



THE COMMITTEE ON ENERGY AND COMMERCE

INTERNAL MEMORANDUM

February 28, 2012

To: Members of the Subcommittee on Commerce, Manufacturing, and Trade
From: Majority Committee Staff
Re: Hearing on "Prescription Drug Diversion: Combating the Scourge"

On Thursday, March 1, 2012, at 10:15 a.m., the Subcommittee on Commerce, Manufacturing, and Trade will hold a hearing entitled "Prescription Drug Diversion: Combating the Scourge" in 2322 Rayburn House Office Building. Witnesses are by invitation only.

I. Witnesses

Three panels of witnesses will testify before the Subcommittee.

Panel I

The Honorable Richard G. Kerlikowske
Director
Office of National Drug Control Policy

Panel II

The Honorable Pamela Jo Bondi
Attorney General, State of Florida

The Honorable Jack Conway
Attorney General, State of Kentucky

Aaron E. Haslam
Senior Assistant Attorney General, State of Ohio

Joseph T. Rannazzisi
Deputy Assistant Administrator
Drug Enforcement Administration

Panel III

John M. Gray
President & CEO
Healthcare Distribution Management Association

Joseph H. Harmison, R. Ph.
Owner, DFW Prescriptions
on behalf of National Community Pharmacists Association

Kevin N. Nicholson, R. Ph.
Vice President
National Association of Chain Drug Stores

Kendra A. Martello
Assistant General Counsel
Pharmaceutical Research and Manufacturers of America

David Gaugh, R. Ph.
Vice President for Regulatory Science
Generic Pharmaceuticals Association (GPhA)

II. Background

According to the Centers for Disease Control and Prevention (CDC), approximately 27,000 unintentional drug overdose deaths occurred in the United States during 2007—a number that has increased five-fold since 1990.¹ The recent increases in unintentional drug overdose death rates have been driven by an alarming rise in use of a class of prescription drugs called opioid analgesics.² Since 2003, more overdose deaths have involved these prescription painkillers than heroin and cocaine combined. Moreover, for every overdose death, there are nine admissions for treatment of abuse and 35 emergency room visits for misuse or abuse.³

Nearly 7 million people over age 12 reported non-medical use of controlled prescription drugs in 2009, a 12 percent increase over the prior year.⁴ Of those 7 million, approximately 2.2 million users were first-time users of prescription pain killers compared to 2.4 million who tried marijuana for the first time.⁵

Federal Efforts to Prevent Drug Diversion

The Drug Enforcement Administration (DEA) Office of Diversion Control is specifically dedicated to tracking and preventing diversion of prescription drugs. To facilitate DEA's tracking efforts, federal law requires registration of: (1) businesses that import, export, manufacture, or distribute controlled substances; (2) health professionals who prescribe, dispense, or administer controlled substances; and (3) pharmacies that dispense controlled substances. The Office of Diversion Control's investigations include "physicians who sell prescriptions to drug dealers or abusers; pharmacists who falsify records and subsequently sell the drugs; employees who steal from inventory and falsify orders to cover illicit sales;

¹ See CDC Grand Rounds: Prescription Drug Overdoses—A U.S. Epidemic, <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6101a3.htm>.

² *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 *Id.*

⁴ See National Drug Threat Assessment (2011) at 37. Available at <http://www.justice.gov/ndic/pubs44/44849/44849p.pdf>

⁵ *Id.* at 6.

prescription forgers; and individuals who commit armed robbery of pharmacies and drug distributors.”⁶

To assist in the tracking, the Controlled Substances Act requires manufacturers and distributors to report controlled substances transactions. The reporting system used to monitor the flow of controlled substances through the distribution chain, starting at the point of manufacture and ending at the point of sale, is called “ARCOS,” an acronym for the “Automation of Reports and Consolidated Orders System.” ARCOS aggregates all the transaction information and can be used by the DEA and State officials to identify diversions.⁷

State Efforts to Prevent Drug Diversion

A fast-growing problem, 13.9 percent of State and local law enforcement agencies identified controlled prescription drugs as their greatest drug threat in a 2010 survey.⁸ As of June 2011, 48 States have operational prescription drug monitoring programs (PDMP), though some are unfunded or poorly funded.⁹ These programs utilize a State-wide database containing data on controlled substances dispensed within the State to identify, deter, and prevent drug abuse and diversion.

In addition to implementing PDMPs, States are adopting legislation to fight the growing epidemic on other fronts. In 2010, 90 of the 100 most prolific Oxycodone prescribers were in Florida. Since Florida adopted a law that became effective July 1, 2011, to address the drug diversion problems there, that number dropped to 13, with the total number of Oxycodone pills prescribed in the State falling 97 percent.¹⁰ Chief among the law’s changes was a ban on doctors and pain clinics selling prescription painkillers.

Additionally, the law now has new reporting and statutory due diligence requirements for manufacturers, wholesalers, retail pharmacy wholesale distributors, and repackagers. Both in-State and out of State wholesale distributors are required to report distribution information to the State of Florida in the same manner as they report under the DEA’s ARCOS system. Penalties for false reports are treated as a third degree felony.

Wholesale distributors must also conduct due diligence and report “suspicious” orders and transactions. Identifying suspicious transactions includes evaluating the transaction based on the nature of the client’s order history, location and population served, manner of payment, and clinical needs. Due diligence is required prior to distribution

Texas also adopted a law in 2010 targeting pill mills. That law requires clinics to register with and submit to inspections by the Texas Medical Board if half of patients seen are given

⁶ See http://www.deadiversion.usdoj.gov/prog_dscrpt/index.html.

⁷ See <http://www.deadiversion.usdoj.gov/arcos/handbook/section1/1.htm>.

⁸ See id. at 38.

⁹ See id. See also <http://www.usatoday.com/news/nation/story/2011-10-13/pill-mill-drug-trafficking/50896242/1>.

¹⁰ See http://blogs.miaminewtimes.com/riptide/2012/02/floridas_oxycodone_party_is_ov.php. See also http://www.nytimes.com/2011/09/01/us/01drugs.html?_r=1&pagewanted=all.

controlled prescriptions.¹¹ Unfortunately, rogue prescribers are finding ways around the new law by simply calling themselves something other than a clinic.

III. Questions for Consideration

- What is DEA doing to improve the success of its anti-diversion efforts? How does DEA measure success?
- Does DEA partner with State and local law enforcement to ascertain how drugs are diverted on the local level?
- Does the current reporting system provide enough information to the supply chain to adequately evaluate potential diversion transactions and patterns?
- What role can State reform efforts play in the effort to prevent prescription drug diversion and what are the consequences for consistent enforcement and health care delivery?
- What steps are being taken by the private sector to combat drug diversions?

Please contact Brian McCullough, Gib Mullan, or Shannon Weinberg at (202) 225-2927 with any questions.

¹¹ See <http://www.chron.com/news/houston-texas/article/Pill-mills-skirt-law-by-playing-name-game-2429616.php>.