

109TH CONGRESS  
1ST SESSION

# H. R. 2345

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.

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## IN THE HOUSE OF REPRESENTATIVES

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

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

1 in accordance with title 18, United States Code, or impris-  
2 oned for any term of years or for life, or both.”.

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

7 “(3) A manufacturer of a drug that receives or other-  
8 wise becomes aware of information that reasonably sug-  
9 gests that a violation described in paragraph (3) or (4)  
10 of section 303(a) may have occurred with respect to the  
11 drug shall report such information to the Secretary not  
12 later than 48 hours after first receiving or otherwise be-  
13 coming aware of the information.”.

14 **SEC. 3. USE OF TECHNOLOGIES FOR PREVENTING COUN-**  
15 **TERFEITING OF DRUGS.**

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

19 “(x) If it is a drug and it is not manufactured in  
20 accordance with any regulations of the Secretary requiring  
21 the use of technologies that the Secretary has determined  
22 are technically feasible and will assist in preventing viola-  
23 tions of this Act to which paragraphs (3) and (4) of sec-  
24 tion 303(a) apply (relating to the knowing adulteration or

1 misbranding of drugs and the knowing misrepresentation  
2 of drugs).”.

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

6 (a) STRIKING OF EXEMPTIONS FOR AUTHORIZED  
7 DISTRIBUTORS OF RECORD.—Section 503(e) of the Fed-  
8 eral Food, Drug, and Cosmetic Act (21 U.S.C. 353(e))  
9 is amended—

10 (1) in paragraph (1)—

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

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

16 (C) by striking subparagraph (B) and in-  
17 serting the following:

18 “(B) The Secretary shall by regulation establish re-  
19 quirements that supersede subparagraph (A) (referred to  
20 in this subparagraph as ‘alternative requirements’) to  
21 identify the chain of custody of a drug subject to sub-  
22 section (b) from the manufacturer of the drug throughout  
23 the wholesale distribution of the drug to a pharmacist who  
24 intends to sell the drug at retail if the Secretary deter-  
25 mines that—

1           “(i) the alternative requirements (which may in-  
2           clude standardized anticounterfeiting or track-and-  
3           trace technologies) will identify such chain of cus-  
4           tody, or the identity of the discrete package of the  
5           drug from which the drug is dispensed, with equal  
6           or greater certainty than the requirements of sub-  
7           paragraph (A); and

8           “(ii) the alternative requirements are tech-  
9           nically feasible.”; and

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

16           (b) CONFORMING AMENDMENT.—Section 503(d) of  
17           the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
18           353(d)) is amended by adding at the end the following:

19           “(4) Each manufacturer of a drug subject to sub-  
20           section (b) shall maintain at its corporate offices a current  
21           list of the authorized distributors of record of such drug.

22           “(5) For purposes of this subsection, the term ‘au-  
23           thorized distributors of record’ means any distributor that  
24           a manufacturer designates as an authorized distributor of

1 record and whose name the manufacturer makes publicly  
2 available.”.

3 (c) FINAL RULE.—The Secretary shall ensure that,  
4 not later than 90 days after the date of the enactment  
5 of this Act, there is in effect a final rule to implement  
6 section 503(e) of the Federal Food, Drug, and Cosmetic  
7 Act, including the amendments made by this section.

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, there is authorized to be appropriated \$60,000,000  
17 for each of the fiscal years 2006 through 2010, in addition  
18 to other authorizations of appropriations that are available  
19 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 section:

10 **“SEC. 506D. RECALL AUTHORITY.**

11 “(a) ORDER TO CEASE DISTRIBUTION OF DRUG; NO-  
 12 TIFICATION 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(a)) is amended by adding at the end  
19 the 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.”.

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