Calendar No. 436

108TH CONGRESS
2D SESSION

S. 2137

To authorize the Secretary of Health and Human Services to promulgate regulations for the reimportation of prescription drugs, and for other purposes.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 26, 2004

Mr. DORGAN (for himself, Ms. SNOWE, Ms. STABENOW, Mr. MCCAIN, and Mr. DASCHLE) introduced the following bill; which was read the first time

FEBRUARY 27, 2004

Read the second time and placed on the calendar

A BILL

To authorize the Secretary of Health and Human Services to promulgate regulations for the reimportation of prescription drugs, 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 Market Access Act of 2003''.

SEC. 2. FINDINGS.

Congress finds that—

(1) Americans unjustly pay up to 1000 percent more to fill their prescriptions than consumers in other countries;

(2) the United States is the largest market for pharmaceuticals in the world, yet American consumers pay the highest prices for pharmaceuticals in the world;

(3) an unaffordable drug is neither safe nor effective;

(4) allowing and structuring the importation of prescription drugs ensures access to affordable drugs, thus providing a level of safety to American consumers that consumers do not currently enjoy;

(5) according to the Congressional Budget Office, American seniors alone will spend $1,800,000,000,000 on pharmaceuticals over the next 10 years; and

(6) allowing open pharmaceutical markets could save American consumers at least $635,000,000,000 each year.

SEC. 3. PURPOSES.

The purposes of this Act are—

(1) to give all Americans immediate relief from the outrageously high cost of pharmaceuticals;

(2) to reverse the perverse economics of American pharmaceutical markets;

(3) to allow the importation of drugs (excluding pharmaceutical narcotics) only if the drugs and the facilities in which the drugs are manufactured are approved by the Food and Drug Administration; and

(4) to require that imported prescription drugs be packaged and shipped using counterfeit-resistant technologies approved by the Bureau of Engraving and Printing, similar to the technologies used to secure United States currency.

SEC. 4. IMPORTATION OF PRESCRIPTION DRUGS.

Section 804 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384) is amended—

(1) in subsection (a)—

(A) by striking ''The Secretary'' and inserting ''Not later than 181 days after the date of enactment of the Pharmaceutical Market Access Act of 2003, the Secretary''; and

(B) by striking ''pharmacists and wholesalers'' and inserting ''pharmacists, wholesalers, and qualifying individuals'';

(2) in subsection (b)—

(A) by striking paragraph (1) and inserting the following:

''(1) require that each covered product imported under that subsection complies with sections 501, 502, and 505 and other applicable requirements of this Act; and'';

(B) in paragraph (2), by striking '', including subsection (d); and'' and inserting a period; and

(C) by striking paragraph (3);

(3) in subsection (c), by inserting ''by pharmacists and wholesalers (but not qualifying individuals)'' after ''importation of covered products'';

(4) in subsection (d)—

(A) by striking paragraphs (3) and (10);

(B) in paragraph (5), by striking '', including the professional license number of the importer, if any'';

(C) in paragraph (6)—

(i) in subparagraph (C), by inserting ''(if required under subsection (e))'' before the period;

(ii) in subparagraph (D), by inserting ''(if required under subsection (e))'' before the period; and

(iii) in subparagraph (E), by striking ''labeling'';

(D) in paragraph (7)—

(i) in subparagraph (A), by inserting ''(if required under subsection (e))'' before the period; and

(ii) by striking subparagraph (B) and inserting the following:

''(B) Certification from the importer or manufacturer of the product that the product meets all requirements of this Act.''; and

(E) by redesignating paragraphs (4) through (9) as paragraphs (3) through (8), respectively;

(5) by striking subsection (e) and inserting the following:

''(e) TESTING.—

''(1) IN GENERAL.—Subject to paragraph (2), regulations under subsection (a) shall require that testing referred to in paragraphs (5) through (7) of subsection (d) be conducted by the importer of the covered product, unless the covered product is a prescription drug subject to the requirements of section 505B for counterfeit-resistant technologies.

''(2) EXCEPTION.—The testing requirements of paragraphs (5) through (7) of subsection (d) shall

not apply to an importer unless the importer is a wholesaler.'';

(6) in subsection (f), by striking ''or designated by the Secretary, subject to such limitations as the Secretary determines to be appropriate to protect the public health'';

(7) in subsection (g)—

(A) by striking ''counterfeit or''; and

(B) by striking ''and the Secretary determines that the public is adequately protected from counterfeit and violative covered products being imported pursuant to subsection (a)'';

(8) in subsection (i)(1)—

(A) by striking subparagraph (A) and inserting the following:

''(A) STUDY.—

''(i) IN GENERAL.—The Secretary shall conduct, or contract with an entity to conduct, a study on the imports permitted under subsection (a), including consideration of the information received under subsection (d).

''(ii) EVALUATION.— In conducting the study, the Secretary or entity shall—

''(I) evaluate the compliance of importers with regulations under subsection (a), and the incidence of shipments under that subsection, if any, that have been determined to be misbranded or adulterated; and

''(II) determine how that compliance contrasts with the incidence of shipments of prescription drugs transported within the United States that have been determined to be misbranded or adulterated.''; and

(B) in subparagraph (B), by striking ''Not later than 2 years after the effective date of final regulations under subsection (a),'' and inserting ''Not later than 18 months after the date of enactment of the Pharmaceutical Market Access Act of 2003,'';

(9) in subsection (k)(2)—

(A) by redesignating subparagraphs (D) and (E) as subparagraphs (E) and (F), respectively; and

(B) by inserting after subparagraph (C) the following:

''(D) QUALIFYING INDIVIDUAL.—The term 'qualifying individual' means an individual who is not a pharmacist or a wholesaler. ''; and

(10) by striking subsections (l) and (m).

SEC. 5. USE OF COUNTERFEIT-RESISTANT TECHNOLOGIES TO PREVENT COUNTERFEITING.

(a) MISBRANDING.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended by adding at the end the following:

''(w) If it is a drug subject to section 503(b), unless the packaging of the drug complies with the requirements of section 505B for counterfeit-resistant technologies.''.

(b) REQUIREMENTS.—Title V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 505A the following:

''SEC. 505B. COUNTERFEIT-RESISTANT TECHNOLOGIES.

''(a) INCORPORATION OF COUNTERFEIT-RESISTANT TECHNOLOGIES INTO PRESCRIPTION DRUG PACKAGING.—The Secretary shall require that the packaging of any drug subject to section 503(b) incorporate—

''(1) overt optically variable counterfeit-resistant technologies that are described in subsection (b) and comply with the standards of subsection (c); or

''(2) technologies that have an equivalent function of security, as determined by the Secretary.

''(b) ELIGIBLE TECHNOLOGIES.—Technologies described in this subsection—

''(1) shall be visible to the naked eye, providing for visual identification of product authenticity without the need for readers, microscopes, lighting devices, or scanners;

''(2) shall be similar to the technologies used by the Bureau of Engraving and Printing to secure United States currency;

''(3) shall be manufactured and distributed in a highly secure, tightly controlled environment; and

''(4) should incorporate additional layers of nonvisible covert security features up to and including forensic capability.

''(c) STANDARDS FOR PACKAGING.—

''(1) MULTIPLE ELEMENTS.—For the purpose of making it more difficult to counterfeit the packaging of drugs subject to section 503(b), a manufacturer of the drugs shall incorporate the technologies described in subsection (b) into multiple elements of the physical packaging of the drugs, including blister packs, shrink wrap, package labels, package seals, bottles, and boxes.

''(2) LABELING OF SHIPPING CONTAINER.—

''(A) IN GENERAL.—A shipment of a drug described in subsection (a) shall include a label on the shipping container that incorporates the technologies described in subsection (b), so that officials inspecting the packages will be able to determine the authenticity of the shipment.

''(B) CHAIN-OF-CUSTODY PROCEDURES.—

''(i) IN GENERAL.—A manufacturer of a drug described in subsection (a) shall ensure that chain-of-custody procedures apply to a label required under subparagraph (A).

''(ii) REQUIRED PROCEDURES.—Chain-of-custody procedures required under clause (i) shall include—

''(I) procedures applicable to contractual agreements for the use and distribution of the labels;

''(II) methods to audit the use of the labels; and

''(III) database access for the relevant governmental agencies for audit or verification of the use and distribution of the labels.''.

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