescription drugs more than \$824 billion over the past decade. Generics now save consumers and taxpayers about \$1 billion every three days. Through competition, generic manufacturers drive down costs and support public health by providing access to affordable medicine.

GPhA's member companies manufacture FDA-approved generic versions of brand name drugs in all therapeutic categories, including prescription pain killers. We are as concerned as the Members of this Committee when medications that are made to improve lives or alleviate pain are abused.

We believe that addressing this issue will require continued coordination among Federal and State agencies, state, local, and Federal law enforcement, health professionals, drug manufacturers, pharmacists, patients and their families. Because it is a multifaceted problem, it requires a multifaceted solution.

And as we work together to shape public policy to end the misuse of pain medications, we must recognize that the overwhelming majority of individuals, including millions of seniors and cancer patients, rely on these important drug products for the proper treatment of pain.

Security of Prescription Drug Supply Chain

GPhA member companies are absolutely committed to the safe and reliable manufacturing and delivery of generic drugs. As an industry, we have invested millions of dollars into technologies and delivery systems to help assure that our products reach their destination safely and securely.

For example, with respect to opioid pain medicines, under the Federal Controlled Substances Act, the DEA has a “closed” system of distribution to prevent diversion. Our industry works with the DEA to assure that these products do not fall into the hands of abusers. For example, the DEA administers drug allotment and accountability systems to ensure against the loss and diversion of controlled substances. In addition, we are required under DEA regulations to:

- Maintain steel vaults in our manufacturing facilities of specific shape and size to protect against theft;

- Build special cages to store controlled substances with ceiling and doors made of specific reinforced material, with certain alarm systems to protect against theft;
- Restrict access to areas which manufacture or hold controlled substances;
- Develop a system to identify suspicious orders of controlled substances to guard against them falling into the wrong hands.
- Utilize systems such as GPS tracking to continuously monitor the delivery of these controlled substances once they leave secure manufacturing and storage facilities.

Manufacturers typically ship to wholesalers or distributors, who in turn sell the drugs to all kinds of health care outlets, including pharmacies, hospitals, clinics, doctors' offices, nursing homes, mail order facilities and others for prescribing by physicians and dispensing to patients and consumers. Addressing the abuse and diversion issue will require cooperation of all these parties in the supply chain.

Main Source of Prescription Diversion

Recent studies suggest that the problem of prescription drug abuse in the U.S. today primarily stems not from drugs that have escaped the legitimate supply chain or been obtained illegally through the black market, but instead from those that were legally prescribed and available in the home.

According to the 2009 National Study of Drug Use and Healthⁱ, 55 percent of people aged 12 or older who used pain relievers nonmedically in the previous year obtained those drugs from a friend or relative for free. In addition, another 10 percent bought their drugs from a friend or relative and 5 percent took them from a friend or relative without asking. That

means that close to 70 percent of people abusing prescription drugs were doing so with products they obtained from a friend or relative.

Why are people able to share these medications with others? Shouldn't they have already taken these medications? Medication non-compliance is a huge problem in the United States.

When medications go unused, it can cost the health care system billions of dollars in other medical interventions because of medication non-adherence. It is common to find that many medicine cabinets in America are stocked with unused prescription medications. Some of these may be for occasional mild conditions, such as allergy, while others may be unused medications that were prescribed to treat the discomfort from a surgery, such as a pain medication.

Many Americans have had no recourse to return these unused medications – especially controlled substances – because Federal law prohibits the transfer of controlled substances from an ultimate user to anyone other than law enforcement. That is, patients can't return unused controlled substances to pharmacies or other non law enforcement entities at this time.

This will soon change as DEA implements the Safe and Secure Drug Disposal Act of 2010, which will permit ultimate users – such as patients with excess controlled substances in their medicine cabinets – to return them to DEA registrants such as willing pharmacies – so they can be destroyed. The law also allows for such returns of controlled substances from nursing homes, which is also a source of controlled substance waste, as many nursing home patients expire or have their medication changed before all of it is used.

Congress also enacted a policy as part of the health care reform law, which would require that medications such as brand name pain killers only be dispensed to Part D patients in nursing homes in limited supplies so to avoid waste, prevent potential diversion, and reduce costs. As is evident, there are several ways that this issue must be addressed in order for us to continue to reduce the potential for diversion of these medications.

Generic Drug Industry Efforts to Reduce Diversion

What has our industry been doing to help address this problem? In general we have tried to support efforts that are dedicated to raising awareness to the dangers of prescription drug abuse as well as the need to properly dispose of unneeded or unwanted prescription medications.

We think that education is a key component to addressing this issue. For example, we help to support efforts such as the *American Medicine Chest Challenge*, which is a community-based public health initiative, with law enforcement partnership, to raise awareness about the dangers of drug abuse and provide a nationwide day of disposal for the collection of unwanted or expired medications. We are also members of SmartRx, an educational initiative that raises awareness about the proper way to dispose of unused or unwanted medicine. GPhA is also a Board Member of the National Council on Prescription Information and Education – known as NCPIE. This is a broad-based coalition focused on addressing and raising awareness about prescription drug abuse. For example, NCPIE most recently developed a College Resource Kit to help educate students about the dangerous of prescription drug misuse.

In addition, over the last few years, our industry companies have also focused efforts in this area by joining with the brand name industry, patient groups and the FDA on working on a REMS program for long acting and extended release opioid medications.

REMS – short for Risk Evaluation and Mitigation Strategies – are special programs that are used by the FDA to help prevent adverse outcomes in patients from prescription medications.

At this point, it is not clear how FDA intends to proceed with the REMS program for these products. We believe that an efficient, effective REMS could help improve the use of these medications and address some of the abuse problems that exist. We also believe that this REMS program could be enhanced by e-prescribing, which would give physicians more information about these medications at the point of prescribing.

Conclusion

Madame Chairwoman, we applaud you for the countless hours you have devoted to raising awareness about this issue and the great work you have done to help put an end to drug diversion and misuse. You know more than anyone that the problem of prescription drug abuse in this country is a multi-faceted issue that will require a multi-faceted solution.

With the cooperation of physicians, law enforcement and others we can expand education efforts and help to ensure that parents and family members are not alone in this fight. When 70 percent of people abusing prescription drugs in this country are getting those products directly from a friend or relative, it's going to take intervention and hard work from all of us at the most personal level to really make a difference.

Thank you, Madame Chairwoman, for holding this important hearing and I would be happy to answer any questions you may have.

¹ <http://oas.samhsa.gov/NSDUH/2k9NSDUH/2k9ResultsP.pdf>