

ONE HUNDRED ELEVENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
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MEMORANDUM

July 20, 2010

To: Members of the Subcommittee on Health

Fr: Democratic Health Subcommittee Staff

**Re: Hearing on H.R. 5710, the National All-Schedules Electronic Reporting
Reauthorization Act of 2010; and H.R. _____, the Safe Drug Disposal Act**

On Thursday, July 22, 2010, at 10:00 a.m., in room 2322 of the Rayburn House Office Building, the Subcommittee on Health will hold a legislative hearing on H.R. 5710, the National All-Schedules Electronic Reporting Reauthorization Act of 2010, and H.R. _____, the Safe Drug Disposal Act.

I. BACKGROUND ON ABUSE OF PRESCRIPTION MEDICATIONS

The abuse of prescription medications is a growing public health concern in the United States. According to the 2010 National Drug Control Strategy¹ released by the White House, prescription drug abuse is the fastest growing drug problem in the United States. In a study released last week, the Substance Abuse and Mental Health Services Administration (SAMHSA) found that between 1998 and 2008 there was a 400% increase in hospital admissions for those aged 12 and over reporting abuse of prescription pain relievers.²

¹ Office of National Drug Control Policy, *The 2010 National Drug Control Strategy*, p. 29 (online at www.whitehousedrugpolicy.gov/publications/policy/ndcs10/ndcs2010.pdf).

² Substance Abuse and Mental Health Services Administration, *Substance Abuse Treatment Admissions Involving Abuse of Pain Relievers: 1998-2008*, released July 15, 2010 (online at oas.samhsa.gov/2k10/230/230PainRelvr2k10Web.pdf).

In a report published last month, the Centers for Disease Control and Prevention (CDC) noted that emergency department visits associated with non-medical use of prescription controlled substances doubled between 2004 and 2008, reaching a million visits.³

In a 2008 study⁴, SAMHSA found that youth between the ages of 12 and 17 abuse prescription drugs more often than cocaine, heroin, and methamphetamine combined. It also showed that the scale of the problem is vast: more than six million Americans used a prescription medication for nonmedical purposes in a one-month period. The study further found that 70% of people who abuse prescription pain relievers obtained them from friends or relatives, who had obtained them from a doctor.

II. H.R. 5710

A. BACKGROUND

The National All-Schedules Prescription Electronic Reporting Act (NASPER), enacted in 2005, created an HHS grant program administered by SAMHSA for states to establish prescription drug monitoring programs (PDMPs).⁵ PDMPs track drug prescriptions, with the goal of preventing overuse and illegal diversion. Approximately 40 states maintain PDMPs or have laws that authorize their establishment.⁶ To be eligible for a NASPER grant, state programs must track drugs that fall under schedules II, III, and IV of the Controlled Substances Act, and must adhere to certain privacy, reporting, and interoperability requirements.

The law authorized \$15 million in each of fiscal years 2006 and 2007, and \$10 million each year for fiscal years 2008 through 2010. In FY2009 and in FY2010, Congress appropriated \$2 million to support NASPER grants in 13 states.

B. SECTION-BY-SECTION SUMMARY OF THE LEGISLATION

Section 1. Short Title

Section 2. Amendment to Purpose

³ Centers for Disease Control and Prevention, *Emergency Department Visits Involving Nonmedical Use of Selected Prescription Drugs - United States, 2004-2008*, June 18, 2010. (online at www.cdc.gov/mmwr/preview/mmwrhtml/mm5923a1.htm).

⁴ Substance Abuse and Mental Health Services Administration, *Results from the 2008 National Survey on Drug Use and Health*, p. 15-30. (online at www.oas.samhsa.gov/nsduh/2k8nsduh/2k8Results.pdf).

⁵ P.L. 109-60.

⁶ Substance Abuse and Mental Health Services Administration, *SAMHSA FY2011 Congressional Budget Justification* (online at samhsa.gov/Budget/FY2011/SAMHSA_FY11CJ.pdf).

Amends the purpose of the act to include giving health care providers accurate prescription history information to identify patients at risk for addiction and prevent negative health outcomes; and to give law enforcement, regulatory, and licensing authorities the ability to investigate drug diversion and inappropriate prescribing practices.

Section 3. Amendment to Controlled Substance Monitoring Program

Expands permitted use of funds to include maintaining existing programs. Under current law, states can use NASPER funds to “establish and implement” or “make improvements to” a PDMP.

Specifies that state interoperability plans must include timelines for implementation, and directs the Secretary of the Department of Health and Human Services (HHS) to monitor such efforts. Under current law, states adjacent to other states with NASPER grants must submit a plan for interoperability among the states’ systems.

Directs funds returned by states with terminated grants or programs to be redistributed based on existing formula.

Requires states that are not in compliance with all reporting requirements to submit a plan for entering compliance.

Requires that states give HHS Secretary aggregate data and other information needed to evaluate the success of a state’s program and to fulfill Congressional reporting requirements.

Permits entities receiving non-identifiable, summary data from a PDMP to make such data available to other entities for research purposes.

Requires states to take certain steps to promote prescriber use of the monitoring system and education on the system’s benefits.

Makes commonwealths and territories of the United States eligible for NASPER grants.

Authorizes \$15 million for fiscal year 2011 and \$10 million for each of fiscal years 2012 through 2015.

III. DRUG TAKE-BACK LEGISLATION

A. DRUG TAKE-BACK PROGRAMS

Drug take-back programs are one way to help address this growing problem of prescription drug abuse. As noted above, a major factor in the increasing trend of prescription drug abuse is the availability of such drugs in the home. These programs provide a means by which patients can safely dispose of their unused medicines. Such programs also help the

environment by decreasing the amount of pharmaceuticals that might otherwise enter waterways when they are flushed down the toilet.

Under current law, the Controlled Substances Act (CSA) creates a barrier for many drug take-back programs. The CSA regulates controlled substances⁷ through a closed registration system designed to prevent diversion.⁸ Under this system, any entity other than the “ultimate user” (i.e., the patient who is prescribed a controlled pharmaceutical) who receives or distributes a controlled substance must be registered with the Drug Enforcement Administration (DEA). In other words, although patients do not have to be registered with DEA in order to receive a controlled substance, they cannot lawfully deliver a controlled substance to another entity for any purpose, including disposal of the drug.⁹

Under current law, the only entities authorized to take possession of expired or otherwise unwanted controlled substances for the purpose of disposal are known as “reverse distributors.” Other registrants, such as pharmacies, may dispose of controlled substances already in their possession (for instance, if they are expired, damaged, or contaminated), but may not accept controlled substances from patients or any other person solely for the purpose of disposal.¹⁰

In January 2009, in response to growing concerns raised by individuals, interest groups, the healthcare industry, and the law enforcement community, DEA solicited public comments on the disposal of controlled substances dispensed to individual patients, as well as to long term care facilities. Although DEA received numerous comments during the public comment period, which ended on March 23, 2009, the agency has stated it cannot move forward with a regulatory proposal in the absence of authorizing legislation.¹¹

B. PROPOSED LEGISLATION

Two bills have been introduced on the subject of safe drug disposal. Reps. Inslee (D-WA) and Moran (D-VA) have introduced H.R.1191, the “Safe Drug Disposal Act of 2009.” Rep. Bart Stupak (D-MI) and Judiciary Committee Ranking Member Lamar Smith (R-TX) have introduced H.R.1359, the “Secure and Responsible Drug Disposal Act of 2009.” Both bills

⁷ Controlled substances are those substances listed in the schedules of the CSA and 21 CFR 1308.11–1308.15, and generally include drugs that have a potential for abuse and physical and psychological dependence, such as narcotics, stimulants, depressants, anabolic steroids and hallucinogens.

⁸ Drug Enforcement Administration, *Testimony for the Special Committee on Aging Hearing on Drug Waste and Disposal: When Prescriptions Become Poison, Statement of Joseph T.Rannazzisi*, p. 3(June 30, 2010) (hereinafter, “DEA Testimony”) (online at aging.senate.gov/events/hr223gk.pdf).

⁹ *Id.*

¹⁰ 21 CFR 1300.01(b)(41)

¹¹ DEA Testimony, *supra* note 6, at 5.

amend the CSA to permit individuals to lawfully deliver their unused controlled substances to DEA-authorized individuals. H.R. 1191 includes additional state and environmental requirements over and above what is required in H.R. 1359. It is anticipated that a proposal drawing on provisions from both of these initiatives will be introduced by Reps. Inslee, Smith, and Stupak.

IV. WITNESSES

The following witnesses have been invited to testify:

The Honorable R. Gil Kerlikowske, M.A.

Director

Office of National Drug Control Policy

Joseph Rannazzisi, J.D.

Deputy Assistant Administrator

United States Drug Enforcement Agency