Department of Justice

STATEMENT FOR THE RECORD OF

JOSEPH T. RANNAZZISI
DEPUTY ASSISTANT ADMINISTRATOR
OFFICE OF DIVERSION CONTROL
DRUG ENFORCEMENT ADMINISTRATION

BEFORE THE

ENERGY AND COMMERCE COMMITTEE
SUBCOMMITTEE ON HEALTH
UNITED STATES HOUSE OF REPRESENTATIVES

HEARING ON PENDING PUBLIC HEALTH LEGISLATION

JULY 22, 2010

Statement for the Record
Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control
Drug Enforcement Administration
United States Department of Justice

Energy and Commerce Committee, Subcommittee on Health
U.S. House of Representatives
Hearing on Pending Public Health Legislation
July 22, 2010

Chairman Pallone, Ranking Member Shimkus, and distinguished Members of the Subcommittee, on behalf of Acting Administrator Michele Leonhart and the more than 9,600 men and women of the Drug Enforcement Administration (DEA), I am honored to have the opportunity to appear before you today to provide testimony concerning the disposal of pharmaceutical controlled substances and prescription drug monitoring programs (PDMPs).

Addressing the growing problem of the diversion and abuse of controlled pharmaceuticals continues to be one of the top priorities of DEA. DEA has made great strides in dealing with this ever-changing, global drug issue. We continue to concentrate on identifying, targeting, and dismantling large-scale organizations that seek to divert and distribute controlled pharmaceuticals in violation of the Controlled Substances Act (CSA).

DEA's obligation under the law and to the public is to ensure that pharmaceutical controlled substances are prescribed and dispensed only for legitimate medical purposes in accordance with the Controlled Substances Act. By carrying out this obligation, DEA strives to minimize the diversion of pharmaceutical controlled substances for abuse while ensuring that such medications are fully available to patients in accordance with the sound medical judgments of their physicians. In this manner, DEA is committed to balancing the need for prevention, education, and enforcement with the need for legitimate access to these drugs.

Today's hearing is focused on two areas of concern related to sources of diversion: unused pharmaceutical controlled substances, and those fraudulently obtained through a practice known as "doctor shopping." The desire to provide the public with effective means to dispose of unused pharmaceutical controlled substances is based on two main concerns: (1) protecting the safety and welfare of the American people by preventing the diversion of such drugs into either licit or illicit channels for the purpose of abuse or profit; and (2) developing drug disposal methods that help prevent contamination of the nation's water supplies.

"Doctor shopping" by drug addicts is one of the most common ways that addicts unlawfully obtain pharmaceutical controlled substances. Generally, this term refers to the visit by an individual—who may or may not have legitimate medical needs—to several doctors, each of whom writes a prescription for a controlled substance. The individual will visit several pharmacies, receiving more of the drug than intended by any single physician, typically for the

purpose of feeding an addiction. Associated illegal activities may include the forgery of prescriptions, or the sale or transfer of the drug to others. Unfortunately, in many states, physicians and pharmacists have not been able to automatically cross-check multiple prescriptions given to the same patient.

To address this problem, Congress first appropriated funds to the Department of Justice in 2003 to promote the deployment of Prescription Drug Monitoring Programs (PDMPs) by States. That commitment continues as part of the Administration's National Drug Control Strategy for 2010. Expanding prescription drug monitoring programs is one of several steps outlined in the Strategy to combat prescription drug abuse. Currently, these programs are operating in 34 states. The Administration supports establishment of these programs in every state, and is seeking to ensure new and existing monitoring programs effectively use the data they acquire and share information across state lines. PDMPs help cut down on prescription fraud and doctor shopping by giving physicians and pharmacists more complete information about a patient's prescriptions for controlled substances. The Office of National Drug Control Policy (ONDCP) is currently working with interested agencies, state representatives and professional organizations to combine the best practices of existing programs to develop PDMP standards. DEA looks forward to working closely with ONDCP to promote these standards. The goal is for 26 states and territories to implement the PDMP standards over a five year period

While the specifics of these programs vary from state to state, they generally share the characteristic of allowing prescribers (for example, a physician) and dispensers (for example, a pharmacist) to input and receive accurate and timely controlled substance prescription history information while ensuring patient access to needed treatment. Many states have some mechanism for law enforcement to receive this information in cases where criminal activity is suspected. Some states also allow health care providers to use this information as a tool for the early identification of patients at risk for addiction in order to initiate appropriate medical interventions. In other states the justice system can use this information to assist in the enforcement of laws controlling the sale and use of controlled substance prescription medication.

Unused Prescription Drugs as a Potential Source of Diversion

The diversion of pharmaceutical controlled substances is a significant problem in the United States, as all reliable indicators show that the abuse (non-medical use) of these drugs has reached alarming levels in recent years. (These indicators include, but are not limited to; the National Survey on Drug Use and Health, Monitoring the Future Study, Partnership Attitude Tracking Study, and Drug Abuse Warning Network (DAWN) data.) One factor that may contribute to the increased abuse is the availability of these drugs in household medicine cabinets. In many cases, dispensed controlled substances remain in household medicine cabinets well after medication therapy has been completed, thus providing easy access to non-medical users for abuse, accidental ingestion, or to sell for profit. Accidental ingestion of medication, including a controlled substance, by the elderly and children, is more likely when the household medicine cabinet contains unused medications that are no longer needed for therapy. The medicine cabinet also provides ready access to persons, especially teenagers, who seek to abuse medications. For example, the 2009 Partnership Attitude Tracking Study (PATS) noted that 62 percent of those teens surveyed believe that most teens get prescription drugs from their

own family's medicine cabinets.[1] The Administration recognizes the issue of prescription drug abuse as described in the 2010 National Drug Control Strategy. One of the action items set forth in the Strategy is to increase prescription return/take-back and disposal programs.[2]

Statistics concerning the abuse of pharmaceutical controlled substances and prescription medication also reveal disturbing trends. As recently as June 18, 2010, the Centers for Disease Control and Prevention released a morbidity and mortality report that showed increasing morbidity associated with non-medical use of pharmaceutical controlled substances.[3] Persons between the ages of 12 and 17 abuse prescription drugs more than cocaine, heroin, and methamphetamine combined.[4] In this age group, prescription drug abuse is second only to marijuana abuse.[5] The ease of access to prescription medication is a contributing factor in this growing trend of abuse.

Another factor that may contribute to the overall upward trend of abuse is that teenagers and young adults believe that prescription medications are safer than other drugs of abuse such as heroin, cocaine, marijuana and methamphetamine. The 2008 PATS study noted that 41 percent of teenagers mistakenly believe that prescription medications are "much safer" than illicit drugs.[6] Prescription medications are surrounded by a false sense of security because they are manufactured by pharmaceutical companies, prescribed by physicians and other medical professionals, and dispensed by pharmacies. This false sense of security can end in tragedy. In 2008, 4.7 million teens admitted to abusing prescription drugs at some point in their lives.[7]

In conjunction with the increased abuse of prescription medication, there has been an increase in the number of poisoning deaths related to prescription drug abuse. For the period 1999 to 2006, the Centers for Disease Control and Prevention reported a approximately 270 percent increase in the number of unintentional poisoning deaths (i.e., overdoses) in which opioid analgesics were mentioned..[8] The 2009 Monitoring the Future study reported that Vicodin, the most widely prescribed brand name pain reliever containing the narcotic hydrocodone, is one of the most commonly abused drugs among 12th graders: in 2009, 1 in 10 reported non-medical use in the previous year.[9] On average, every day, 2,500 12-17 year olds abuse a prescription pain reliever for the first time.[10]

Unused Prescription Drugs as a Potential Source of Contamination

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[1] Partnership for a Drug-Free America, The Partnership Attitude Tracking Study (PATS) Teens 2009 Report. March 2, 2010..
[2] 2010 National Drug Control Strategy, p. 32
[3] Centers for Disease Control and Prevention, *Emergency Department Visits Involving Nonmedical Use of Selected Prescription Drugs – United States, 2004-2008*, June 18, 2010.
[4] Substance Abuse and Mental Health Services Administration. Results from the 2008 National Survey on Drug Use and Health.
[5] Ibid, p. 20.
[6] Partnership for a Drug-Free America, 2008 Partnership Attitude Tracking Study, Key Findings.
[7] National Survey on Drug Use and Health, Table 1.17A, SAMHSA, Sept 2009
[8] Centers for Disease Control and Prevention, 2007 Unintentional Poisoning Deaths, United States,. March 19, 2010, figure 2. http://www.cdc.gov/HomeandRecreationalSafety/pdf/poison-issue-brief.pdf
[9] 2009 Monitoring the Future Study. University of Michigan, Ann Arbor. December 2009 Press Release.
[10] Substance Abuse and Mental Health Services Administration, Office of Applied Studies. (October 18, 2007). The OAS Report: A Day in the Life of American Adolescents: Substance Use Facts. Rockville, MD.

Recent studies by EPA and others have detected pharmaceutical drugs in varying concentrations in our nation's water supplies. While drugs in waterways also result from normal excretion routes and metabolic process, there has been an increasing interest among the public in developing methods to dispose of unused pharmaceuticals to reduce their introduction into the water supply. The overwhelming majority (approximately 90 percent) of pharmaceuticals dispensed in the United States are non-controlled substances, which are not subject to the provisions of the Controlled Substances Act (CSA).[11] Any organized collection of unused pharmaceuticals will, in all likelihood, involve the collection of both pharmaceutical controlled substances and non-controlled substances, as the public is generally unaware of the distinctions between controlled and non-controlled substances. As explained below, when controlled substances are involved, the CSA provides stringent limitations on the circumstances in which it is lawful to procure, distribute and possess such drugs.

Current Statutory Requirements

Under the CSA, Congress established a "closed system" of distribution designed to prevent the diversion of controlled substances.[12] In furtherance of the closed system, no controlled substance may be transferred between two entities unless the entities are DEA registrants or exempt from registration. In addition, DEA registrants must maintain copious records of all transactions involving controlled substances. The closed system is monitored by a DEA system that accounts for all controlled substances received, stored, distributed, dispensed, or otherwise disposed.

To maintain the closed system, every entity that distributes controlled substances, or proposes to engage in the distribution of any controlled substance, must obtain a DEA registration authorizing such activity. 21 U.S.C. § 822(a). "The term 'distribute' means to deliver (other than by administering or dispensing) a controlled substance . . . ." 21 U.S.C. § 802(11). "The terms 'deliver' or 'delivery' means the actual, constructive, or attempted transfer of a controlled substance …, whether or not there exists an agency relationship." 21 U.S.C. § 802(8).

"Ultimate users" are exempt from the requirement of registration if the ultimate user lawfully obtained the substance, and possesses the controlled substance for a specified purpose, i.e., for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household. 21 U.S.C. §§ 802(27), 822(c)(3). Most important, this statutory exception does not allow a patient to deliver a controlled substance to any another entity for any purpose, including disposal of the drug.

To summarize, the CSA specifically allows ultimate users to obtain and possess controlled substances for personal use only. The statute does not contemplate that ultimate users may need to dispose of unused pharmaceutical controlled substances. Under current law, an ultimate user is not authorized to deliver or distribute controlled substances for purposes of disposal. Any such distribution by an ultimate user, regardless of the purpose, is illegal.

[11] Source: IMS Health.
[12] H.R. Rep. No. 91-1444 at 3 (1970).

As an interim measure, DEA offices throughout the country continue to provide technical assistance to law enforcement agencies that conduct community "take-back" programs that collect unused pharmaceutical controlled substances. These "take-back" programs involve duly authorized law enforcement officials collecting unused controlled substances from ultimate users. Upon receipt, the authorized law enforcement agency must maintain custody of the controlled substances up to and including destruction. The manner of destruction must comply with applicable federal and state laws including those related to the public health and environment.

In April 2009, a law enforcement collection program was conducted in North Carolina that included several local sheriffs' offices and the North Carolina State Bureau of Investigation. "Operation Pill Crusher" collected more than 144,000 dosage units of expired and unused prescription medications from local residents. All pills collected were hand-counted, recorded, and transported to an incineration unit for destruction.

In November 2009, DEA's Newark Field Division Office, in conjunction with state and local municipalities, conducted a state-wide take-back program entitled "Operation Medicine Cabinet". More than 440 municipalities in all of New Jersey's 21 counties participated in the event. Over 9,000 pounds of pharmaceuticals were collected and properly destroyed.

Though these programs were successful, they are only a stop-gap measure due to the current statutory constraints.

Current Guidance Pertaining to Unused Prescription Drugs

On February 20, 2007, the U.S. Office of National Drug Control Policy (ONDCP) announced guidelines for the disposal of ultimate user medications, including dispensed controlled substances. The guidelines were published by ONDCP in conjunction with the Department of Health and Human Services (HHS), and the Environmental Protection Agency (EPA).[13] The guidelines advise the public to flush medications only if the prescription label or accompanying patient information specifically states to do so. For all other medications, ONDCP recommends mixing the drug product with an undesirable substance (e.g. coffee grounds or kitty litter) prior to disposal in common household trash or at community pharmaceutical "take-back" programs. The press release announcing the guidelines stated:

> The new Federal guidelines are a balance between public health concerns and potential environmental concerns. "While EPA continues to research the effects of pharmaceuticals in water sources, one thing is clear: improper drug disposal is a prescription for environmental and societal concern," said EPA Administrator Stephen L. Johnson. "Following these new guidelines will protect our Nation's waterways and keep pharmaceuticals out of the hands of potential abusers."

Due to concerns about public safety, the U.S. Food and Drug Administration has currently identified a small number of prescription drugs which contain one of 10 controlled substances for which the FDA currently recommends disposal by flushing. Primarily narcotics,

[13] Office of National Drug Control Policy, Executive Office of the President. Proper Disposal of Prescription Drugs. February 2007. http://www.whitehousedrugpolicy.gov/publications/pdf/prescrip_disposal.pdf

these preparations have life-threatening capabilities if improperly handled or improperly ingested.

Regulatory Action

On January 21, 2009, DEA published an Advance Notice of Proposed Rulemaking in the Federal Register entitled *Disposal of Controlled Substances by Persons Not Registered With the Drug Enforcement Administration.* Through this Notice, DEA sought information from all interested members of the public concerning the safe and responsible disposal of controlled substances. A variety of interest groups were solicited including ultimate users; state and local law enforcement agencies; concerned interest groups; long-term care facilities; hospices and in-home care groups; pharmacies; reverse distributors;[14] state regulatory agencies; and other interested parties.

The public comment period expired on March 23, 2009. DEA received 158 comments from a wide variety of sources including: the general public; the pharmacy community; hospitals; long-term care facilities; and reverse distributors. The DEA cannot move forward with a regulatory proposal without legislation such as those described below.

Problems that the Public is Experiencing in Handling Substances to be Destroyed

Because the CSA currently does not authorize ultimate users to dispose of controlled substances, except under limited circumstances, the distribution of a controlled substance by an ultimate user to another person, regardless of the purpose, violates the CSA. At this time, most U.S. communities do not offer programs to properly dispose of excess controlled substances or waste medication. Many consumers keep the drugs in their possession because they do not know how to dispose of them.

Legislative Proposals

DEA strongly supports legislation that authorizes DEA to address this issue through its rulemaking authority. DEA notes that Congress has offered proposed legislation in both chambers. The legislative intent appears consistent: to provide DEA the regulatory authority to give citizens lawful means to safely dispose of controlled substances that prevents their diversion, while also allowing the destruction of those substances in an environmentally safe manner that is consistent with EPA objectives.

In May 2009, the Department of Justice issued a views letter in support of H.R. 1359, the Secure and Responsible Drug Disposal Act of 2009.[15] A second bill, H.R. 1191, has also been introduced, but DEA has concerns about the complexity of the regulatory scheme called for in that bill, as well as the fact that it does not properly assign responsibility for environmental considerations in implementing take back disposal programs. We have been encouraged by conversations with the bill sponsor regarding these concerns. Additionally, we are hopeful that

[14] Reverse distributors are registered by DEA and authorized to accept controlled substances for destruction only from other DEA-registered persons or companies.
[15] The Senate companion bill is S-1292.

the Energy and Commerce committee, which has jurisdiction over both H.R. 1359 and H.R. 1191, will work toward finding a compromise approach to this important issue. If DEA is given the necessary statutory authority, it will be in a position to promulgate regulations that set forth a comprehensive framework for communities and regulated entities to use as guides to establish secure disposal programs for unused controlled substances. Conceivably, a variety of models will be able to operate under the established regulatory framework.

H.R. 1359, and its companion measures, S.1292 and S.3397, affords the Attorney General discretion to promulgate regulations and provides the requisite flexibility to address this important issue in a comprehensive manner. It would provide a means by which ultimate users may lawfully distribute controlled substances to other persons for disposal. It would do so by amending section 302 of the Act (21 U.S.C. § 822), to clearly state that an ultimate user who has lawfully obtained a controlled substance may, without being registered, deliver the controlled substance to another person for the purpose of disposing of the controlled substance. The person receiving the controlled substance must be authorized under the CSA to engage in such activity. The disposal must take place in accordance with regulations issued by the Attorney General to prevent diversion of controlled substances. This provision is necessary because the CSA currently does not allow for ultimate users to deliver controlled substances to others for the purposes of disposal.

This proposed legislation would also amend section 302 of the CSA to add a new provision (section 302(g)(2)) authorizing the Attorney General to promulgate regulations that authorize long-term care facilities, as defined by the Attorney General to dispose of controlled substances on behalf of ultimate users. The disposal would occur in a manner that the Attorney General determines will provide effective controls against diversion and be consistent with the public health and safety. This provision is necessary because nursing homes and other long-term care facilities sometimes gain possession of controlled substances that are no longer needed by patients, but the CSA currently does not allow such facilities, which are usually not registered under the Act, to deliver controlled substances to others for the purposes of disposal. Addressing the unique nature of long-term care facilities is consistent with the numerous regulations promulgated by DEA to address the needs of ultimate users in these facilities.

For consistency with the foregoing amendments, the legislation also amends section 308(b) of the Controlled Substances Act (21 U.S.C. 828(b)) to make clear that the written order form requirement, which is generally a prerequisite under the Act for distributing a schedule I or II controlled substance, does not apply to the delivery of a controlled substance for the purpose of disposal by an ultimate user or long-term care facility acting in accordance with new section 302(g) of the Act.

The authority proposed to be afforded to DEA in H.R. 1359 and its companion measures is straightforward, the ensuing regulations can be implemented uniformly throughout the nation, and the regulatory scheme is envisioned to allow a wide variety of disposal methods that are consistent with effective controls against diversion. In addition, H.R. 1359 and its companion measures would give DEA the flexibility to allow, by regulation, new methods of disposal if and when they are developed in the future.

Conclusion

DEA has the vital statutory responsibility of promulgating and enforcing regulations that will minimize the availability of pharmaceutical controlled substances to non-medical users and preserve the integrity of the closed system of distribution. The collection, removal, and safe disposal of unused medication from households and long-term care facilities is one method of preventing these drugs from getting into the hands of the non-medical user. DEA also supports EPA's mission to dispose of these substances in a manner that is consistent with federal, state, and local environmental laws and regulations. It removes a potential avenue of diversion, limits the availability of medications to drug seekers/abusers and decreases the potential for accidental ingestion/poisoning. It is a priority for this Administration.

The Administration's commitment to supporting the establishment of PDMPs is highlighted in the National Drug Control Strategy for 2010. Expanding prescription drug monitoring programs is one of several steps outlined in the Strategy to combat prescription drug abuse. The Administration supports establishment of these programs in every state, and is seeking to ensure new and existing monitoring programs effectively use the data they acquire and share information across state lines. PDMPs help cut down on prescription fraud and doctor shopping by giving physicians and pharmacists more complete information about a patient's prescriptions for controlled substances.

Chairman Pallone, Ranking Member Shimkus, and distinguished Members of the Subcommittee, I thank you for the opportunity to appear before you today to discuss this important issue and welcome any questions that you may have.