

108TH CONGRESS
1ST SESSION

H. R. 3297

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

OCTOBER 15, 2003

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

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.

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 the “Counterfeit Drug En-
5 forcement Act”.

1 **SEC. 2. RECALL AUTHORITY REGARDING DRUGS.**

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

5 **“SEC. 506D. RECALL AUTHORITY.**

6 **“(a) ORDER TO CEASE DISTRIBUTION OF DRUG; NO-**
7 **TIFICATION OF HEALTH PROFESSIONALS.—**

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

15 **“(A)** to immediately cease distribution of
16 the drug; and

17 **“(B)** to immediately notify health profes-
18 sionals of the order and to instruct such profes-
19 sionals to cease administering or prescribing the
20 drug.

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

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

6 “(b) ORDER TO RECALL DRUG.—

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

17 “(2) CERTAIN ACTIONS.—An amended order
18 under paragraph (1)—

19 “(A) shall not include recall of a drug from
20 individuals; and

21 “(B) shall provide for notice to individuals
22 subject to the risks associated with the use of
23 the drug.

24 “(3) ASSISTANCE OF HEALTH PROFES-
25 SIONALS.—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

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

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

10 (c) INCREASED FUNDING FOR INSPECTIONS, EXAMI-
11 NATIONS, AND INVESTIGATIONS.—For the purpose of in-
12 creasing the capacity of the Food and Drug Administra-
13 tion to conduct inspections, examinations, and investiga-
14 tions under the Federal Food, Drug, and Cosmetic Act
15 with respect to violations described in section 303(a)(3)
16 of such Act, there is authorized to be appropriated
17 \$60,000,000 for each of the fiscal years 2004 through
18 2008, in addition to other authorizations of appropriations
19 that are available for such purpose.

20 **SEC. 4. OTHER CRIMINAL PENALTIES; CLARIFICATION RE-**
21 **GARDING FINES.**

22 Section 303 of the Federal Food, Drug, and Cosmetic
23 Act (21 U.S.C. 333) is amended—

24 (1) in subsection (a)—

1 (A) in paragraph (1), by striking “shall be
2 imprisoned” and all that follows and inserting
3 the following: “shall be fined in accordance with
4 title 18, United States Code, or imprisoned not
5 more than one year, or both.”; and

6 (B) in paragraph (2), by striking “shall be
7 imprisoned” and all that follows and inserting
8 the following: “shall be fined in accordance with
9 title 18, United States Code, or imprisoned not
10 more than three years, or both.”; and

11 (2) in subsection (b)(1), in the matter after and
12 below subparagraph (D), by striking “shall be im-
13 prisoned” and all that follows an inserting the fol-
14 lowing: “shall be fined in accordance with title 18,
15 United States Code, or imprisoned not more than 10
16 years, or both.”.

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