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109TH CONGRESS
2D SESSION

H. R. 4829

To direct the Secretary of Health and Human Services to require the incorporation of counterfeit-resistant technologies into the packaging of prescription drugs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 1, 2006

Mr. BURTON of Indiana (for himself, Mr. GUTKNECHT, Mr. SANDERS, Mr. EMANUEL, Ms. HERSETH, Mrs. NORTHUP, Mr. JONES of North Carolina, Mr. DEFAZIO, and Mr. SOUDER) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To direct the Secretary of Health and Human Services to require the incorporation of counterfeit-resistant technologies into the packaging 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 ''Reducing Fraudulent and Imitation Drugs Act of 2006''.

SEC. 2. COUNTERFEIT-RESISTANT TECHNOLOGIES FOR PRESCRIPTION DRUGS.

(a) REQUIRED TECHNOLOGIES.—The Secretary of Health and Human Services shall require that the packaging of any prescription drug incorporate—

(1) radio frequency identification (RFID) tagging technology, or similar trace and track technologies that have an equivalent function;

(2) tamper-indicating technologies; and

(3) blister security packaging when possible.

(b) USE OF TECHNOLOGIES.—

(1) AUTHORIZED USES.—The Secretary shall require that technologies described in subsection (a)(1) be used exclusively to authenticate the pedigree of prescription drugs, including by—

(A) implementing inventory control;

(B) tracking and tracing prescription drugs;

(C) verifying shipment or receipt of prescription drugs;

(D) authenticating finished prescription drugs; and

(E) electronically authenticating the pedigree of prescription drugs.

(2) PRIVACY PROTECTION.—The Secretary shall prohibit technologies required by subsection (a)(1)

from containing or transmitting any information that may be used to identify a health care practitioner or the prescription drug consumer.

(3) PROHIBITION AGAINST ADVERTISING.—The Secretary shall prohibit technologies required by subsection (a)(1) from containing or transmitting any advertisement or information about prescription drug indications or off-label prescription drug uses.

(c) RECOMMENDED TECHNOLOGIES.—The Secretary shall encourage the manufacturers and distributors of prescription drugs to incorporate into the packaging of such drugs, in addition to the technologies required under subsection (a), overt optically variable counterfeit-resistant technologies that—

(1) are visible to the naked eye, providing for visual identification of prescription drug authenticity without the need for readers, microscopes, lighting devices, or scanners;

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

(3) are manufactured and distributed in a highly secure, tightly controlled environment; and

(4) incorporate additional layers of non-visible covert security features up to and including forensic capability.

(d) STANDARDS FOR PACKAGING.—

(1) MULTIPLE ELEMENTS.—For the purpose of making it more difficult to counterfeit the packaging of prescription drugs, the Secretary shall require manufacturers of prescription drugs to incorporate the technologies described in paragraphs (1), (2), and (3) of subsection (a), and shall encourage manufacturers and distributors of prescription drugs to incorporate the technologies described in subsection (c), into multiple elements of the physical packaging of the drugs, including—

(A) blister packs, shrink wrap, package labels, package seals, bottles, and boxes; and

(B) at the item level.

(2) LABELING OF SHIPPING CONTAINER.—Shipments of prescription drugs shall include a label on the shipping container that incorporates the technologies described in subsection (a)(1), so that members of the supply chain 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.

(e) PENALTY.—A prescription drug is deemed to be misbranded for purposes of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) if the packaging or labeling of the drug is in violation of a requirement or prohibition applicable to the drug under subsection (a), (b), or (d).

(f) TRANSITIONAL PROVISIONS; EFFECTIVE DATES.—

(1) NATIONAL SPECIFIED LIST OF SUSCEPTIBLE PRESCRIPTION DRUGS.—

(A) INITIAL PUBLICATION.—Not later than 180 days after the date of the enactment of this Act, the Secretary of Health and Human Services shall publish in the Federal Register a list, to be known as the National Specified List of Susceptible Prescription Drugs, consisting of not less than 30 of the prescription drugs that are most frequently subject to counterfeiting in the United States (as determined by the Secretary).

(B) REVISION.—Not less than annually through the end of calendar year 2009, the Secretary shall review and, as appropriate, revise the National Specified List of Susceptible Prescription Drugs. The Secretary may not revise the List to include fewer than 30 prescription drugs.

(2) EFFECTIVE DATES.—The Secretary shall implement the requirements and prohibitions of subsections (a), (b), and (d)—

(A) with respect to prescription drugs on the National Specified List of Susceptible Prescription Drugs, beginning not later than the earlier of—

(i) 1 year after the initial publication of such List; or

(ii) December 31, 2007; and

(B) with respect to all prescription drugs, beginning not later than December 31, 2010.

(3) AUTHORIZED USES DURING TRANSITIONAL PERIOD.—In lieu of the requirements specified in subsection (b)(1), for the period beginning on the effective date applicable under paragraph (2)(A) and ending on the commencement of the effective date applicable under paragraph (2)(B), the Secretary

shall require that technologies described in subsection (a)(1) be used exclusively to verify the authenticity of prescription drugs.

(g) DEFINITIONS.—In this Act:

(1) The term ''pedigree''—

(A) means the history of each prior sale, purchase, or trade of the prescription drug involved to a distributor or retailer of the drug (including the date of the transaction and the names and addresses of all parties to the transaction); and

(B) excludes information about the sale, purchase, or trade of the drug to the drug consumer.

(2) The term ''prescription drug'' means a drug subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)(1)).

(3) The term ''Secretary'' means the Secretary of Health and Human Services.

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