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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

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A BILL

To provide for the disposal of drugs pursuant to national pharmaceutical stewardship programs, 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 ''Pharmaceutical Stewardship Act of 2011''.

SEC. 2. NATIONAL PHARMACEUTICAL STEWARDSHIP PROGRAMS.

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

(1) the certified national pharmaceutical stewardship program of the National Pharmaceutical Stewardship Organization; or

(2) another certified national pharmaceutical stewardship program.

(b) NATIONAL PHARMACEUTICAL STEWARDSHIP ORGANIZATION.—

(1) ESTABLISHMENT.—There shall be established in accordance with this section a nonprofit private corporation to be known as the National Pharmaceutical Stewardship Organization. The Organization shall not be an agency or instrumentality of the Federal Government, and officers, employees, and members of the board of the Organization shall not, by virtue of such service, be considered officers or employees of the Federal Government.

(2) PURPOSE.—The purpose of the Organization shall be to establish and, not later than 2 years after the date of the enactment of this Act, begin implementation of a certified national pharmaceutical stewardship program.

(3) BOARD OF DIRECTORS.—The Organization shall have a board of directors including representatives of manufacturers and brand owners of drugs and public health stakeholders. The Administrator shall appoint the initial members of the board of directors.

(4) BYLAWS.—The board of directors shall establish the general policies of the Organization for carrying out the purpose described in paragraph (2), including the establishment of the bylaws of the Organization. The board of directors shall ensure that the bylaws of the Organization include bylaws for the following:

(A) Entering into contracts and agreements with service providers and entities as necessary, useful, or convenient to provide all or portions of the national pharmaceutical stewardship program of the Organization.

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

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

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

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

(F) Allowing the Administrator—

(i) to audit the activities of the Organization as the Administrator deems necessary; and

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

(5) NONPROFIT STATUS.—In carrying out the purpose described in paragraph (2), the board of directors shall establish such policies and bylaws under paragraph (4) as may be necessary to ensure that the Organization maintains its status as an organization that—

(A) is described in subsection (c)(3) of section 501 of the Internal Revenue Code of 1986; and

(B) is, under subsection (a) of such section, exempt from taxation.

(6) CONTRIBUTIONS TO NATIONAL PHARMACEUTICAL STEWARDSHIP ORGANIZATION NOT TREATED AS CHARITABLE CONTRIBUTIONS.—A contribution by a manufacturer or brand owner of a drug to the Organization or the Organization's national pharmaceutical stewardship program shall not be treated as a charitable contribution for purposes of section 170 of the Internal Revenue Code of 1986.

(7) ARTICLES OF INCORPORATION.—The Administrator shall ensure that the initial articles of incorporation of the Organization are properly filed not later than 60 days after the date of the enactment of this Act.

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

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

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

(3) The program is developed with input from the public, including an opportunity for public comment and at least one public hearing.

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

(A) is delivered to the program by an individual in the United States; and

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

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

(A) is safe and secure;

(B) results in incineration of the drug in accordance with the hazardous waste incineration requirements under subtitle C of title II of the Solid Waste Disposal Act (42 U.S.C. 6901 et seq.);

(C) protects patient information;

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

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

(ii) if collection is not feasible in a specific county or city, provision of prepaid mailing envelopes to individuals in such county or city for such collection and disposal; and

(E) in the case of a controlled substance, is consistent with section 302(g) of the Controlled Substances Act (21 U.S.C. 822(g)).

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

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

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

tailers, and health care practitioners including doctors and other prescribers, including by—

(A) maintaining a toll-free telephone number and a Web site publicizing such collection and disposal options;

(B) preparing educational and outreach materials—

(i) describing where and how to dispose of drugs through the program; and

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

(C) providing such materials to pharmacies, health care facilities, and other interested parties for dissemination.

(9) The program—

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

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

(i) the percentage of residents of the United States who are aware of the program; and

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

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

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

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

(e) PROGRAM REPORTING REQUIREMENTS.—

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

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

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

(A) a specification of the amount, by weight, of drugs collected through the program, including the amount by weight from each collection method used;

(B) an identification of any safety or security problems which occurred during collection, transportation, or disposal of drugs during the preceding calendar year and a description of the changes which have or will be made to policies, procedures, or tracking mechanisms to alleviate any such problems and to improve safety and security in the future;

(C) a description of the educational and outreach activities under subsection (c)(8);

(D) a description of how collected packaging was recycled to the extent feasible, including the recycling facility or facilities used; and

(E) the total expenditures of the program and a statement on whether the program foresees a need for adjustment of the total annual cost responsibility under subsection (d) of manufacturers and brand owners participating in

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

(3) PROCEDURES.—The Administrator shall establish procedures for reporting under this subsection not later than the date that is one year after the date of the enactment of this Act.

(4) PUBLIC AVAILABILITY.—The Administrator shall make each report submitted under this subsection available to the public.

(f) CERTIFICATION OF NATIONAL PHARMACEUTICAL STEWARDSHIP ORGANIZATION'S PROGRAM.—

(1) APPLICATION.—To seek certification of its program, the Organization shall submit an application to the Administrator containing such information as the Administrator may require.

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

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

(B) within 90 days after receipt of the application, shall—

(i) certify the program if the Administrator determines it meets the requirements of this section; or

(ii) reject the proposed program and provide a written explanation of the reasons for such rejection.

(3) RESPONSE TO REJECTION OF PROPOSED PROGRAM.—If the Administrator rejects the Organization's proposed program under paragraph (2)(B)(ii), the rejection shall be treated as final agency action, and the Organization may—

(A) revise its proposed program and submit a new application under paragraph (1); or

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

(4) SOLICITATION OF PUBLIC COMMENT TO INFORM PROGRAM UPDATES.—

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

(i) annually invite comments from health care facilities, health care practitioners, pharmacists, State and local gov-

ernments, law enforcement personnel, and citizens on their satisfaction with the services provided by the program;

(ii) compile and submit the information received through such comments to the Administrator; and

(iii) use such information in developing updates and changes to the program.

(B) USE BY ADMINISTRATOR.—The Administrator shall use information submitted under subparagraph (A)(ii) in reviewing proposed updates and revisions to certified national pharmaceutical stewardship programs.

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

(5) TERM OF CERTIFICATION; UPDATES.—The term of a certification under paragraph (2)(B)(i) shall be not more than 4 years. Not less than every 4 years, a new application, including any relevant updates to the certified national pharmaceutical stewardship program, shall be submitted under paragraph (1) and approved under paragraph (2)(B)(i) in order for a program's certification under this subsection to remain in effect.

(6) CHANGES TO CERTIFIED PROGRAM.—

(A) IN GENERAL.—Before making any significant change to its certified national pharmaceutical stewardship program, the Organization shall seek and obtain approval for the change from the Administrator. Not later than 15 days after submission of a request for a change under the preceding sentence, the Administrator shall approve the change or reject the change and provide a written explanation of the reasons for the rejection.

(B) CHANGES TO COLLECTION LOCATIONS.—Not less than 15 days after making any change to a location for the collection of drugs through its certified national pharmaceutical stewardship program, the Organization shall inform the Administrator of the change.

(7) SUBMISSION REQUIREMENTS.—

(A) PUBLICATION.—Not later than 6 months after the date of the enactment of this Act, the Administrator shall publish requirements for the submission of applications under paragraph (1) and requests for changes under paragraph (6), including requirements for the contents of such submissions.

(B) FAILURE TO PUBLISH.—If the Administrator fails to publish such requirements by the deadline specified in subparagraph (A), the requirements of this section applicable to manufacturers and brand owners of drugs shall nonetheless apply.

(g) CERTIFICATION OF OTHER PROGRAMS.—

(1) APPLICATION.—In lieu of participating in the certified national pharmaceutical stewardship program of the Organization, one or more manufacturers or brand owners of a drug may submit an application to the Administrator seeking certification of a separate national pharmaceutical stewardship program.

(2) GOVERNING PROVISIONS.—The provisions of subsection (f) shall apply with respect to an application for certification of a program under paragraph (1) to the same extent and in the same manner as such provisions apply to an application for certification of a program by the Organization under subsection (e), except as follows:

(A) The reference to 90 days in subsection (f)(2)(B) (relating to the period of the Administrator's review of an application) shall be treated as a reference to 120 days.

(B) If the Administrator rejects the proposed program, in lieu of submitting a new application under paragraph (1) or seeking judicial review of the rejection, the manufacturers or brand owners may choose to participate in the certified national pharmaceutical stewardship program of the Organization.

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

(h) PROCESS TO CHANGE DISPOSAL MECHANISM.—

(1) PETITIONS.—On petition by any person, the Administrator may authorize a national pharmaceutical stewardship program to use, in lieu of the disposal technologies otherwise required by subsection (c)(5)(B), one of more other disposal technologies described in paragraph (2).

(2) REQUIRED LEVELS OF PROTECTION.—The Administrator may authorize the use of a disposal technology under paragraph (1) only if the technology—

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

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

(i) Monitoring of any emissions or waste.

(ii) Worker health and safety.

(iii) Air, water, or land emissions contributing to persistent, bioaccumulative, and toxic pollution.

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

(i) SUSPENSION OF PROGRAM.—

(1) IMMINENT DANGER.—The Administrator may suspend, in whole or in part, the certification of any national pharmaceutical stewardship program if the Administrator determines that such action is necessary to protect the public from imminent danger.

(2) FAILURE TO COMPLY.—If the Administrator determines that a national pharmaceutical stewardship is in violation of the requirements of this section, the Administrator—

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

(B) if the program has not rectified each violation identified in such warning within 30 days of receipt of such warning, may suspend, in whole or in part, the certification of the program.

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

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

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

(k) REGULATORY POWER.—The Administrator may adopt rules or guidance necessary to implement, administer, and enforce this section. The Administrator, in consultation with the Secretary of Health and Human Services, the Administrator of the Drug Enforcement Agency, the Director of National Drug Control Policy, and the

Commissioner of Food and Drugs, may include in such regulations or guidance any performance standards determined appropriate for implementing the program requirements specified in this section.

(l) STATE, TRIBAL, AND LOCAL REGULATION.—This section does not preempt the authority of State, tribal, and local governments to impose more stringent requirements relating to the disposal of drugs.

(m) REPORT TO CONGRESS.—By December 31, 2016, the Environmental Protection Agency shall report to the appropriate committees of the Congress concerning the status of the national pharmaceutical stewardship programs under this section, including any recommendations for changes to this section.

(n) SEVERABILITY.—If any provision of this section or the application of such provision to any person or circumstance is held to be unconstitutional, the remainder of this section, and the application of the provisions of such remainder to any person or circumstance, shall not be affected thereby.

(o) DEFINITIONS.—In this section:

(1) The term ''Administrator'' means the Administrator of the Environmental Protection Agency.

(2) The term ''board of directors'' means the board of directors of the Organization.

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

(4) The term ''certified national pharmaceutical stewardship program'' means a national pharmaceutical stewardship program with a certification in effect under subsection (f) or (g).

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

(6) The term ''drug'' has the meaning given to such term in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) except that such term excludes any drug for which a take-back program is in effect pursuant to a risk evaluation and mitigation strategy under section 505–1 of such Act (21 U.S.C. 355–1).

(7) The term ''Organization'' means the National Pharmaceutical Stewardship Organization established in accordance with subsection (b).

(p) FEES.—The Administrator may assess and collect fees from manufacturers and brand owners of drugs to pay the administrative costs of carrying out this section. 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) to increase awareness among members of the public regarding how drugs may be lawfully disposed consistent with public safety, public health, and environmental protection through national pharmaceutical stewardship programs under section 2 and by other appropriate means; and

(2) to link members of the public to the national and local educational and outreach activities conducted by such programs.

(b) EVALUATION.—

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

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

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

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

SEC. 4. COMMISSION ON DRUG DISPOSAL AND ITS PUBLIC SAFETY, PUBLIC HEALTH, AND ENVIRONMENTAL IMPACTS.

(a) ESTABLISHMENT.—The Administrator of the Environmental Protection Agency shall establish an interagency commission, to be known as the Commission on Drug Disposal and its Public Safety, Public Health, and Environmental Impacts (in this section referred to as the ''Commission'').

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

(1) The Administrator of the Environmental Protection Agency.

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

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

(4) The Administrator of the Drug Enforcement Administration.

(5) The Commissioner of Food and Drugs.

(6) The Secretary of Veterans Affairs.

(7) The Administrator of the Centers for Medicare & Medicaid Services.

(8) The Director of National Drug Control Policy.

(9) Any other Federal official with relevant expertise appointed or invited to serve on the Commission by the Administrator of the Environmental Protection Agency.

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

(11) Such State and local officials and other stakeholders as may be invited to serve on the Commission by the Administrator of the Environmental Protection Agency.

(c) DUTIES.—The Commission shall—

(1) provide a forum for academic, governmental, and other experts, as appropriate, to develop a strategy to—

(A) prevent the entry of drugs into the Nation's water supply and environment consistent with current public safety standards; and

(B) protect public health and promote public safety by reducing diversion and the risk of abuse and accidental overdose; and

(2) not later than 2 years after the date of the enactment of this Act, and annually thereafter, develop and submit to the Congress such a strategy.

(d) STRATEGY.—

(1) CONTENTS.—The strategy required by subsection (c) shall—

(A) assess risk hazards and strategies for reducing the risks associated with misuse of prescription drugs, including diversion, overdose, and accidental poisoning;

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

(C) include recommendations on minimum environmental standards for disposing of drugs by incineration and any other means determined appropriate by the Administrator of the Environmental Protection Agency; and

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

(2) CONSIDERATION.—In preparing the strategy required by subsection (c), the Commission shall take into consideration the analysis and recommendations in the report under section 5.

(e) TERMINATION.—The Commission shall terminate on the date that is 5 years after the date of the enactment of this Act.

SEC. 5. REPORT ON DRUG BYPRODUCTS IN THE NATION'S WATER SUPPLY.

(a) IN GENERAL.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General of the United States shall submit a report to the Congress on drugs and drug byproducts in surface and ground water in the United States.

(b) CONTENTS.—At a minimum, the report under subsection (a) shall include—

(1) an analysis of—

(A) the quantity and distribution of drugs and drug byproducts in surface and ground water in the United States;

(B) the risks for humans and the environment associated with the presence of drugs and drug byproducts in such water; and

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

(2) recommendations for actions by the Government in order to prevent the entry of drugs and drug byproducts into the ground and surface waters of the United States; and

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

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