

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

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Safe Drug Disposal
3 Act of 2009”.

4 **SEC. 2. STATE TAKE-BACK DISPOSAL PROGRAMS.**

5 (a) IN GENERAL.—Part C of the Controlled Sub-
6 stances Act (21 U.S.C. 821 et seq.) is amended by adding
7 at the end the following:

8 **“SEC. 312. STATE TAKE-BACK DISPOSAL PROGRAMS.**

9 “(a) IN GENERAL.—Not later than 1 year after the
10 date of the enactment of this section, the Attorney General
11 shall promulgate regulations to authorize an ultimate user
12 or care taker to dispose of a controlled substance in ac-
13 cordance with a State program described in subsection (b).

14 “(b) STATE PROGRAMS.—

15 “(1) MODELS; INDIVIDUALIZED PROGRAMS.—

16 The regulations under subsection (a) shall—

17 “(A) include 5 model State programs
18 under which an ultimate user or care taker may
19 dispose of an unused or partially used con-
20 trolled substance through delivery to a des-
21 ignated facility; and

22 “(B) allow a State to work with the Attor-
23 ney General to devise an alternative program
24 for such disposal that—

25 “(i) best suits the State; and

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

3 “(2) REQUIREMENTS.—Each program under
4 paragraph (1) shall—

5 “(A) require a State to enact legislation as
6 a prerequisite to adopting and implementing
7 such program;

8 “(B) protect the public safety;

9 “(C) allow ultimate users and care takers
10 to dispose of controlled substances through per-
11 sons other than law enforcement personnel;

12 “(D) incorporate environmentally sound
13 practices for disposing of controlled substances
14 (by means other than flushing down a public or
15 private wastewater treatment system or dis-
16 posing in a municipal solid waste landfill);

17 “(E) be cost effective for the State;

18 “(F) include convenient take-back options
19 for urban and rural locations; and

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

22 “(3) OTHER DRUGS AND BIOLOGICS.—A pro-
23 gram under paragraph (1) may, at the State’s op-
24 tion, apply to a drug or biological product other than
25 a controlled substance to the same extent and in the

1 same manner as such program applies to a con-
2 trolled substance. For purposes of this paragraph,
3 the terms ‘drug’ and ‘biological product’ have the
4 meanings given to those terms in section 201 of the
5 Federal Food, Drug, and Cosmetic Act and section
6 351 of the Public Health Service Act, respectively.

7 “(c) DEFINITION.—In this section, the term ‘care
8 taker’—

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

12 “(2) may include a physician or other health
13 care professional, a veterinarian, a long-term care
14 facility, a nursing home, a hospital, a jail, or a
15 school.”.

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

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

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

1 (c) CONFORMING AMENDMENT.—The table of con-
 2 tents for the Comprehensive Drug Abuse Prevention and
 3 Control Act of 1970 (Public Law 91–513; 84 Stat. 1236)
 4 is amended by inserting after the item relating to section
 5 311 the following:

“Sec. 312. State take-back disposal programs.”.

6 **SEC. 3. NO LABELING RECOMMENDATIONS TO DISPOSE OF**
 7 **DRUGS AND BIOLOGICAL PRODUCTS BY**
 8 **FLUSHING.**

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

12 “(w) NO LABELING RECOMMENDATIONS TO DIS-
 13 POSE BY FLUSHING.—In approving an application for a
 14 drug under this section, the Secretary shall ensure that
 15 the labeling for such drug does not include any rec-
 16 ommendation or direction to dispose of the drug by means
 17 of a public or private wastewater treatment system, such
 18 as by flushing down the toilet.”.

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

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

1 direction to dispose of the product by means of a public
2 or private wastewater treatment system, such as by flush-
3 ing down the toilet.”.

4 (c) DRUGS AND BIOLOGICAL PRODUCTS ALREADY
5 MARKETED.—

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

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

16 (B) for any such labeling that includes a
17 recommendation or direction to dispose of the
18 drug or biological product by means of a public
19 or private wastewater treatment system, such
20 as by flushing down the toilet, shall order the
21 labeling to be revised to exclude such rec-
22 ommendation or direction.

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

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

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

6 (4) DEFINITIONS.—In this subsection:

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

10 (B) The terms “drug” and “labeling” have
11 the meanings given such terms in section 201
12 of the Federal Food, Drug, and Cosmetic Act
13 (21 U.S.C. 321).

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