

112TH CONGRESS
1ST SESSION

H. R. 2939

To provide for the disposal of drugs pursuant to national pharmaceutical stewardship programs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 15, 2011

Ms. SLAUGHTER introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, 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 provide for the disposal of drugs pursuant to national pharmaceutical stewardship programs, 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,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Pharmaceutical Stew-
5 ardship Act of 2011”.

1 **SEC. 2. NATIONAL PHARMACEUTICAL STEWARDSHIP PRO-**
2 **GRAMS.**

3 (a) **REQUIRED PARTICIPATION.**—Each manufacturer
4 and brand owner of a drug marketed in the United States
5 shall participate in—

6 (1) the certified national pharmaceutical stew-
7 ardship program of the National Pharmaceutical
8 Stewardship Organization; or

9 (2) another certified national pharmaceutical
10 stewardship program.

11 (b) **NATIONAL PHARMACEUTICAL STEWARDSHIP OR-**
12 **GANIZATION.**—

13 (1) **ESTABLISHMENT.**—There shall be estab-
14 lished in accordance with this section a nonprofit
15 private corporation to be known as the National
16 Pharmaceutical Stewardship Organization. The Or-
17 ganization shall not be an agency or instrumentality
18 of the Federal Government, and officers, employees,
19 and members of the board of the Organization shall
20 not, by virtue of such service, be considered officers
21 or employees of the Federal Government.

22 (2) **PURPOSE.**—The purpose of the Organiza-
23 tion shall be to establish and, not later than 2 years
24 after the date of the enactment of this Act, begin
25 implementation of a certified national pharma-
26 ceutical stewardship program.

1 (3) BOARD OF DIRECTORS.—The Organization
2 shall have a board of directors including representa-
3 tives of manufacturers and brand owners of drugs
4 and public health stakeholders. The Administrator
5 shall appoint the initial members of the board of di-
6 rectors.

7 (4) BYLAWS.—The board of directors shall es-
8 tablish the general policies of the Organization for
9 carrying out the purpose described in paragraph (2),
10 including the establishment of the bylaws of the Or-
11 ganization. The board of directors shall ensure that
12 the bylaws of the Organization include bylaws for
13 the following:

14 (A) Entering into contracts and agree-
15 ments with service providers and entities as
16 necessary, useful, or convenient to provide all or
17 portions of the national pharmaceutical stew-
18 ardship program of the Organization.

19 (B) Taking any legal action necessary or
20 proper for the recovery of an assessment for, on
21 behalf of, or against manufacturers or brand
22 owners of a drug participating in such program.

23 (C) Performing such other functions as
24 may be necessary or proper to carry out the
25 purpose described in paragraph (2).

1 (D) Ensuring that the members of the
2 board of directors serve without compensation,
3 but are entitled to reimbursement (solely from
4 the funds of the Organization) for expenses
5 (other than meal or travel expenses) incurred in
6 the discharge of their duties as members of the
7 board of directors.

8 (E) Ensuring that the Organization does
9 not use any State or local government funds to
10 carry out the purpose described in paragraph
11 (2).

12 (F) Allowing the Administrator—

13 (i) to audit the activities of the Orga-
14 nization as the Administrator deems nec-
15 essary; and

16 (ii) to access any facilities or property
17 of the Organization as the Administrator
18 deems necessary to conduct inspections or
19 investigate complaints.

20 (5) NONPROFIT STATUS.—In carrying out the
21 purpose described in paragraph (2), the board of di-
22 rectors shall establish such policies and bylaws under
23 paragraph (4) as may be necessary to ensure that
24 the Organization maintains its status as an organi-
25 zation that—

1 (A) is described in subsection (c)(3) of sec-
2 tion 501 of the Internal Revenue Code of 1986;
3 and

4 (B) is, under subsection (a) of such sec-
5 tion, exempt from taxation.

6 (6) CONTRIBUTIONS TO NATIONAL PHARMA-
7 CEUTICAL STEWARDSHIP ORGANIZATION NOT
8 TREATED AS CHARITABLE CONTRIBUTIONS.—A con-
9 tribution by a manufacturer or brand owner of a
10 drug to the Organization or the Organization's na-
11 tional pharmaceutical stewardship program shall not
12 be treated as a charitable contribution for purposes
13 of section 170 of the Internal Revenue Code of
14 1986.

15 (7) ARTICLES OF INCORPORATION.—The Ad-
16 ministrator shall ensure that the initial articles of
17 incorporation of the Organization are properly filed
18 not later than 60 days after the date of the enact-
19 ment of this Act.

20 (c) PROGRAM REQUIREMENTS.—To be certified
21 under subsection (f) or (g), a program shall meet each
22 of the following:

23 (1) The program is operated pursuant to an
24 agreement among the manufacturers and brand
25 owners of drugs participating in the program.

1 (2) Subject to subsection (d), the costs of the
2 program are fully paid by such manufacturers and
3 brand owners.

4 (3) The program is developed with input from
5 the public, including an opportunity for public com-
6 ment and at least one public hearing.

7 (4) The program provides a system to facilitate
8 the collection and disposal of any drug that—

9 (A) is delivered to the program by an indi-
10 vidual in the United States; and

11 (B) is household waste as defined under
12 the implementing regulations of subtitle C of
13 title II of the Solid Waste Disposal Act (42
14 U.S.C. 6901 et seq.; commonly referred to as
15 the “Resource Conservation and Recovery
16 Act”).

17 (5) Collection and disposal of a drug through
18 the program’s system (described in paragraph (4))
19 occurs in a manner that—

20 (A) is safe and secure;

21 (B) results in incineration of the drug in
22 accordance with the hazardous waste inciner-
23 ation requirements under subtitle C of title II
24 of the Solid Waste Disposal Act (42 U.S.C.
25 6901 et seq.);

1 (C) protects patient information;

2 (D) is accessible in every State, county,
3 and city or town, including—

4 (i) at least one collection site in every
5 county of every State and one collection
6 site in every city with a population of more
7 than 10,000 individuals on an ongoing,
8 year-round basis; or

9 (ii) if collection is not feasible in a
10 specific county or city, provision of prepaid
11 mailing envelopes to individuals in such
12 county or city for such collection and dis-
13 posal; and

14 (E) in the case of a controlled substance,
15 is consistent with section 302(g) of the Con-
16 trolled Substances Act (21 U.S.C. 822(g)).

17 (6) The program shall not impose any fee on
18 individuals for delivery or disposal of a drug through
19 the program.

20 (7) The program promotes the collection and
21 disposal of drugs through the program.

22 (8) The program ensures that options for col-
23 lection and disposal of drugs through the program
24 are widely understood by customers, pharmacists, re-

1 tailers, and health care practitioners including doc-
2 tors and other prescribers, including by—

3 (A) maintaining a toll-free telephone num-
4 ber and a Web site publicizing such collection
5 and disposal options;

6 (B) preparing educational and outreach
7 materials—

8 (i) describing where and how to dis-
9 pose of drugs through the program; and

10 (ii) addressing the risks of diversion
11 of drugs and the importance of awareness
12 about safe storage and disposal of drugs;
13 and

14 (C) providing such materials to phar-
15 macies, health care facilities, and other inter-
16 ested parties for dissemination.

17 (9) The program—

18 (A) annually evaluates the effectiveness of
19 its educational and outreach activities under
20 paragraph (7); and

21 (B) at least every 4 years, includes in such
22 evaluation—

23 (i) the percentage of residents of the
24 United States who are aware of the pro-
25 gram; and

1 (ii) the extent to which residents of
2 the United States find the program to be
3 convenient.

4 (d) MECHANISM FOR TRANSFER OF COSTS AMONG
5 MANUFACTURERS AND BRAND OWNERS.—To be certified
6 under subsection (f) or (g), a program shall include a
7 mechanism that—

8 (1) provides for receiving and transferring
9 funds among all certified national pharmaceutical
10 stewardship programs in such amounts as may be
11 necessary to ensure that the manufacturers and
12 brand owners of drugs participating in such pro-
13 grams bear the costs of such programs in proportion
14 to the market shares of their respective drugs; and

15 (2) is specified in a written agreement among
16 all manufacturers and brand owners of drugs.

17 (e) PROGRAM REPORTING REQUIREMENTS.—

18 (1) IN GENERAL.—To be certified under sub-
19 section (f) or (g), a program shall agree to submit
20 a report to the Environmental Protection Agency by
21 not later than January 1st of the first calendar year
22 following such certification, and annually thereafter.

23 (2) CONTENTS.—Each report submitted by a
24 program under paragraph (1) shall describe the pro-

1 gram's activities during the preceding calendar year,
2 including at a minimum—

3 (A) a specification of the amount, by
4 weight, of drugs collected through the program,
5 including the amount by weight from each col-
6 lection method used;

7 (B) an identification of any safety or secu-
8 rity problems which occurred during collection,
9 transportation, or disposal of drugs during the
10 preceding calendar year and a description of the
11 changes which have or will be made to policies,
12 procedures, or tracking mechanisms to alleviate
13 any such problems and to improve safety and
14 security in the future;

15 (C) a description of the educational and
16 outreach activities under subsection (e)(8);

17 (D) a description of how collected pack-
18 aging was recycled to the extent feasible, in-
19 cluding the recycling facility or facilities used;
20 and

21 (E) the total expenditures of the program
22 and a statement on whether the program fore-
23 sees a need for adjustment of the total annual
24 cost responsibility under subsection (d) of man-
25 ufacturers and brand owners participating in

1 the program as a result of changes in volumes
2 of collected drugs or other costs.

3 (3) PROCEDURES.—The Administrator shall es-
4 tablish procedures for reporting under this sub-
5 section not later than the date that is one year after
6 the date of the enactment of this Act.

7 (4) PUBLIC AVAILABILITY.—The Administrator
8 shall make each report submitted under this sub-
9 section available to the public.

10 (f) CERTIFICATION OF NATIONAL PHARMACEUTICAL
11 STEWARDSHIP ORGANIZATION’S PROGRAM.—

12 (1) APPLICATION.—To seek certification of its
13 program, the Organization shall submit an applica-
14 tion to the Administrator containing such informa-
15 tion as the Administrator may require.

16 (2) CONSIDERATION BY ADMINISTRATOR.—
17 Upon receipt of an application under paragraph (1),
18 the Administrator—

19 (A) shall consult with the Administrator of
20 the Drug Enforcement Agency on the adequacy
21 of the proposed program’s security measures
22 for collection, transportation, and disposal of
23 drugs, disposal systems, and mechanisms for
24 secure tracking and handling; and

1 (B) within 90 days after receipt of the ap-
2 plication, shall—

3 (i) certify the program if the Adminis-
4 trator determines it meets the require-
5 ments of this section; or

6 (ii) reject the proposed program and
7 provide a written explanation of the rea-
8 sons for such rejection.

9 (3) RESPONSE TO REJECTION OF PROPOSED
10 PROGRAM.—If the Administrator rejects the Organi-
11 zation’s proposed program under paragraph
12 (2)(B)(ii), the rejection shall be treated as final
13 agency action, and the Organization may—

14 (A) revise its proposed program and sub-
15 mit a new application under paragraph (1); or

16 (B) seek judicial review of the rejection not
17 later than 60 days after receiving notice of the
18 rejection.

19 (4) SOLICITATION OF PUBLIC COMMENT TO IN-
20 FORM PROGRAM UPDATES.—

21 (A) IN GENERAL.—A certified national
22 product stewardship program shall—

23 (i) annually invite comments from
24 health care facilities, health care practi-
25 tioners, pharmacists, State and local gov-

1 ernments, law enforcement personnel, and
2 citizens on their satisfaction with the serv-
3 ices provided by the program;

4 (ii) compile and submit the informa-
5 tion received through such comments to
6 the Administrator; and

7 (iii) use such information in devel-
8 oping updates and changes to the program.

9 (B) USE BY ADMINISTRATOR.—The Ad-
10 ministrator shall use information submitted
11 under subparagraph (A)(ii) in reviewing pro-
12 posed updates and revisions to certified national
13 pharmaceutical stewardship programs.

14 (C) GUIDANCE.—The Administrator shall
15 issue guidance on the process for complying
16 with this paragraph.

17 (5) TERM OF CERTIFICATION; UPDATES.—The
18 term of a certification under paragraph (2)(B)(i)
19 shall be not more than 4 years. Not less than every
20 4 years, a new application, including any relevant
21 updates to the certified national pharmaceutical
22 stewardship program, shall be submitted under para-
23 graph (1) and approved under paragraph (2)(B)(i)
24 in order for a program’s certification under this sub-
25 section to remain in effect.

1 (6) CHANGES TO CERTIFIED PROGRAM.—

2 (A) IN GENERAL.—Before making any sig-
3 nificant change to its certified national pharma-
4 ceutical stewardship program, the Organization
5 shall seek and obtain approval for the change
6 from the Administrator. Not later than 15 days
7 after submission of a request for a change
8 under the preceding sentence, the Adminis-
9 trator shall approve the change or reject the
10 change and provide a written explanation of the
11 reasons for the rejection.

12 (B) CHANGES TO COLLECTION LOCA-
13 TIONS.—Not less than 15 days after making
14 any change to a location for the collection of
15 drugs through its certified national pharma-
16 ceutical stewardship program, the Organization
17 shall inform the Administrator of the change.

18 (7) SUBMISSION REQUIREMENTS.—

19 (A) PUBLICATION.—Not later than 6
20 months after the date of the enactment of this
21 Act, the Administrator shall publish require-
22 ments for the submission of applications under
23 paragraph (1) and requests for changes under
24 paragraph (6), including requirements for the
25 contents of such submissions.

1 (B) FAILURE TO PUBLISH.—If the Admin-
2 istrator fails to publish such requirements by
3 the deadline specified in subparagraph (A), the
4 requirements of this section applicable to manu-
5 facturers and brand owners of drugs shall none-
6 theless apply.

7 (g) CERTIFICATION OF OTHER PROGRAMS.—

8 (1) APPLICATION.—In lieu of participating in
9 the certified national pharmaceutical stewardship
10 program of the Organization, one or more manufac-
11 turers or brand owners of a drug may submit an ap-
12 plication to the Administrator seeking certification
13 of a separate national pharmaceutical stewardship
14 program.

15 (2) GOVERNING PROVISIONS.—The provisions
16 of subsection (f) shall apply with respect to an appli-
17 cation for certification of a program under para-
18 graph (1) to the same extent and in the same man-
19 ner as such provisions apply to an application for
20 certification of a program by the Organization under
21 subsection (e), except as follows:

22 (A) The reference to 90 days in subsection
23 (f)(2)(B) (relating to the period of the Adminis-
24 trator’s review of an application) shall be treat-
25 ed as a reference to 120 days.

1 (B) If the Administrator rejects the pro-
2 posed program, in lieu of submitting a new ap-
3 plication under paragraph (1) or seeking judi-
4 cial review of the rejection, the manufacturers
5 or brand owners may choose to participate in
6 the certified national pharmaceutical steward-
7 ship program of the Organization.

8 (C) The references to 4 years in subsection
9 (f)(5) (relating to the term of certification and
10 to submission of a new application) shall be
11 treated as references to 3 years.

12 (h) PROCESS TO CHANGE DISPOSAL MECHANISM.—

13 (1) PETITIONS.—On petition by any person, the
14 Administrator may authorize a national pharma-
15 ceutical stewardship program to use, in lieu of the
16 disposal technologies otherwise required by sub-
17 section (c)(5)(B), one of more other disposal tech-
18 nologies described in paragraph (2).

19 (2) REQUIRED LEVELS OF PROTECTION.—The
20 Administrator may authorize the use of a disposal
21 technology under paragraph (1) only if the tech-
22 nology—

23 (A) is proven, available, and consistent
24 with Federal and State legal requirements; and

1 (B) provides equivalent environmental and
2 human health protection in each, and superior
3 environmental and human health protection in
4 one or more, of the following areas:

5 (i) Monitoring of any emissions or
6 waste.

7 (ii) Worker health and safety.

8 (iii) Air, water, or land emissions con-
9 tributing to persistent, bioaccumulative,
10 and toxic pollution.

11 (iv) Overall impact to the environment
12 and human health.

13 (i) SUSPENSION OF PROGRAM.—

14 (1) IMMINENT DANGER.—The Administrator
15 may suspend, in whole or in part, the certification
16 of any national pharmaceutical stewardship program
17 if the Administrator determines that such action is
18 necessary to protect the public from imminent dan-
19 ger.

20 (2) FAILURE TO COMPLY.—If the Adminis-
21 trator determines that a national pharmaceutical
22 stewardship is in violation of the requirements of
23 this section, the Administrator—

1 (A) may issue a written warning to the
2 program stating that the program is in violation
3 of this section; and

4 (B) if the program has not rectified each
5 violation identified in such warning within 30
6 days of receipt of such warning, may suspend,
7 in whole or in part, the certification of the pro-
8 gram.

9 (j) CIVIL PENALTIES.—Beginning on the date that
10 is 2 years after the date of the enactment of this Act,
11 a manufacturer or brand owner of a drug shall be liable
12 for a civil penalty of not more than \$50,000 for each cal-
13 endar day on which, as determined by the Administrator,
14 the manufacturer or brand owner—

15 (1) is not participating in a certified national
16 pharmaceutical program; or

17 (2) is in violation of its obligation to contribute
18 to the costs of such a program under subsection
19 (c)(2).

20 (k) REGULATORY POWER.—The Administrator may
21 adopt rules or guidance necessary to implement, admin-
22 ister, and enforce this section. The Administrator, in con-
23 sultation with the Secretary of Health and Human Serv-
24 ices, the Administrator of the Drug Enforcement Agency,
25 the Director of National Drug Control Policy, and the

1 Commissioner of Food and Drugs, may include in such
2 regulations or guidance any performance standards deter-
3 mined appropriate for implementing the program require-
4 ments specified in this section.

5 (l) STATE, TRIBAL, AND LOCAL REGULATION.—This
6 section does not preempt the authority of State, tribal,
7 and local governments to impose more stringent require-
8 ments relating to the disposal of drugs.

9 (m) REPORT TO CONGRESS.—By December 31,
10 2016, the Environmental Protection Agency shall report
11 to the appropriate committees of the Congress concerning
12 the status of the national pharmaceutical stewardship pro-
13 grams under this section, including any recommendations
14 for changes to this section.

15 (n) SEVERABILITY.—If any provision of this section
16 or the application of such provision to any person or cir-
17 cumstance is held to be unconstitutional, the remainder
18 of this section, and the application of the provisions of
19 such remainder to any person or circumstance, shall not
20 be affected thereby.

21 (o) DEFINITIONS.—In this section:

22 (1) The term “Administrator” means the Ad-
23 ministrator of the Environmental Protection Agency.

24 (2) The term “board of directors” means the
25 board of directors of the Organization.

1 (3) The term “brand owner”, with respect to a
2 drug, means the holder of an approved application
3 for the drug under section 505 of the Federal Food,
4 Drug, and Cosmetic Act (21 U.S.C. 355).

5 (4) The term “certified national pharmaceutical
6 stewardship program” means a national pharma-
7 ceutical stewardship program with a certification in
8 effect under subsection (f) or (g).

9 (5) The term “controlled substance” has the
10 meaning given to such term in section 102 of the
11 Controlled Substances Act (21 U.S.C. 802).

12 (6) The term “drug” has the meaning given to
13 such term in section 201 of the Federal Food, Drug,
14 and Cosmetic Act (21 U.S.C. 321) except that such
15 term excludes any drug for which a take-back pro-
16 gram is in effect pursuant to a risk evaluation and
17 mitigation strategy under section 505–1 of such Act
18 (21 U.S.C. 355–1).

19 (7) The term “Organization” means the Na-
20 tional Pharmaceutical Stewardship Organization es-
21 tablished in accordance with subsection (b).

22 (p) FEES.—The Administrator may assess and col-
23 lect fees from manufacturers and brand owners of drugs
24 to pay the administrative costs of carrying out this section.
25 The Administrator shall allocate such fees among manu-

1 facturers and brand owners in proportion to the market
2 shares of their respective drugs.

3 (q) AUTHORIZATION OF APPROPRIATIONS.—

4 (1) IN GENERAL.—There is authorized to be
5 appropriated to the Environmental Protection Agen-
6 cy \$8,000,000 for fiscal year 2012 and each subse-
7 quent fiscal year to pay the administrative costs of
8 carrying out this section, including the costs of certi-
9 fying, evaluating, and auditing national pharma-
10 ceutical stewardship programs under this section.

11 (2) SOURCE OF FUNDS.—Amounts authorized
12 to be appropriated pursuant to paragraph (1) shall
13 be derived exclusively from amounts collected as civil
14 penalties under subsection (j) or fees under sub-
15 section (p).

16 **SEC. 3. EDUCATION CAMPAIGN ON DRUG DISPOSAL; EVAL-**
17 **UATION OF NATIONAL PHARMACEUTICAL**
18 **STEWARDSHIP PROGRAM.**

19 (a) EDUCATION AND OUTREACH CAMPAIGN.—Not
20 later than 18 months after the date of the enactment of
21 this Act, the Director of National Drug Control Policy,
22 in consultation with the Secretary of Health and Human
23 Services and the Administrator of the Environmental Pro-
24 tection Agency, shall establish and begin implementation
25 of an education and outreach campaign—

1 (1) to increase awareness among members of
2 the public regarding how drugs may be lawfully dis-
3 posed consistent with public safety, public health,
4 and environmental protection through national phar-
5 maceutical stewardship programs under section 2
6 and by other appropriate means; and

7 (2) to link members of the public to the na-
8 tional and local educational and outreach activities
9 conducted by such programs.

10 (b) EVALUATION.—

11 (1) IN GENERAL.—Not later than 2 years after
12 the date of the enactment of this Act, and annually
13 thereafter, the Director of National Drug Control
14 Policy, in consultation with the Secretary of Health
15 and Human Services and the Administrator of the
16 Environmental Protection Agency, shall conduct an
17 evaluation of the effectiveness of the national phar-
18 maceutical stewardship programs under section 2
19 and submit a report to the Congress on the results
20 of each such evaluation, including recommendations
21 for improving the programs.

22 (2) METRICS.—The evaluation under paragraph
23 (1) shall address each of the following:

24 (A) Access to national pharmaceutical
25 stewardship programs under section 2.

1 (B) Awareness of such programs, including
2 awareness of the risks of diversion of drugs and
3 awareness of the importance of safe storage and
4 safe disposal of pharmaceuticals.

5 **SEC. 4. COMMISSION ON DRUG DISPOSAL AND ITS PUBLIC**
6 **SAFETY, PUBLIC HEALTH, AND ENVIRON-**
7 **MENTAL IMPACTS.**

8 (a) ESTABLISHMENT.—The Administrator of the En-
9 vironmental Protection Agency shall establish an inter-
10 agency commission, to be known as the Commission on
11 Drug Disposal and its Public Safety, Public Health, and
12 Environmental Impacts (in this section referred to as the
13 “Commission”).

14 (b) MEMBERSHIP.—The members of the Commission
15 shall include the following:

16 (1) The Administrator of the Environmental
17 Protection Agency.

18 (2) The Director of the Centers for Disease
19 Control and Prevention.

20 (3) The Director of the National Institute of
21 Environmental Health Sciences.

22 (4) The Administrator of the Drug Enforce-
23 ment Administration.

24 (5) The Commissioner of Food and Drugs.

25 (6) The Secretary of Veterans Affairs.

1 (7) The Administrator of the Centers for Medi-
2 care & Medicaid Services.

3 (8) The Director of National Drug Control Pol-
4 icy.

5 (9) Any other Federal official with relevant ex-
6 pertise appointed or invited to serve on the Commis-
7 sion by the Administrator of the Environmental Pro-
8 tection Agency.

9 (10) Such individuals with expertise in public
10 health, public safety, or the environment as may be
11 appointed to serve on the Commission by the Admin-
12 istrator of the Environmental Protection Agency.

13 (11) Such State and local officials and other
14 stakeholders as may be invited to serve on the Com-
15 mission by the Administrator of the Environmental
16 Protection Agency.

17 (c) DUTIES.—The Commission shall—

18 (1) provide a forum for academic, govern-
19 mental, and other experts, as appropriate, to develop
20 a strategy to—

21 (A) prevent the entry of drugs into the Na-
22 tion’s water supply and environment consistent
23 with current public safety standards; and

1 (B) protect public health and promote pub-
2 lic safety by reducing diversion and the risk of
3 abuse and accidental overdose; and

4 (2) not later than 2 years after the date of the
5 enactment of this Act, and annually thereafter, de-
6 velop and submit to the Congress such a strategy.

7 (d) STRATEGY.—

8 (1) CONTENTS.—The strategy required by sub-
9 section (c) shall—

10 (A) assess risk hazards and strategies for
11 reducing the risks associated with misuse of
12 prescription drugs, including diversion, over-
13 dose, and accidental poisoning;

14 (B) address all sources of contamination,
15 including development, manufacturing, disposal,
16 and metabolic processing;

17 (C) include recommendations on minimum
18 environmental standards for disposing of drugs
19 by incineration and any other means deter-
20 mined appropriate by the Administrator of the
21 Environmental Protection Agency; and

22 (D) be designed to inform the regulations
23 and guidance of the Environmental Protection
24 Agency.

1 (C) the current efforts of Government
2 agencies to prevent the entry of drugs and drug
3 byproducts into the water supply;

4 (2) recommendations for actions by the Govern-
5 ment in order to prevent the entry of drugs and
6 drug byproducts into the ground and surface waters
7 of the United States; and

8 (3) recommendations for additional research on
9 drugs and drug byproducts in surface and ground
10 water in the United States, including a budget for
11 such research.

○