

113TH CONGRESS
2^D SESSION

H. R. 5874

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 establish recall authority regarding drugs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

DECEMBER 11, 2014

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 increase criminal penalties for the sale or trade of prescription drugs knowingly caused to be adulterated or misbranded, 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 2014”.

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

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

1 caused to be so misrepresented, the person shall be fined
2 in accordance with title 18, United States Code, or impris-
3 oned for any term of years or for life, or both.”.

4 (b) NOTIFICATION OF FOOD AND DRUG ADMINIS-
5 TRATION BY MANUFACTURERS.—Section 505(k) of the
6 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(k))
7 is amended by adding at the end the following paragraph:
8 “(6) A manufacturer of a drug that receives or other-
9 wise becomes aware of information that reasonably sug-
10 gests that a violation described in paragraph (3) or (4)
11 of section 303(a) may have occurred with respect to the
12 drug shall report such information to the Secretary not
13 later than 48 hours after first receiving or otherwise be-
14 coming aware of the information.”.

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

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

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

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

3 **SEC. 4. COUNTERFEIT DRUGS; INCREASED FUNDING FOR**
4 **INSPECTIONS, EXAMINATIONS, AND INVES-**
5 **TIGATIONS.**

6 For the purpose of increasing the capacity of the
7 Food and Drug Administration to conduct inspections, ex-
8 aminations, and investigations under the Federal Food,
9 Drug, and Cosmetic Act with respect to violations de-
10 scribed in paragraphs (3) and (4) of section 303(a) of such
11 Act, there is authorized to be appropriated \$60,000,000
12 for each of the fiscal years 2015 through 2018, in addition
13 to other authorizations of appropriations that are available
14 for such purpose.

15 **SEC. 5. PUBLIC EDUCATION REGARDING COUNTERFEIT**
16 **DRUGS.**

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

21 (b) AUTHORIZATION OF APPROPRIATIONS.—For the
22 purpose of carrying out subsection (a), there is authorized
23 to be appropriated \$5,000,000 for each of the fiscal years
24 2015 through 2018, in addition to other authorizations
25 of appropriations that are available for such purpose.

1 **SEC. 6. 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 506F the following section:

5 **“SEC. 506G. RECALL AUTHORITY.**

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

8 “(1) IN GENERAL.—If the Secretary finds that
9 a drug intended for human use may constitute a
10 threat to the public health, the Secretary shall issue
11 an order requiring the appropriate person (including
12 the manufacturers, importers, distributors, or retail-
13 ers of the drug)—

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

16 “(B) to immediately notify health profes-
17 sionals of the order and to instruct such profes-
18 sionals to cease administering, distributing, sell-
19 ing, or prescribing the drug.

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

1 after providing an opportunity for such a hearing,
2 the Secretary determines that inadequate grounds
3 exist to support the actions required by the order,
4 the Secretary shall vacate the order.

5 “(b) ORDER TO RECALL DRUG.—

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

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

18 “(A) shall not require recall of a drug from
19 individuals; and

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

23 “(3) ASSISTANCE OF HEALTH PROFES-
24 SIONALS.—In providing the notice required by para-
25 graph (2)(B), the Secretary may use the assistance

1 of health professionals who administered the drug
2 involved to individuals or prescribed the drug for in-
3 dividuals. If a significant number of such individuals
4 cannot be identified, the Secretary shall notify such
5 individuals pursuant to section 705(b).”.

6 **SEC. 7. AUTHORITY TO ISSUE SUBPOENAS WITH RESPECT**
7 **TO PREVENTING THREATS TO THE PUBLIC**
8 **HEALTH.**

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

12 “(h) The Secretary and the Attorney General shall
13 develop and implement a procedure through which the
14 Chief Counsel in the Food and Drug Administration is au-
15 thorized to issue subpoenas regarding investigations under
16 this Act of acts or omissions that may constitute a threat
17 to the public health, including investigations of alleged vio-
18 lations to which paragraph (3) or (4) of subsection (a)
19 apply and alleged violations with respect to which the Sec-
20 retary is considering the use of authorities under section
21 304.”.

○