109TH CONGRESS
1ST SESSION

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

IN THE SENATE OF THE UNITED STATES

NOVEMBER 9, 2005

Mr. SCHUMER introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

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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 ''Tim Fagan's Law'' or the ''Counterfeit Drug Enforcement Act of 2005''.

SEC. 2. SALE OR TRADE OF PRESCRIPTION DRUGS KNOWINGLY CAUSED TO BE ADULTERATED OR MISBRANDED; MISREPRESENTATION AS APPROVED DRUGS.

(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 paragraphs:

''(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.

''(4) Notwithstanding paragraph (1) or (2), in the case of a person who violates section 301(d) with respect to a drug, if the person caused the drug to be misrepresented as a drug that is subject to section 503(b)(1)(B) and for which an approved application is in effect under section 505 and the person 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 so misrepresented, 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 paragraph (3) or (4) of section 303(a) 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.''.

SEC. 3. USE OF TECHNOLOGIES FOR PREVENTING COUNTERFEITING OF DRUGS.

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

''(x) If it is a drug and it is not manufactured in accordance with any regulations of the Secretary requiring the use of technologies that the Secretary has determined are technically feasible and will assist in preventing viola-

tions of this Act to which paragraphs (3) and (4) of section 303(a) apply (relating to the knowing adulteration or misbranding of drugs and the knowing misrepresentation of drugs).''.

SEC. 4. WHOLESALE DISTRIBUTION OF DRUGS; STATEMENTS REGARDING PRIOR SALE, PURCHASE, OR TRADE.

(a) STRIKING OF EXEMPTIONS FOR MANUFACTURERS AND AUTHORIZED DISTRIBUTORS OF RECORD.—Section 503(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(e)) is amended—

(1) in paragraph (1)—

(A) by striking ''and who is not the manufacturer or an authorized distributor of record of such drug'';

(B) by striking ''to an authorized distributor of record or''; and

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

''(B) The Secretary shall by regulation establish requirements that supersede subparagraph (A) (referred to in this subparagraph as 'alternative requirements') to identify the chain of custody of a drug subject to subsection (b) from the manufacturer of the drug throughout

the wholesale distribution of the drug to a pharmacist who intends to sell the drug at retail if the Secretary determines that—

''(i) the alternative requirements, which may include standardized anti-counterfeiting or track-and-trace technologies, will identify such chain of custody or the identity of the discrete package of the drug from which the drug is dispensed with equal or greater certainty to the requirements of subparagraph (A); and

''(ii) the alternative requirements are economically and technically feasible.''; and

(2) in paragraph (3), by striking ''and subsection (d)—'' in the matter preceding subparagraph (A) and all that follows through ''the term 'wholesale distribution' means'' in subparagraph (B) and inserting the following: ''and subsection (d), the term 'wholesale distribution' means''.

(b) CONFORMING AMENDMENT.—Section 503(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(d)) is amended by adding at the end the following:

''(4) Each manufacturer of a drug subject to subsection (b) shall maintain at its corporate offices

a current list of the authorized distributors of record of such drug.

''(5) For purposes of this subsection, the term 'authorized distributors of record' means any distributor that a manufacturer designates as an authorized distributor of record and whose name the manufacturer makes publicly available.''.

(c) EFFECTIVE DATE.—

(1) IN GENERAL.—The amendments made by subsections (a) and (b) shall take effect on January 1, 2010.

(2) HIGH-RISK DRUGS.—

(A) IN GENERAL.—Notwithstanding paragraph (1), the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') may apply the amendments made by subsections (a) and (b) before January 1, 2010, with respect to a prescription drug if the Secretary—

(i) determines that the drug is at high risk for being counterfeited; and

(ii) publishes the determination and the basis for the determination in the Federal Register.

(B) PEDIGREE NOT REQUIRED.—Notwithstanding a determination under subparagraph (A) with respect to a prescription drug, the amendments described in such subparagraph shall not apply with respect to a wholesale distribution of such drug if the drug is distributed by the manufacturer of the drug to a person that distributes the drug to a retail pharmacy for distribution to the consumer or patient, with no other intervening transactions.

(C) LIMITATION.—The Secretary may make the determination under subparagraph (A) with respect to not more than 50 drugs before January 1, 2010.

(3) ALTERNATIVE REQUIREMENTS.—The Secretary shall issue regulations to establish the alternative requirements, referred to in the amendment made by subsection (a)(1), that take effect not later than—

(A) January 1, 2008, with respect to a prescription drug determined under paragraph (2)(A) to be at high risk for being counterfeited; and

(B) January 1, 2010, with respect to all other prescription drugs.

(4) INTERMEDIATE REQUIREMENTS.—With respect to the prescription drugs described under paragraph (3)(B), the Secretary shall by regulation require the use of standardized anti-counterfeiting or track-and-trace technologies on such prescription drugs at the case and pallet level effective not later than January 1, 2008.

SEC. 5. COUNTERFEIT DRUGS; 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 paragraphs (3) and (4) of section 303(a) of such Act (as added by this 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.

SEC. 6. PUBLIC EDUCATION REGARDING COUNTERFEIT DRUGS.

(a) IN GENERAL.—The Secretary of Health and Human Services shall carry out a program to educate the public and health care professionals on counterfeit drugs, including techniques to identify drugs as counterfeit.

(b) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out subsection (a), there is authorized to be appropriated $5,000,000 for each of the fiscal years 2006 through 2010, in addition to other authorizations of appropriations that are available for such purpose.

SEC. 7. 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:

"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 paragraph (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. 8. AUTHORITY TO ISSUE SUBPOENAS WITH RESPECT TO PREVENTING THREATS TO THE PUBLIC HEALTH.

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

''(g) The Secretary and the Attorney General shall develop and implement a procedure through which the Chief Counsel in the Food and Drug Administration is authorized to issue subpoenas regarding investigations under this Act of acts or omissions that may constitute a threat to the public health, including investigations of alleged vio-

lations to which paragraph (3) or (4) of subsection (a) apply and alleged violations with respect to which the Secretary is considering the use of authorities under section 304.''.

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