

109TH CONGRESS
1ST SESSION

S. 1978

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

A BILL

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as “Tim Fagan’s Law” or the
5 “Counterfeit Drug Enforcement Act of 2005”.

1 **SEC. 2. SALE OR TRADE OF PRESCRIPTION DRUGS KNOW-**
2 **INGLY CAUSED TO BE ADULTERATED OR MIS-**
3 **BRANDED; MISREPRESENTATION AS AP-**
4 **PROVED DRUGS.**

5 (a) CRIMINAL PENALTY.—Section 303(a) of the Fed-
6 eral Food, Drug, and Cosmetic Act (21 U.S.C. 333(a))
7 is amended by adding at the end the following paragraphs:

8 “(3) Notwithstanding paragraph (1) or (2), in
9 the case of a person who violates section 301(a),
10 301(b), or 301(c) with respect to a drug that is sub-
11 ject to section 503(b)(1)(B), if the person knowingly
12 caused the drug to be adulterated or misbranded
13 and sells or trades the drug, or the person purchases
14 or trades for the drug knowing or having reason to
15 know that the drug was knowingly caused to be
16 adulterated or misbranded, the person shall be fined
17 in accordance with title 18, United States Code, or
18 imprisoned for any term of years or for life, or both.

19 “(4) Notwithstanding paragraph (1) or (2), in
20 the case of a person who violates section 301(d) with
21 respect to a drug, if the person caused the drug to
22 be misrepresented as a drug that is subject to sec-
23 tion 503(b)(1)(B) and for which an approved appli-
24 cation is in effect under section 505 and the person
25 sells or trades the drug, or the person purchases or
26 trades for the drug knowing or having reason to

1 know that the drug was knowingly caused to be so
2 misrepresented, the person shall be fined in accord-
3 ance with title 18, United States Code, or impris-
4 oned for any term of years or for life, or both.”.

5 (b) NOTIFICATION OF FOOD AND DRUG ADMINIS-
6 TRATION BY MANUFACTURERS.—Section 505(k) of the
7 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(k))
8 is amended by adding at the end the following paragraph:

9 “(3) A manufacturer of a drug that receives or
10 otherwise becomes aware of information that reason-
11 ably suggests that a violation described in paragraph
12 (3) or (4) of section 303(a) may have occurred with
13 respect to the drug shall report such information to
14 the Secretary not later than 48 hours after first re-
15 ceiving or otherwise becoming aware of the informa-
16 tion.”.

17 **SEC. 3. USE OF TECHNOLOGIES FOR PREVENTING COUN-**
18 **TERFEITING OF DRUGS.**

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

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

1 tions of this Act to which paragraphs (3) and (4) of sec-
 2 tion 303(a) apply (relating to the knowing adulteration or
 3 misbranding of drugs and the knowing misrepresentation
 4 of drugs).”.

5 **SEC. 4. WHOLESALE DISTRIBUTION OF DRUGS; STATE-**
 6 **MENTS REGARDING PRIOR SALE, PURCHASE,**
 7 **OR TRADE.**

8 (a) **STRIKING OF EXEMPTIONS FOR MANUFACTUR-**
 9 **ERS AND AUTHORIZED DISTRIBUTORS OF RECORD.**—Sec-
 10 tion 503(e) of the Federal Food, Drug, and Cosmetic Act
 11 (21 U.S.C. 353(e)) is amended—

12 (1) in paragraph (1)—

13 (A) by striking “and who is not the manu-
 14 facturer or an authorized distributor of record
 15 of such drug”;

16 (B) by striking “to an authorized dis-
 17 tributor of record or”; and

18 (C) by striking subparagraph (B) and in-
 19 serting the following:

20 “(B) The Secretary shall by regulation es-
 21 tablish requirements that supersede subpara-
 22 graph (A) (referred to in this subparagraph as
 23 ‘alternative requirements’) to identify the chain
 24 of custody of a drug subject to subsection (b)
 25 from the manufacturer of the drug throughout

1 the wholesale distribution of the drug to a phar-
2 macist who intends to sell the drug at retail if
3 the Secretary determines that—

4 “(i) the alternative requirements,
5 which may include standardized anti-coun-
6 terfeiting or track-and-trace technologies,
7 will identify such chain of custody or the
8 identity of the discrete package of the drug
9 from which the drug is dispensed with
10 equal or greater certainty to the require-
11 ments of subparagraph (A); and

12 “(ii) the alternative requirements are
13 economically and technically feasible.”; and

14 (2) in paragraph (3), by striking “and sub-
15 section (d)—” in the matter preceding subparagraph
16 (A) and all that follows through “the term ‘whole-
17 sale distribution’ means” in subparagraph (B) and
18 inserting the following: “and subsection (d), the
19 term ‘wholesale distribution’ means”.

20 (b) CONFORMING AMENDMENT.—Section 503(d) of
21 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
22 353(d)) is amended by adding at the end the following:

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

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

3 “(5) For purposes of this subsection, the term
4 ‘authorized distributors of record’ means any dis-
5 tributor that a manufacturer designates as an au-
6 thorized distributor of record and whose name the
7 manufacturer makes publicly available.”.

8 (c) EFFECTIVE DATE.—

9 (1) IN GENERAL.—The amendments made by
10 subsections (a) and (b) shall take effect on January
11 1, 2010.

12 (2) HIGH-RISK DRUGS.—

13 (A) IN GENERAL.—Notwithstanding para-
14 graph (1), the Secretary of Health and Human
15 Services (referred to in this section as the “Sec-
16 retary”) may apply the amendments made by
17 subsections (a) and (b) before January 1, 2010,
18 with respect to a prescription drug if the Sec-
19 retary—

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

22 (ii) publishes the determination and
23 the basis for the determination in the Fed-
24 eral Register.

1 (B) PEDIGREE NOT REQUIRED.—Notwith-
2 standing a determination under subparagraph
3 (A) with respect to a prescription drug, the
4 amendments described in such subparagraph
5 shall not apply with respect to a wholesale dis-
6 tribution of such drug if the drug is distributed
7 by the manufacturer of the drug to a person
8 that distributes the drug to a retail pharmacy
9 for distribution to the consumer or patient, with
10 no other intervening transactions.

11 (C) LIMITATION.—The Secretary may
12 make the determination under subparagraph
13 (A) with respect to not more than 50 drugs be-
14 fore January 1, 2010.

15 (3) ALTERNATIVE REQUIREMENTS.—The Sec-
16 retary shall issue regulations to establish the alter-
17 native requirements, referred to in the amendment
18 made by subsection (a)(1), that take effect not later
19 than—

20 (A) January 1, 2008, with respect to a
21 prescription drug determined under paragraph
22 (2)(A) to be at high risk for being counter-
23 feited; and

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

1 (4) INTERMEDIATE REQUIREMENTS.—With re-
2 spect to the prescription drugs described under para-
3 graph (3)(B), the Secretary shall by regulation re-
4 quire the use of standardized anti-counterfeiting or
5 track-and-trace technologies on such prescription
6 drugs at the case and pallet level effective not later
7 than January 1, 2008.

8 **SEC. 5. COUNTERFEIT DRUGS; INCREASED FUNDING FOR**
9 **INSPECTIONS, EXAMINATIONS, AND INVES-**
10 **TIGATIONS.**

11 For the purpose of increasing the capacity of the
12 Food and Drug Administration to conduct inspections, ex-
13 aminations, and investigations under the Federal Food,
14 Drug, and Cosmetic Act with respect to violations de-
15 scribed in paragraphs (3) and (4) of section 303(a) of such
16 Act (as added by this Act), there is authorized to be ap-
17 propriated \$60,000,000 for each of the fiscal years 2006
18 through 2010, in addition to other authorizations of ap-
19 propriations that are available for such purpose.

20 **SEC. 6. PUBLIC EDUCATION REGARDING COUNTERFEIT**
21 **DRUGS.**

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

1 (b) AUTHORIZATION OF APPROPRIATIONS.—For the
2 purpose of carrying out subsection (a), there is authorized
3 to be appropriated \$5,000,000 for each of the fiscal years
4 2006 through 2010, in addition to other authorizations
5 of appropriations that are available for such purpose.

6 **SEC. 7. RECALL AUTHORITY REGARDING DRUGS.**

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

10 **“SEC. 506D. RECALL AUTHORITY.**

11 “(a) ORDER TO CEASE DISTRIBUTION OF DRUG;
12 NOTIFICATION OF HEALTH PROFESSIONALS.—

13 “(1) IN GENERAL.—If the Secretary finds that
14 there is a reasonable probability that a drug in-
15 tended for human use would cause serious, adverse
16 health consequences or death, the Secretary shall
17 issue an order requiring the appropriate person (in-
18 cluding the manufacturers, importers, distributors,
19 or retailers of the drug)—

20 “(A) to immediately cease distribution of
21 the drug; and

22 “(B) to immediately notify health profes-
23 sionals of the order and to instruct such profes-
24 sionals to cease administering or prescribing the
25 drug.

1 “(2) INFORMAL HEARING.—An order under
2 paragraph (1) shall provide the person subject to the
3 order with an opportunity for an informal hearing,
4 to be held not later than 10 days after the date of
5 the issuance of the order, on the actions required by
6 the order and on whether the order should be
7 amended to require a recall of the drug involved. If,
8 after providing an opportunity for such a hearing,
9 the Secretary determines that inadequate grounds
10 exist to support the actions required by the order,
11 the Secretary shall vacate the order.

12 “(b) ORDER TO RECALL DRUG.—

13 “(1) IN GENERAL.—If, after providing an op-
14 portunity for an informal hearing under subsection
15 (a)(2), the Secretary determines that the order
16 should be amended to include a recall of the drug
17 with respect to which the order was issued, the Sec-
18 retary shall, except as provided in paragraphs (2)
19 and (3), amend the order to require a recall. The
20 Secretary shall specify a timetable in which the drug
21 recall will occur and shall require periodic reports to
22 the Secretary describing the progress of the recall.

23 “(2) CERTAIN ACTIONS.—An amended order
24 under paragraph (1)—

1 “(A) shall not include recall of a drug from
2 individuals; and

3 “(B) shall provide for notice to individuals
4 subject to the risks associated with the use of
5 the drug.

6 “(3) ASSISTANCE OF HEALTH PROFES-
7 SIONALS.—In providing the notice required by para-
8 graph (2)(B), the Secretary may use the assistance
9 of health professionals who administered the drug
10 involved to individuals or prescribed the drug for in-
11 dividuals. If a significant number of such individuals
12 cannot be identified, the Secretary shall notify such
13 individuals pursuant to section 705(b).”.

14 **SEC. 8. AUTHORITY TO ISSUE SUBPOENAS WITH RESPECT**
15 **TO PREVENTING THREATS TO THE PUBLIC**
16 **HEALTH.**

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

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

1 lations to which paragraph (3) or (4) of subsection (a)
2 apply and alleged violations with respect to which the Sec-
3 retary is considering the use of authorities under section
4 304.”.

○