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111TH CONGRESS
1ST SESSION

H. R. 1191

To amend the Controlled Substances Act to provide for disposal of controlled substances by ultimate users and care takers through State take-back disposal programs, to amend the Federal Food, Drug, and Cosmetic Act to prohibit recommendations on drug labels for disposal by flushing, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 25, 2009

Mr. INSLEE (for himself, Mr. MORAN of Virginia, Mr. DICKS, Mr. BLUMENAUER, and Mr. GENE GREEN of Texas) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To amend the Controlled Substances Act to provide for disposal of controlled substances by ultimate users and care takers through State take-back disposal programs, to amend the Federal Food, Drug, and Cosmetic Act to prohibit recommendations on drug labels for disposal by flushing, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Safe Drug Disposal Act of 2009''.

SEC. 2. STATE TAKE-BACK DISPOSAL PROGRAMS.

(a) IN GENERAL.—Part C of the Controlled Substances Act (21 U.S.C. 821 et seq.) is amended by adding at the end the following:

''SEC. 312. STATE TAKE-BACK DISPOSAL PROGRAMS.

''(a) IN GENERAL.—Not later than 1 year after the date of the enactment of this section, the Attorney General shall promulgate regulations to authorize an ultimate user or care taker to dispose of a controlled substance in accordance with a State program described in subsection (b).

''(b) STATE PROGRAMS.—

''(1) MODELS; INDIVIDUALIZED PROGRAMS.—The regulations under subsection (a) shall—

''(A) include 5 model State programs under which an ultimate user or care taker may dispose of an unused or partially used controlled substance through delivery to a designated facility; and

''(B) allow a State to work with the Attorney General to devise an alternative program for such disposal that—

''(i) best suits the State; and

''(ii) as determined by the Attorney General, is consistent with this section.

''(2) REQUIREMENTS.—Each program under paragraph (1) shall—

''(A) require a State to enact legislation as a prerequisite to adopting and implementing such program;

''(B) protect the public safety;

''(C) allow ultimate users and care takers to dispose of controlled substances through persons other than law enforcement personnel;

''(D) incorporate environmentally sound practices for disposing of controlled substances (by means other than flushing down a public or private wastewater treatment system or disposing in a municipal solid waste landfill);

''(E) be cost effective for the State;

''(F) include convenient take-back options for urban and rural locations; and

''(G) not restrict the funding which a State may use to implement the program.

''(3) OTHER DRUGS AND BIOLOGICS.—A program under paragraph (1) may, at the State's option, apply to a drug or biological product other than a controlled substance to the same extent and in the

same manner as such program applies to a controlled substance. For purposes of this paragraph, the terms 'drug' and 'biological product' have the meanings given to those terms in section 201 of the Federal Food, Drug, and Cosmetic Act and section 351 of the Public Health Service Act, respectively.

''(c) DEFINITION.—In this section, the term 'care taker'—

''(1) means a person responsible for taking care of one or more individuals or animals, including through provision of controlled substances; and

''(2) may include a physician or other health care professional, a veterinarian, a long-term care facility, a nursing home, a hospital, a jail, or a school.''.

(b) GAO REPORT.—The Comptroller General of the United States shall—

(1) collect data on the State take-back disposal programs implemented pursuant to section 312 of the Controlled Substances Act, as added by subsection (a); and

(2) not less than every 4 years, submit findings and recommendations to the Congress regarding such programs.

(c) CONFORMING AMENDMENT.—The table of contents for the Comprehensive Drug Abuse Prevention and Control Act of 1970 (Public Law 91–513; 84 Stat. 1236) is amended by inserting after the item relating to section 311 the following:

''Sec. 312. State take-back disposal programs.''.

SEC. 3. NO LABELING RECOMMENDATIONS TO DISPOSE OF DRUGS AND BIOLOGICAL PRODUCTS BY FLUSHING.

(a) DRUGS.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by adding at the end the following:

''(w) NO LABELING RECOMMENDATIONS TO DISPOSE BY FLUSHING.—In approving an application for a drug under this section, the Secretary shall ensure that the labeling for such drug does not include any recommendation or direction to dispose of the drug by means of a public or private wastewater treatment system, such as by flushing down the toilet.''.

(b) BIOLOGICAL PRODUCTS.—Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended by adding at the end the following:

''(k) NO LABELING RECOMMENDATIONS TO DISPOSE BY FLUSHING.—In licensing any biological product under this section, the Secretary shall ensure that the labeling for such product does not include any recommendation or

direction to dispose of the product by means of a public or private wastewater treatment system, such as by flushing down the toilet.''.

(c) DRUGS AND BIOLOGICAL PRODUCTS ALREADY MARKETED.—

(1) LABELING REVISION.—With respect to drugs and biological products that are legally marketed under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.) or part F of title III of the Public Health Service Act (42 U.S.C. 262 et seq.) as of the date of the enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs—

(A) shall conduct a review of the labeling of such drugs and biological products; and

(B) for any such labeling that includes a recommendation or direction to dispose of the drug or biological product by means of a public or private wastewater treatment system, such as by flushing down the toilet, shall order the labeling to be revised to exclude such recommendation or direction.

(2) PENALTY.—Any drug or biological product whose labeling is in violation of an order issued under paragraph (1)(B) is deemed to be misbranded

under section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352).

(3) EFFECTIVE DATE.—An order issued under paragraph (1)(B) shall take effect not later than 1 year after the date of the enactment of this Act.

(4) DEFINITIONS.—In this subsection:

(A) The term ''biological product'' has the meaning given such term in section 351 of the Public Health Service Act (42 U.S.C. 262).

(B) The terms ''drug'' and ''labeling'' have the meanings given such terms in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

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