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109TH CONGRESS
1ST SESSION

H. R. 1396

To amend the Federal Food, Drug, and Cosmetic Act to establish recall authority regarding drugs, to increase criminal penalties for the sale or trade of prescription drugs knowingly caused to be adulterated or misbranded, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 17, 2005

Mr. ISRAEL introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to establish recall authority regarding drugs, to increase criminal penalties for the sale or trade of prescription drugs knowingly caused to be adulterated or misbranded, 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 ''Counterfeit Drug Enforcement Act''.

SEC. 2. RECALL AUTHORITY REGARDING DRUGS.

Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 506C the following section:

"SEC. 506D. RECALL AUTHORITY.

"(a) ORDER TO CEASE DISTRIBUTION OF DRUG; NOTIFICATION OF HEALTH PROFESSIONALS.—

"(1) IN GENERAL.—If the Secretary finds that there is a reasonable probability that a drug intended for human use would cause serious, adverse health consequences or death, the Secretary shall issue an order requiring the appropriate person (including the manufacturers, importers, distributors, or retailers of the drug)—

"(A) to immediately cease distribution of the drug; and

"(B) to immediately notify health professionals of the order and to instruct such professionals to cease administering or prescribing the drug.

"(2) INFORMAL HEARING.—An order under paragraph (1) shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than 10 days after the date of the issuance of the order, on the actions required by the order and on whether the order should be

amended to require a recall of the drug involved. If, after providing an opportunity for such a hearing, the Secretary determines that inadequate grounds exist to support the actions required by the order, the Secretary shall vacate the order.

''(b) ORDER TO RECALL DRUG.—

''(1) IN GENERAL.—If, after providing an opportunity for an informal hearing under subsection (a)(2), the Secretary determines that the order should be amended to include a recall of the drug with respect to which the order was issued, the Secretary shall, except as provided in paragraphs (2) and (3), amend the order to require a recall. The Secretary shall specify a timetable in which the drug recall will occur and shall require periodic reports to the Secretary describing the progress of the recall.

''(2) CERTAIN ACTIONS.—An amended order under paragraph (1)—

''(A) shall not include recall of a drug from individuals; and

''(B) shall provide for notice to individuals subject to the risks associated with the use of the drug.

''(3) ASSISTANCE OF HEALTH PROFESSIONALS.—In providing the notice required by para-

graph (2)(B), the Secretary may use the assistance of health professionals who administered the drug involved to individuals or prescribed the drug for individuals. If a significant number of such individuals cannot be identified, the Secretary shall notify such individuals pursuant to section 705(b).''.

SEC. 3. SALE OR TRADE OF PRESCRIPTION DRUGS KNOWINGLY CAUSED TO BE ADULTERATED OR MISBRANDED; KNOWING PURCHASE OR TRADE.

(a) CRIMINAL PENALTY.—Section 303(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(a)) is amended by adding at the end the following paragraph:

''(3) Notwithstanding paragraph (1) or (2), in the case of a person who violates section 301(a), 301(b), or 301(c) with respect to a drug that is subject to section 503(b)(1)(B), if the person knowingly caused the drug to be adulterated or misbranded and sells or trades the drug, or the person purchases or trades for the drug knowing or having reason to know that the drug was knowingly caused to be adulterated or misbranded, the person shall be fined in accordance with title 18, United States Code, or imprisoned for any term of years or for life, or both.''.

(b) NOTIFICATION OF FOOD AND DRUG ADMINISTRATION BY MANUFACTURERS.—Section 505(k) of the

Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(k)) is amended by adding at the end the following paragraph:

''(3) A manufacturer of a drug that receives or otherwise becomes aware of information that reasonably suggests that a violation described in section 303(a)(3) may have occurred with respect to the drug shall report such information to the Secretary not later than 48 hours after first receiving or otherwise becoming aware of the information.''.

(c) INCREASED FUNDING FOR INSPECTIONS, EXAMINATIONS, AND INVESTIGATIONS.—For the purpose of increasing the capacity of the Food and Drug Administration to conduct inspections, examinations, and investigations under the Federal Food, Drug, and Cosmetic Act with respect to violations described in section 303(a)(3) of such Act, there is authorized to be appropriated $60,000,000 for each of the fiscal years 2006 through 2010, in addition to other authorizations of appropriations that are available for such purpose.

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