



THE COMMITTEE ON ENERGY AND COMMERCE

INTERNAL MEMORANDUM

April 12, 2011

To: Members of the Subcommittee on Commerce, Manufacturing, and Trade
From: Majority Committee Staff
Re: Hearing on “Warning: The Growing Danger of Prescription Drug Diversion”

I. Summary

On Thursday, April 14, 2011, at 9:00 a.m., the Subcommittee on Commerce, Manufacturing, and Trade will hold a hearing entitled “Warning: The Growing Danger of Prescription Drug Diversion” in 2123 Rayburn House Office Building. Witnesses are by invitation only.

II. Witnesses

Four panels of witnesses will testify before the Subcommittee.

Panel I

The Honorable Rick Scott, Governor, State of Florida
The Honorable Steve Beshear, Governor, Commonwealth of Kentucky
The Honorable Gil Kerlikowske, Director, Office of National Drug Control Policy
The Honorable Michele M. Leonhart, Administrator, Drug Enforcement Administration

Panel II

Phil Bauer, Surviving Father of Mark Bauer; Parent Advisory Board Member, Partnership for a Drug-Free America
Courtney Creedon, Surviving Sister of Ryan Creedon
Kathy Creedon, Surviving Mother of Ryan Creedon; Founder, Mothers Against Prescription Drug Abuse
April Rovero, Surviving Mother of Joey Rovero; Founder of National Coalition Against Prescription Drug Abuse; Parent Ambassador, Partnership for a Drug-Free America
Dan Harrison, Drug Court Graduate
Dr. Carol Boyd, PhD, RN, Fellow of the American Academy of Nursing; Professor of Nursing and Director of the Institute for Research on Women and Gender, University of Michigan-Ann Arbor
Dr. Amelia M. Arria, PhD, Director, Center on Young Adult Health and Development, University of Maryland

Panel III

Sean Clarkin, Executive Vice President and Director of Creative Development, Partnership for a Drug-Free America
General Arthur Dean, Chairman and CEO, Community Anti-Drug Coalitions of America

Dr. John Coster, PhD, R.Ph., Senior Vice President of Government Affairs, Generic
Pharmaceutical Association

Kendra Martello, Assistant General Counsel, Pharmaceutical Research and
Manufacturers of America

Michael Mayer, President, Frank Mayer & Associates (manufacturer of MedReturn)

Patrick Coyne, RN, MSN, on behalf of the Oncology Nursing Society; Clinical Director,
Thomas Palliative Care Unit, Virginia Commonwealth University Medical Center

III. Background

According to the Centers for Disease Control and Prevention (CDC), drug (illegal, prescription, or over-the-counter) overdose rates increased fivefold since 1990.¹ Among deaths attributed to drugs, the most common drug categories are cocaine, heroin, and a type of prescription drug called opioid painkillers.² Unintentional poisoning deaths (including both drug overdose in recreational use or excessive use for non-recreational purposes) are the second leading cause of accidental deaths in the United States behind motor vehicle crash fatalities, accounting for over 29,000 deaths in 2007.³ The CDC reports the increase in drug overdose rates is attributable to prescription opioid painkillers.

What are opioids?

Opioids are classified as Schedule II drugs. The U.S. Drug Enforcement Administration (DEA) regulates the legal production of Schedule II drugs and establishes production quotas for both bulk⁴ and procurement⁵ manufacturers. These quotas limit the amount of particular drugs that may be produced while ensuring adequate and uninterrupted supply.

Opioid painkillers reduce pain and, in conjunction with an increasing focus on pain management over the last two decades, have risen in popularity. According to the CDC, there has been a tenfold increase in the medical use of opioid painkillers during that time period. Similarly, because opioids cause euphoria, misuse and abuse of these painkillers has also risen. When taken in excess, however, opioids can suppress breathing and cause death.

The Drug Abuse Warning Network (DAWN) estimates emergency room visits for non-medical use of legal drugs – such as prescription painkillers – equals the number of emergency room visits for illegal drugs. Approximately 30 percent of the emergency room visits for legal drugs involved the use of opioids. Opioid abusers have eight times the direct health care costs as non-abusers, and the estimated cost to society was over \$9 billion in 2005 dollars.

¹ See <http://www.cdc.gov/HomeandRecreationalSafety/pdf/poision-issue-brief.pdf>

² See id. Opioids are a synthetic version of opium. Examples of opioids are oxycodone (and its brand prescription drug OxyContin®), hydrocodone (and its brand prescription drug Vicodin®), and methadone.

³ <http://www.cdc.gov/HomeandRecreationalSafety/Poisoning/poisoning-factsheet.htm>

⁴ A bulk manufacturer makes large quantities of the active pharmaceutical ingredient (API), e.g., oxycodone. The DEA sets manufacturing quotas under 21 USC s. 826.

⁵ A procurement manufacturer is authorized to use the API to manufacture a specific branded or generic drug, e.g. OxyContin. The DEA establishes procurement quotas under 21 CFR s. 1303.12.

Drug diversion and DEA quotas

According to the DEA, most drug diversion happens after the pharmaceuticals leave the manufacturers' warehouses. It is unclear, however, at what level most of the diversion occurs - at the pharmacy level, at doctors' offices, or in the home.⁶ When establishing the appropriate procurement quotas (e.g., the amount a drug manufacturer can produce), the DEA considers the medical need for a drug (as determined by the FDA), the existing inventory, the level of imports and exports, past sales, and diversion.

In determining the diversion factor, the DEA relies upon primarily its case information and theft reports filed by manufacturers in accordance with DEA regulations. These amounts, however, are generally negligible and do not significantly impact a manufacturer's individual quota.

Prescription Drug Take Back Program

According to the Partnership for a Drug-Free America, approximately 2,500 teens every day try prescription drugs for the first time to get high and, according to a 2009 SAMHSA report, nearly 70 percent of those users obtain prescription drugs from the family medicine cabinet or friends.⁷ To stem this alarming tide, Congress passed the Secure and Responsible Drug Disposal Act in October 2010.

Local State and law enforcement agencies have created take-back programs to remove unwanted drugs from households. However, the Controlled Substances Act (CSA) prevented these programs from accepting controlled substances without specific permission from the DEA. This legislation amended the CSA to allow individuals to whom controlled drugs had been legally prescribed the ability to deliver unused and unwanted drugs to individuals authorized under the CSA. Highlighting the potential for success of these State and local programs is the DEA's own National Take Back Initiative. The result was the National Take Back Initiative. The DEA held its first National Take Back Day on September 25, 2010 in conjunction with approximately 3,000 State and local law enforcement agencies, receiving more than approximately 121 tons of pills. The second National Take Back Day will be held on April 30, 2011. The Secure and Responsible Drug Disposal Act permits the DEA to promulgate guidelines.

⁶ A 2009 survey conducted by the HHS Substance Abuse and Mental Health Services Administration (SAMHSA) identifies the following as sources of prescription drugs:

Among persons aged 12 or older in 2008-2009 who used pain relievers nonmedically in the past 12 months, 55.3 percent got the drug they most recently used from a friend or relative for free. Another 17.6 percent reported they got the drug from one doctor. Only 4.8 percent got pain relievers from a drug dealer or other stranger, and 0.4 percent bought them on the Internet.

Available at <http://oas.samhsa.gov/2k10/230/230PainRelvr2k10.htm>.

⁷ <http://oas.samhsa.gov/2k10/230/230PainRelvr2k10.htm>

Alarming Statistics

For first time drug users in 2009, nonmedical use of pain killers was a close second to marijuana. Approximately 2.2 million people ages 12 and older tried prescription pain killers for the first time compared to 2.4 million who tried marijuana for the first time. Those two categories were followed distantly by nonmedical use of tranquilizers at 1.2 million, Ecstasy at 1.1 million, inhalants at 800,000, stimulants at 700,000, and cocaine at 600,000.

While there was a decrease in the rate of nonmedical uses of prescription drugs from 4 percent in 2002 to 3.1 percent in 2009, over that same time, there was an increase specifically among young adults aged 18 to 25 in the rate of current nonmedical use of prescription-type drugs from 5.5 to 6.3 percent.

IV. Questions for Consideration

- Does the DEA consider any data other than diverted drugs of which they have direct knowledge (e.g., a DEA drug bust)?
- Does DEA partner with State and local law enforcement to ascertain how drugs are diverted on the local level?
- Does DEA gather drug statistics from its “drug take back” program?
- Should we consider “non-traditional” take-back mechanisms that do not involve law enforcement at the forefront?
- What is the status of DEA’s drug take-back regulations to be promulgated under the Secure and Responsible Drug Disposal Act of 2010?
- What State level programs and industry-established programs exist to educate parents about the risks of prescription drugs?

Please contact Brian McCullough, Gib Mullan, or Shannon Weinberg at ext. 5-2927 with any questions.