SUMMARY OF THE GENERIC PHARMACEUTICAL ASSOCIATION TESTIMONY
BEFORE THE ENERGY AND COMMERCE SUBCOMMITTEE ON COMMERCE, MANUFACTURING, AND TRADE
UNITED STATES HOUSE OF REPRESENTATIVES – MARCH 1, 2012
"PRESCRIPTION DRUG DIVERSION: COMBATING THE SCOURGE"

I am David Gaugh, Vice President for Regulatory Sciences at the Generic Pharmaceutical Association and a licensed pharmacist. GPhA represents the manufacturers and distributors of finished dose generic pharmaceuticals, manufacturers and distributors of bulk pharmaceutical chemicals and suppliers of other goods and services to the generic industry. Generic pharmaceuticals fill 80 percent of the prescriptions dispensed in the U.S. but consume just 25 percent of the total drug spending.

GPhA's member companies manufacture FDA-approved generic versions of brand name drugs in all therapeutic categories, including prescription pain killers. We share the concern of the members of this committee when medications that are made to improve quality of lives or alleviate pain are abused. We must also recognize that the overwhelming majority of individuals, including millions of seniors and cancer patients, rely on these important drug products to treat pain. In our collective efforts to curb drug diversion, we must be careful not to inadvertently punish the patients who need these medicines. Rather, we should punish the criminals who illegally acquire and sell these products outside the normal chain of distribution.

Security of Prescription Drug Supply Chain
As an industry, we have invested millions of dollars in technologies and delivery systems to help assure that our products reach their destination safely and securely. For opioid pain medicines, the DEA has a closed system of distribution to prevent diversion, and our industry works with the agency to assure that these products do not fall into the hands of abusers. We do not believe that reevaluating the DEA quota system is an appropriate way to address concerns with prescription drug abuse, as further restrictions could hinder access to important therapies for patients.

GPhA has also been participating with the Pharmaceutical Distribution Security Alliance (PDSA) to develop a consensus technological model for increasing the security of the drug supply chain in the U.S. Manufacturers have committed to maintaining a database that would associate unit-level data with lot numbers of products, delivering greater patient safety and enhancing the identification of suspect product. It is also important to understand that the diversion of prescription drugs away from the intended user or the intended use could occur at various points within the normal supply chain. The cooperation of all parties will be required if we are to truly address the issue of drug diversion and abuse.

Main Source of Prescription Diversion
No matter how secure we make the supply chain for prescription drugs, ensuring the safe use of these products is a responsibility that rests with all of us inside of our own homes. In fact, 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.

Generic Drug Industry Efforts to Reduce Diversion
The generic drug industry has been a leader in addressing the problem of drug diversion. We believe that education is a key component to addressing this issue and, as such, support efforts such as the *American Medicine Chest Challenge,* a community-based public health initiative. We are also members of SmartRx, an educational initiative that raises awareness about the proper way to dispose of unused or unwanted medicine, and the National Council on Prescription Information and Education (NCPIE), which is a coalition focused on addressing and raising awareness about prescription drug abuse. In addition, over the last few years, our industry has focused its efforts in this area by joining with the brand-name industry, patient groups and the FDA to develop a Risk Evaluation and Mitigation Strategies (REMS) program for long acting and extended release opioid medications.

TESTIMONY OF

DAVID R. GAUGH., R.PH.

VICE PRESIDENT FOR REGULATORY SCIENCES

GENERIC PHARMACEUTICAL ASSOCIATION

HEARING ON "PRESCRIPTION DRUG DIVERSION: COMBATING THE SCOURGE"

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

U.S. HOUSE OF REPRESENTATIVES
MARCH 1, 2012

Good morning Chairman Bono Mack, Ranking Member Butterfield, and members of the Energy and Commerce Subcommittee on Commerce, Manufacturing and Trade. I am David Gaugh, Vice President for Regulatory Sciences at the Generic Pharmaceutical Association and a licensed pharmacist. GPhA represents the manufacturers and distributors of finished dose generic pharmaceuticals, manufacturers and distributors of bulk pharmaceutical chemicals and suppliers of other goods and services to the generic industry.

Prior to joining GPhA, I was Vice President and General Manager for Bedford Laboratories, the generic injectable division of Ben Venue Laboratories. I have also served as Senior Director, Pharmacy Contracting and Marketing, for VHA/Novation, one of the largest Group Purchasing Organizations in the U.S., and was System Director of Pharmacy for a regional referral tertiary-care healthcare system in the Midwest.

Background

Let me begin by giving some background on the role of the generic drug industry in the United States. Generic pharmaceuticals now fill 80 percent of all prescriptions dispensed in the U.S., but consume just 25 percent of the total drug spending for prescription medicines.

According to a 2011 analysis by IMS Health, the world's leading data source for pharmaceutical sales, the use of FDA-approved generic drugs in place of their brand counterparts has saved U.S. consumers, patients and the health care system more than $931 billion over the past decade — $158 billion in 2010 alone — which equates to $3 billion in savings every week.

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

We believe that addressing this issue will require continued coordination among Federal agencies, state, local, and Federal law enforcement, health professionals, drug manufacturers, patients and caregivers. And as we work together to shape public policy to control 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 to treat pain. In our collective efforts to curb drug diversion, we must be careful not to inadvertently punish the patients who need these medicines. Rather, we should punish the criminals who illegally acquire and sell these products outside the normal chain of distribution.

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 in 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, and our industry works with the agency to assure that these products do not fall into the hands of abusers. 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 ceilings 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; and
- Develop a system to identify suspicious orders of controlled substances to guard against them falling into the wrong hands.

Like other manufacturers, our members employ systems such as GPS tracking to monitor the delivery of these controlled substances once they leave the manufacturing facilities.

The DEA also administers drug allotment and accountability systems to ensure against the loss and diversion of controlled substances.

While some have questioned whether this quota system needs to be reevaluated, we do not believe that doing so is an appropriate way to address concerns with prescription drug abuse. Further restrictions on the quota system could hinder access to important medical therapies for the patients who rely on them. For example, there are drugs specifically designed to treat Attention Deficit Disorder and Attention Deficit Hyperactivity Disorder (Ritalin and Adderall) in the quota system that are on FDA's drug shortage list. The quota system cuts both ways and we are concerned that if Congress starts to tip the balance in the quota system, it could have unintended consequences.

GPhA has also been participating with the Pharmaceutical Distribution Security Alliance, or PDSA, to develop a consensus technological model for increasing the security of the drug supply chain in the U.S. As part of this model, manufacturers have committed to maintaining a database that would associate unit-level data with lot numbers of products.

GPhA believes this model will deliver greater patient safety and help to achieve FDA's stated goals of enhancing the identification of suspect product.

Having said this, it is also important to understand that the diversion of prescription drugs away from the intended user or the intended use could occur at various points within the normal supply chain as products make their way from manufacturer to the patient and beyond.

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 by health care professionals to patients and consumers. The cooperation of all these parties will be required if we are to truly address the issue of drug diversion and abuse.

Main Source of Prescription Diversion

But no matter how secure we make the supply chain for prescription drugs, ensuring the safe use of these products is a responsibility that rests with all of us inside of our own homes. In fact, 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 2010 National Study of Drug Use and Health[i], 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 11 percent bought their drugs from a friend or relative and 5 percent took them from a friend or relative without asking. That means that more than 70 percent of people abusing prescription drugs were doing so with products they obtained from a friend or relative.

Medication non-compliance represents an additional and significant problem. When medications go unused, it can cost the health care system billions of dollars in other medical treatments 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 allergies, 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 are unable to return unused controlled substances to pharmacies or other non law enforcement entities at this time.

This is already changing 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

The generic drug industry has been a leader in addressing the problem of drug diversion. We believe that education is a key component to addressing this issue and, as such, support efforts such as the *American Medicine Chest Challenge,* which is a community-based public health initiative, partnering with law enforcement, 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, and the National Council

on Prescription Information and Education – known as NCPIE - which is a coalition focused on addressing and raising awareness about prescription drug abuse.

In addition, over the last few years, our industry has focused its efforts in this area by joining with the brand-name industry, patient groups and the FDA to develop 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.

The intended goal of this effort was to help reduce the potential for abuse, misuse, overdose and addiction, through the education of key participants about the risks associated with these medicines and the proper, legitimate medical use of these drugs. Participants in this collaboration included physicians, nurses, pharmacists and patients. However, the group was also committed — as we believe was FDA — to assure that any REMS program did not impede access to these medications for patients in pain, which, again, are the overwhelming majority of patients who take these 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 the REMS program could be enhanced by e-prescribing, which would give physicians more information about these medications at the point of prescribing.

Conclusion

Madame Chairman, thanks to your tireless efforts to combat the problem of prescription drug abuse in this country, you know more than anyone that this 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 more than 70 percent of people abusing prescription drugs in this country are getting those products directly from a friend or relative, it is clearly going to require the hard work and dedication of all of us to truly make a difference.

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

[i] http://www.oas.samhsa.gov/NSDUH/2k10NSDUH/2k10Results.pdf.