111TH CONGRESS
2d Session
HOUSE OF REPRESENTATIVES
REPT. 111–618
Part 1

SAFE DRUG DISPOSAL ACT OF 2010

SEPTEMBER 22, 2010.—Committed to the Committee of the Whole House on the State of the Union, and ordered printed

Mr. WAXMAN, from the Committee on Energy and Commerce, submitted the following

R E P O R T

[To accompany H.R. 5809]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 5809) to amend the Controlled Substances Act to provide for take-back disposal of controlled substances in certain instances, and for other purposes, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

CONTENTS

AMENDMENT

The amendment is as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Safe Drug Disposal Act of 2010".

SEC. 2. DELIVERY OF CONTROLLED SUBSTANCES BY ULTIMATE USERS FOR DISPOSAL.

(a) REGULATORY AUTHORITY.—Section 302 of the Controlled Substances Act (21 U.S.C. 822) is amended by adding at the end the following:

"(g)(1) An ultimate user who has lawfully obtained a controlled substance in accordance with this title may, without being registered, deliver the controlled substance to another person for the purpose of disposal of the controlled substance if—

"(A) the person receiving the controlled substance is authorized under this title to receive and dispose of the controlled substance; and

"(B) the delivery and disposal takes place in accordance with regulations issued by the Attorney General to prevent diversion of controlled substances.

The regulations referred to in subparagraph (B) shall be consistent with the public health and safety. In developing such regulations, the Attorney General shall take into consideration the ease and cost of program implementation and participation by various communities. Such regulations may not require any entity to establish or operate a delivery or disposal program.

"(2) The Attorney General shall, by regulation, authorize long-term care facilities, as defined by the Attorney General by regulation, to deliver for disposal controlled substances on behalf of ultimate users in a manner that the Attorney General determines will provide effective controls against diversion and be consistent with the public health and safety.

"(3) If a person dies while lawfully in possession of a controlled substance for personal use, any person lawfully entitled to dispose of the decedent's property may deliver the controlled substance to another person for the purpose of disposal under the same conditions as provided in paragraph (1) for an ultimate user.".

(b) CONFORMING AMENDMENT.—Section 308(b) of the Controlled Substances Act (21 U.S.C. 828(b)) is amended—

(1) by striking the period at the end of paragraph (2) and inserting "; or"; and

(2) by adding at the end the following:

"(3) the delivery of such a substance for the purpose of disposal by an ultimate user, long-term care facility, or other person acting in accordance with section 302(g).".

SEC. 3. PUBLIC EDUCATION CAMPAIGN.

The Director of National Drug Control Policy, in consultation with the Administrator of the Environmental Protection Agency, shall carry out a public education and outreach campaign to increase awareness of how ultimate users may lawfully and safely dispose of prescription drugs, including controlled substances, through drug take-back programs and other appropriate means.

SEC. 4. GAO REPORT.

The Comptroller General of the United States shall—

(1) collect data on the delivery, transfer, and disposal of controlled substances under section 302(g) of the Controlled Substances Act, as added by section 2; and

(2) not later than 4 years after the date of the enactment of this Act, submit findings and recommendations to the Congress regarding use, effectiveness, and accessibility of disposal programs.

SEC. 5. EPA STUDY OF ENVIRONMENTAL IMPACTS.

(a) STUDY.—The Administrator of the Environmental Protection Agency (in this section referred to as the "Administrator") shall—

(1) in consultation with relevant State and local officials and other sources of relevant technical expertise, conduct a study to—

(A) examine the environmental impacts resulting from the ultimate disposal of controlled substances through existing methods;

(B) taking into consideration such impacts, and the ease and cost of implementation of drug take-back programs and participation in such programs by various communities, formulate appropriate recommendations on the destruction or ultimate disposal of prescription drugs, including controlled substances; and

(C) identify additional authority needed to carry out such recommendations if the Administrator determines that the Administrator's existing legal authorities are insufficient to implement such recommendations; and

(2) not later than 18 months after the date of the enactment of this Act, submit a report to the Congress on the results of such study.

(b) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to affect the Administrator's authority under other provisions of law.

PURPOSE AND SUMMARY

H.R. 5809, the "Safe Drug Disposal Act of 2010", was introduced by Representatives Jay Inslee (D–WA), Lamar Smith (R–TX), Bart Stupak (D–MI), and James P. Moran (D–VA) on July 21, 2010. The bill was referred to the Committee on Energy and Commerce, and in addition to the Committee on the Judiciary.

The legislation has two overriding goals:

- To allow individuals, as well as long-term care facilities on behalf of their patients, to deliver unused prescription drugs to an appropriate person for disposal purposes, as determined by the Attorney General.
- To enhance understanding of the environmental impacts of the disposal of unused medicines through existing methods.

BACKGROUND AND NEED FOR LEGISLATION

The abuse of prescription medications is a growing public health concern in the United States. According to the 2010 National Drug Control Strategy released by the White House, prescription drug abuse is the fastest growing drug problem in the United States.[1] Several recent studies underscore this point:

- In a study released in July 2010, 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]
- In a report published in June 2010, 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 study, SAMHSA found that youth between the ages of 12 and 17 abuse prescription drugs more often than cocaine, heroin, and methamphetamine combined.[4] 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.

Drug take-back programs are one way to help address this growing and serious problem. As noted, 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

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[1] Office of National Drug Control Policy, *The 2010 National Drug Control Strategy,* p. 29 (online at *www.whitehousedrugpolicy.gov/publications/policy/ndcs 10/ndcs2010.pdf*).

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

[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/mm5923al.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*).

decrease the amount of pharmaceuticals that might otherwise enter waterways via municipal waste water systems if such pharmaceuticals are flushed down the toilet.

According to the Environmental Protection Agency, we know that pharmaceuticals have health effects at the therapeutic dose, but we do not know if there are effects to human health associated with long-term exposure to pharmaceuticals at much lower concentrations in drinking water. Some laboratory and other studies have demonstrated effects on fish and aquatic life of low-level exposure to pharmaceuticals. There are no known human health effects of low-level exposures to pharmaceuticals in drinking water in the general population, but EPA believes that more investigation is required to determine whether sensitive human populations (such as developing fetuses) are experiencing such effects.

Under current law, the Controlled Substances Act (CSA) creates a barrier for many drug take-back programs. The CSA regulates controlled substances[5] through a closed registration system designed to prevent diversion.[6] 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.[7]

Under current law as well, 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.[8]

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 responses 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.[9]

COMMITTEE CONSIDERATION

H.R. 5809, the "Safe Drug Disposal Act of 2010", was introduced by Representatives Inslee (D–WA), Smith (R–TX), Stupak (D–MI),

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[5] 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.

[6] 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).

[7] *Id.*

[8] 21 CFR 1300.01(b)(41).

[9] DEA Testimony, *supra* note 6, at 5.

and Moran (D–VA) on July 21, 2010, and referred to the Committee on Energy and Commerce, and subsequently to the Subcommittee on Health on the same day. The Subcommittee on Health conducted a legislative hearing on the bill and afterwards met in open markup session to consider H.R. 5809 on July 22, 2010. An amendment in the nature of a substitute (manager's amendment) by Representative Stupak was adopted by a voice vote. Subsequently, H.R. 5809 was favorably forwarded to the full Committee, amended, by a voice vote.

On July 28, 2010, the Committee on Energy and Commerce met in open markup session and considered H.R. 5809 as approved by the Subcommittee. An amendment in the nature of a substitute (manager's amendment) offered by Representative Pallone (D–NJ) was adopted by a voice vote. Subsequently, the Committee ordered H.R. 5809 favorably reported to the House, amended, by a voice vote.

COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list each record vote on the motion to report legislation and amendments thereto. A motion by Mr. Waxman ordering H.R. 5809 reported to the House, amended, was approved by a voice vote. There were no record votes taken during consideration of this bill.

COMMITTEE OVERSIGHT FINDINGS AND RECOMMENDATIONS

In compliance with clause 3(c)(1) of rule XIII and clause 2(b)(1) of rule X of the Rules of the House of Representatives, the oversight findings and recommendations of the Committee are reflected in the descriptive portions of this report, including the finding that drug take-back programs provide one means of addressing the growing and serious problem of prescription drug abuse.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

Regarding compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 5809 would result in no new budget authority, entitlement authority, or tax expenditures or revenues.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

In accordance with clause 3(c)(4) of rule XIII of the Rules of the House of Representatives, the performance goals and objectives of the Committee are reflected in the descriptive portions of this report, including the goal of facilitating the delivery of unused prescription drugs to appropriate persons for disposal purposes, and enhancing scientific understanding of the environmental impacts of the disposal of unused medicines through existing methods.

CONSTITUTIONAL AUTHORITY STATEMENT

Pursuant to clause 3(d)(1) of rule XIII of the Rules of the House of Representatives, the Committee finds that the constitutional au-

thority for H.R. 5809 is provided under Article I, section 8, clauses 3 and 18 of the Constitution of the United States.

EARMARKS AND TAX AND TARIFF BENEFITS

H.R. 5809 does not contain any congressional earmarks, limited tax benefits, or limited tariff benefits as defined in clause 9(d), 9(e), or 9(f) of rule XXI of the Rules of the House of Representatives.

FEDERAL ADVISORY COMMITTEE STATEMENT

The Committee finds that the legislation does not establish or authorize the establishment of an advisory committee within the definition of 5 U.S.C. App., section 5(b) of the Federal Advisory Committee Act.

APPLICABILITY OF LAW TO THE LEGISLATIVE BRANCH

Section 102(b)(3) of Public Law 104–1 requires a description of the application of this bill to the legislative branch where the bill relates to terms and conditions of employment or access to public services and accommodations. H.R. 5809 contains no such provisions.

FEDERAL MANDATES STATEMENT

Section 423 of the Congressional Budget and Impoundment Control Act of 1974 (as amended by section 101(a)(2) of the Unfunded Mandates Reform Act, P.L. 104–4) requires a statement on whether the provisions of the report include unfunded mandates. In compliance with this requirement the Committee adopts as its own the estimates of federal mandates prepared by the Director of the Congressional Budget Office.

COMMITTEE COST ESTIMATE

Pursuant to clause 3(d)(2) of rule XIII of the Rules of the House of Representatives, the Committee adopts as its own the cost estimate of H.R. 5809 prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

With respect to the requirements of clause (3)(c)(3) of rule XIII of the Rules of the House of Representatives and section 402 of the Congressional Budget Act of 1974, the Committee has received the following cost estimate for H.R. 5809 from the Director of the Congressional Budget Office:

AUGUST 5, 2010.

Hon. HENRY A. WAXMAN,
Chairman, Committee on Energy and Commerce,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 5809, the Safe Drug Disposal Act of 2010.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Mark Grabowicz.

Sincerely,

DOUGLAS W. ELMENDORF.

Enclosure.

H.R. 5809—Safe Drug Disposal Act of 2010

CBO estimates that implementing H.R. 5809 would cost about $2 million in fiscal year 2011 and less than $500,000 annually over the 2012–2014 period, from appropriated amounts. The bill would not affect direct spending or revenues; therefore, pay-as-you-go procedures do not apply. H.R. 5809 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act and would impose no costs on state, local, or tribal governments.

H.R. 5809 would require the Department of Justice (DOJ) to authorize long-term care facilities (such as nursing homes) to arrange for the appropriate disposal of certain controlled substances. Based on information from DOJ, CBO estimates that implementing the bill would not significantly affect the department's spending on drug control programs.

In addition, H.R. 5809 would direct the Office of National Drug Control Policy to carry out a public outreach campaign relating to the safe disposal of prescription drugs. H.R. 5809 also would require the Environmental Protection Agency (EPA) to conduct a study on the environmental impacts of disposing of controlled substances and would require the Government Accountability Office (GAO), within four years of the date of enactment, to prepare a report on implementation of the bill's provisions.

Based on the costs of similar activities, CBO estimates that the public outreach campaign and the EPA study would cost about $1 million each in 2011 and the GAO report would cost less than $500,000 annually over the 2011–2014 period, from appropriated funds.

On August 3, 2010, CBO transmitted a cost estimate for S. 3397, the Secure and Responsible Drug Disposal Act of 2010, as reported by the Senate Committee on the Judiciary on July 29, 2010. The two bills are similar, but S. 3397 did not require a public outreach campaign or any reports and we estimated that its implementation would have no significant cost to the federal government.

The CBO staff contact for this estimate is Mark Grabowicz. The estimate was approved by Theresa Gullo, Deputy Assistant Director for Budget Analysis.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title

Section 1 designates that the short title may be cited as the "Safe Drug Disposal Act of 2010".

Section 2. Delivery of controlled substances by ultimate users for disposal

Section 2 amends the Controlled Substances Act to permit an ultimate user who has lawfully obtained a controlled substance and who is not registered with the DEA to deliver that controlled sub-

stance to another person for the purpose of disposal if the person receiving the controlled substance is authorized to do so under the Act, and if the delivery and disposal takes place in accordance with regulations to be issued by the Attorney General to prevent diversion of controlled substances. In developing such regulations, the Attorney General is to consider both the ease and cost of program implementation and participation by various communities. The legislation prohibits the DEA from requiring any entity to establish a drug take back program.

Section 2 also requires the Attorney General to issue regulations to authorize long-term care facilities to deliver for disposal controlled substances on behalf of ultimate users.

In addition, Section 2 authorizes any person lawfully entitled to dispose of a decedent's property to deliver controlled substances belonging to that decedent to another person for the purpose of disposal.

Section 3. Public education campaign

Section 3 requires the Director of National Drug Control Policy (ONDCP), in consultation with EPA, to carry out a public education and outreach campaign to increase awareness of drug take-back programs.

Section 4. GAO report

Section 4 requires the Comptroller General to submit a report to Congress on the delivery, transfer, and disposal of controlled substances under the Controlled Substances Act (as amended by the legislation) that includes findings and recommendations regarding the use, effectiveness, and accessibility of drug disposal programs.

Section 5. EPA study of environmental impacts

Section 5 requires the EPA administrator, in consultation with relevant state and local officials and other relevant experts, to conduct a study to:

- Examine the environmental impacts from the final disposal of controlled substances through existing methods.
- Consider the ease and cost of implementation of drug take-back programs, and participation in such programs by various communities.
- Make recommendations on the appropriate ways to dispose of prescription drugs.
- Identify additional authority needed to carry out such recommendations if the Administrator determines that existing legal authorities are insufficient to implement them.

EPA is required to submit the results of the study to Congress within 18 months of the enactment of the legislation.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

CONTROLLED SUBSTANCES ACT

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TITLE II—CONTROL AND ENFORCEMENT

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PART C—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES; PIPERIDINE REPORTING

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PERSONS REQUIRED TO REGISTER

SEC. 302. (a) * * *

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(g)(1) An ultimate user who has lawfully obtained a controlled substance in accordance with this title may, without being registered, deliver the controlled substance to another person for the purpose of disposal of the controlled substance if—

(A) the person receiving the controlled substance is authorized under this title to receive and dispose of the controlled substance; and

(B) the delivery and disposal takes place in accordance with regulations issued by the Attorney General to prevent diversion of controlled substances.

The regulations referred to in subparagraph (B) shall be consistent with the public health and safety. In developing such regulations, the Attorney General shall take into consideration the ease and cost of program implementation and participation by various communities. Such regulations may not require any entity to establish or operate a delivery or disposal program.

(2) The Attorney General shall, by regulation, authorize long-term care facilities, as defined by the Attorney General by regulation, to deliver for disposal controlled substances on behalf of ultimate users in a manner that the Attorney General determines will provide effective controls against diversion and be consistent with the public health and safety.

(3) If a person dies while lawfully in possession of a controlled substance for personal use, any person lawfully entitled to dispose of the decedent's property may deliver the controlled substance to another person for the purpose of disposal under the same conditions as provided in paragraph (1) for an ultimate user.

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ORDER FORMS

SEC. 308. (a) * * *

(b) Nothing in subsection (a) shall apply to—

(1) * * *

(2) the delivery of such a substance to or by a common or contract carrier for carriage in the lawful and usual course of its business, or to or by a warehouseman for storage in the lawful and usual course of its business; but where such carriage or storage is in connection with the distribution by the owner of the substance to a third person, this paragraph shall

not relieve the distributor from compliance with subsection (a)**[**.**]***; or*

(3) the delivery of such a substance for the purpose of disposal by an ultimate user, long-term care facility, or other person acting in accordance with section 302(g).

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