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(Original Signature of Member)

111TH CONGRESS
2D SESSION

H. R.

To provide for the mandatory recall of adulterated or misbranded drugs.

IN THE HOUSE OF REPRESENTATIVES

Mr. TOWNS introduced the following bill; which was referred to the Committee
on _____

A BILL

To provide for the mandatory recall of adulterated or
misbranded drugs.

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. NOTIFICATION, NONDISTRIBUTION, AND RE-**
4 **CALL OF ADULTERATED OR MISBRANDED**
5 **DRUGS.**

6 (a) PROHIBITED ACTS.—Section 301 of the Federal
7 Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amend-
8 ed by adding at the end the following:

9 “(uu) The failure to comply with—

1 “(1) the notification requirement under section
2 568(a);

3 “(2) an order issued under paragraph (1) of
4 section 568(e), following a hearing, if requested,
5 under paragraph (2)(C) of such section;

6 “(3) an order amended under paragraph (2) or
7 paragraph (3) of section 568(e); or

8 “(4) an emergency order issued under section
9 568(d).”.

10 (b) NONDISTRIBUTION AND RECALL OF ADULTER-
11 ATED OR MISBRANDED DRUGS.—Subchapter E of chapter
12 V of the Federal Food, Drug, and Cosmetic Act (21
13 U.S.C. 360bbb et seq.) is amended by adding at the end
14 the following:

15 **“SEC. 568. NOTIFICATION, NONDISTRIBUTION, AND RECALL**
16 **OF CERTAIN ADULTERATED OR MISBRANDED**
17 **DRUGS.**

18 “(a) NOTIFICATION REGARDING CERTAIN ADULTER-
19 ATED OR MISBRANDED DRUGS.—

20 “(1) IN GENERAL.—Any person required to reg-
21 ister under section 510 shall, as soon as practicable,
22 notify the Secretary of the identity and location of
23 a drug, if such person has reason to believe—

24 “(A) that such drug, when introduced into
25 or while in interstate commerce, or while held

1 for sale (regardless of whether the first sale)
2 after shipment in interstate commerce, is adul-
3 terated or misbranded; and

4 “(B) there is a reasonable probability that
5 the use or consumption of, or exposure to, the
6 drug (or an ingredient or component used in
7 any such drug) will cause a threat of serious
8 adverse health consequences or death to hu-
9 mans or animals.

10 “(2) MANNER OF NOTIFICATION.—Notification
11 under paragraph (1) shall be made in such manner
12 and by such means as the Secretary may require by
13 regulation or guidance.

14 “(b) VOLUNTARY RECALL.—The Secretary may re-
15 quest that any person who distributes a drug that the Sec-
16 retary has reason to believe is adulterated, misbranded,
17 or otherwise in violation of this Act voluntarily—

18 “(1) recall such drug; and

19 “(2) provide for notice, including to individuals
20 as appropriate, to persons who may be affected by
21 the recall.

22 “(c) ORDER TO CEASE DISTRIBUTION AND RECALL
23 DRUG AND RELATED PROCEDURES.—

24 “(1) ISSUANCE OF ORDER.—If the Secretary
25 has reason to believe that the use or consumption of,

1 or exposure to, a drug (or an ingredient or compo-
2 nent used in any such drug) may cause serious ad-
3 verse health consequences or death to humans or
4 animals, the Secretary shall have the authority to
5 issue an order requiring any person who distributes
6 such drug—

7 “(A) to immediately cease distribution of
8 such drug; and

9 “(B) to provide for notice, including to in-
10 dividuals as appropriate, to persons who may be
11 affected by such cessation of distribution.

12 “(2) ACTION FOLLOWING ORDER.—

13 “(A) CEASE DISTRIBUTION AND NOTIFICA-
14 TION.—Any person who is subject to an order
15 under paragraph (1) shall immediately cease
16 distribution of such drug and provide notifica-
17 tion as required by such order.

18 “(B) APPEAL.— Any person who is subject
19 to an order under paragraph (1) may appeal
20 within 24 hours of issuance such order to the
21 Secretary. Such appeal may include a request
22 for an informal hearing and a description of
23 any efforts to recall such drug undertaken vol-
24 untarily by the person, including after a request
25 under subsection (b).

1 “(C) INFORMAL HEARING.—Except as pro-
2 vided in subsection (d), if an appeal made
3 under subparagraph (B) contains a request for
4 an informal hearing, such hearing shall be held
5 as soon as practicable, but not later than 5 cal-
6 endar days, or less as determined by the Sec-
7 retary, after such an appeal is filed, unless the
8 parties jointly agree to an extension.

9 “(D) DETERMINATION.—After affording
10 an opportunity for an informal hearing, the
11 Secretary shall determine—

12 “(i) whether—

13 “(I) the order under paragraph
14 (1) should be amended to require a
15 recall of such drug; or

16 “(II) inadequate grounds exist to
17 support the actions required by the
18 order; or

19 “(ii) that the order under paragraph
20 (1) was appropriate as issued.

21 “(E) AMENDMENT OR VACATION OF
22 ORDER.—

23 “(i) AMENDMENT.—In the case of a
24 determination made under subparagraph
25 (D)(i)(I), the Secretary shall amend the

1 order made under paragraph (1) accord-
2 ingly.

3 “(ii) VACATION.—In the case of a de-
4 termination made under subparagraph
5 (D)(i)(II), the Secretary shall vacate the
6 order made under paragraph (1).

7 “(3) ORDER TO RECALL.—

8 “(A) AMENDMENT.—Except as provided
9 under subsection (d), if after providing an op-
10 portunity for an informal hearing under para-
11 graph (2)(C), the Secretary determines that the
12 order should be amended to include a recall of
13 the drug with respect to which the order was
14 issued, the Secretary shall amend the order to
15 require a recall.

16 “(B) CONTENTS.—An amended order
17 under subparagraph (A) shall—

18 “(i) specify a timetable in which the
19 recall will occur;

20 “(ii) require periodic reports to the
21 Secretary describing the progress of the re-
22 call; and

23 “(iii) provide for notice, including to
24 individuals as appropriate, to persons who
25 may be affected by the recall.

1 In providing for such notice, the Secretary may
2 allow for the assistance of health professionals,
3 State or local officials, or other individuals des-
4 ignated by the Secretary.

5 “(C) NONDELEGATION.—An amended
6 order under this paragraph shall be ordered by
7 the Secretary or an official designated by the
8 Secretary. An official may not be so designated
9 unless the official is the director of the district
10 under this Act in which the drug involved is lo-
11 cated, or is an official senior to such director.

12 “(d) EMERGENCY RECALL ORDER.—

13 “(1) IN GENERAL.—If the Secretary has cred-
14 ible evidence or information that a drug subject to
15 an order under subsection (c)(1) presents an immi-
16 nent threat of serious adverse health consequences
17 or death to humans or animals, the Secretary may
18 issue an order requiring any person who distributes
19 such drug—

20 “(A) to immediately recall such drug; and

21 “(B) to provide for notice, including to in-
22 dividuals as appropriate, to persons who may be
23 affected by the recall.

24 “(2) ACTION FOLLOWING ORDER.—

1 “(A) RECALL AND NOTIFICATION.—Any
2 person who is subject to an emergency recall
3 order under this subsection shall immediately
4 recall such drug and provide notification as re-
5 quired by such order.

6 “(B) APPEAL.—

7 “(i) TIMING.—Any person who is sub-
8 ject to an emergency recall order under
9 this subsection may appeal within 24 hours
10 after issuance such order to the Secretary.

11 “(ii) CONTINUATION OF RECALL.—
12 The person subject to an emergency recall
13 order shall conduct the recall notwith-
14 standing the pendency of any appeal of
15 such order.

16 “(C) INFORMAL HEARING.—An informal
17 hearing shall be held as soon as practicable but
18 not later than 5 calendar days, or less as deter-
19 mined by the Secretary, after an appeal under
20 subparagraph (B) is filed, unless the parties
21 jointly agree to an extension.

22 “(D) DETERMINATION.—After affording
23 an opportunity for an informal hearing, the
24 Secretary shall determine—

25 “(i) whether—

1 “(I) the order under paragraph
2 (1) should be amended to require a
3 recall of such drug; or

4 “(II) inadequate grounds exist to
5 support the actions required by the
6 order; or

7 “(ii) that the order under paragraph
8 (1) was appropriate as issued.

9 “(E) AMENDMENT OR VACATION OF
10 ORDER.—

11 “(i) AMENDMENT.—In the case of a
12 determination made under subparagraph
13 (D)(i)(I), the Secretary shall amend the
14 order made under paragraph (1) accord-
15 ingly.

16 “(ii) VACATION.—In the case of a de-
17 termination made under subparagraph
18 (D)(i)(II), the Secretary shall vacate the
19 order made under paragraph (1).

20 “(3) NONDELEGATION.—An order under this
21 subsection shall be issued by the Commissioner of
22 Food and Drugs, the Principal Deputy Commis-
23 sioner, or the Associate Commissioner for Regu-
24 latory Affairs of the Food and Drug Administration.

1 “(e) NOTICE TO CONSUMERS AND HEALTH OFFI-
2 CIALS.—The Secretary shall, as the Secretary determines
3 to be necessary, provide notice of a recall order under this
4 section to consumers to whom the drug was, or may have
5 been, distributed and to appropriate State and local health
6 officials.

7 “(f) SAVINGS CLAUSE.—Nothing contained in this
8 section shall be construed as limiting—

9 “(1) the authority of the Secretary to issue an
10 order to cease distribution of, or to recall, a drug
11 under any other provision of this Act or the Public
12 Health Service Act; or

13 “(2) the ability of the Secretary to request any
14 person to perform a voluntary activity related to any
15 drug subject to this Act or the Public Health Service
16 Act.”.

17 (c) EFFECTIVE DATE.—The amendments made by
18 this section shall take effect one year period after the date
19 of the enactment of this Act.