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108TH CONGRESS
1ST SESSION

# H. R. 2427

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

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IN THE HOUSE OF REPRESENTATIVES

JUNE 11, 2003

Mr. GUTKNECHT (for himself, Mr. JONES of North Carolina, Mr. SHAYS, Mr. JANKLOW, Mr. PETRI, Mr. KINGSTON, Mrs. EMERSON, Mr. BEREUTER, Mr. OSBORNE, Mr. HOEKSTRA, Mr. BARTLETT of Maryland, Mr. SMITH of Michigan, Mr. PAUL, Mr. DUNCAN, Mrs. NORTHUP, Mr. GILCHREST, Mr. ROHRABACHER, Mr. BURTON of Indiana, Mr. HENSARLING, Mr. EMANUEL, Mr. FRANK of Massachusetts, Mr. PETERSON of Minnesota, Mr. RAMSTAD, Mr. REHBERG, Mr. ISTOOK, Mr. BROWN of South Carolina, and Mr. TAYLOR of North Carolina) introduced the following bill; which was referred to the Committee on Energy and Commerce

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# 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.**

The Congress finds as follows:

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

(2) The United States is the world's largest market for pharmaceuticals yet consumers still pay the world's highest prices.

(3) An unaffordable drug is neither safe nor effective. Allowing and structuring the importation of prescription drugs ensures access to affordable drugs, thus providing a level of safety to American consumers they do not currently enjoy.

(4) According to the Congressional Budget Office, American seniors alone will spend $1.8 trillion dollars on pharmaceuticals over the next ten years.

(5) Allowing open pharmaceutical markets could save American consumers at least $635 billion of their own money each year.

**SEC. 3. PURPOSES.**

The purposes of this Act are as follows:

(1) To give all Americans immediate relief from the outrageously high cost of pharmaceuticals.

(2) To reverse the perverse economics of the American pharmaceutical markets.

(3) To allow the importation of drugs only if the drugs and the facilities where they are manufactured are approved by the Food and Drug Administration, and to exclude pharmaceutical narcotics.

(4) To require that imported prescription drugs be packaged and shipped using counterfeit-resistant technologies approved by the Bureau of Engraving and Printing (technologies similar to those 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 180 days after the date of the 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 amending paragraph (1) to read as follows:

''(1) require that each covered product imported pursuant to such 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 amending subparagraph (B) to read as follows:

''(B) Certification from the importer or manufacturer of such 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 amending subsection (e) to read as follows:

''(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 amending subparagraph (A) to read as follows:

''(A) IN GENERAL.—The Secretary shall conduct, or contract with an entity to conduct, a study on the imports permitted pursuant to subsection (a), including consideration of the information received under subsection (d). In conducting such study, the Secretary or entity shall evaluate the compliance of importers with regulations under subsection (a), and the incidence of shipments pursuant to such subsection, if any, that have been determined to be misbranded or adulterated, and determine how such 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 the 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) 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; deeming drugs and devices to be misbranded) is amended by adding at the end the following:

''(w) If it is a drug subject to section 503(b), unless the packaging of such 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 that 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 non-visible 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), manufacturers 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.—Shipments of drugs 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. Chain of custody procedures shall apply to such labels and shall include procedures applicable to contractual

agreements for the use and distribution of the labels, methods to audit the use of the labels, and database access for the relevant governmental agencies for audit or verification of the use and distribution of the labels.''.

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