## <sup>111TH CONGRESS</sup> 2D SESSION H.R. 5740

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

## IN THE HOUSE OF REPRESENTATIVES

JULY 14, 2010

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

## 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 amend8 ed by adding at the end the following:

9 "(uu) The failure to comply with—

10 "(1) the notification requirement under section
11 568(a);

1	((2) an order issued under paragraph $(1)$ of
2	section 568(c), following a hearing, if requested,
3	under paragraph $(2)(C)$ of such section;
4	((3) an order amended under paragraph $(2)$ or
5	paragraph (3) of section 568(c); or
6	"(4) an emergency order issued under section
7	568(d).".
8	(b) Nondistribution and Recall of Adulter-
9	ATED OR MISBRANDED DRUGS.—Subchapter E of chapter
10	V of the Federal Food, Drug, and Cosmetic Act (21
11	U.S.C. 360bbb et seq.) is amended by adding at the end
12	the following:
13	"SEC. 568. NOTIFICATION, NONDISTRIBUTION, AND RECALL
13 14	"SEC. 568. NOTIFICATION, NONDISTRIBUTION, AND RECALL OF CERTAIN ADULTERATED OR MISBRANDED
14	OF CERTAIN ADULTERATED OR MISBRANDED
14 15	OF CERTAIN ADULTERATED OR MISBRANDED DRUGS.
14 15 16	<b>OF CERTAIN ADULTERATED OR MISBRANDED</b> <b>DRUGS.</b> "(a) NOTIFICATION REGARDING CERTAIN ADULTER-
14 15 16 17	OF CERTAIN ADULTERATED OR MISBRANDED DRUGS. "(a) Notification Regarding Certain Adulter- Ated or Misbranded Drugs.—
14 15 16 17 18	OF CERTAIN ADULTERATED OR MISBRANDED DRUGS. "(a) NOTIFICATION REGARDING CERTAIN ADULTER- ATED OR MISBRANDED DRUGS.— "(1) IN GENERAL.—Any person required to reg-
14 15 16 17 18 19	OF CERTAIN ADULTERATED OR MISBRANDED DRUGS. "(a) NOTIFICATION REGARDING CERTAIN ADULTER- ATED OR MISBRANDED DRUGS.— "(1) IN GENERAL.—Any person required to reg- ister under section 510 shall, as soon as practicable,
<ol> <li>14</li> <li>15</li> <li>16</li> <li>17</li> <li>18</li> <li>19</li> <li>20</li> </ol>	OF CERTAIN ADULTERATED OR MISBRANDED DRUGS. "(a) NOTIFICATION REGARDING CERTAIN ADULTER- ATED OR MISBRANDED DRUGS.— "(1) IN GENERAL.—Any person required to reg- ister under section 510 shall, as soon as practicable, notify the Secretary of the identity and location of
<ol> <li>14</li> <li>15</li> <li>16</li> <li>17</li> <li>18</li> <li>19</li> <li>20</li> <li>21</li> </ol>	OF CERTAIN ADULTERATED OR MISBRANDED DRUGS. "(a) NOTIFICATION REGARDING CERTAIN ADULTER- ATED OR MISBRANDED DRUGS.— "(1) IN GENERAL.—Any person required to reg- ister under section 510 shall, as soon as practicable, notify the Secretary of the identity and location of a drug, if such person has reason to believe—

1	after shipment in interstate commerce, is adul-
2	terated or misbranded; and
3	"(B) there is a reasonable probability that
4	the use or consumption of, or exposure to, the
5	drug (or an ingredient or component used in
6	any such drug) will cause a threat of serious
7	adverse health consequences or death to hu-
8	mans or animals.
9	"(2) MANNER OF NOTIFICATION.—Notification
10	under paragraph (1) shall be made in such manner
11	and by such means as the Secretary may require by
12	regulation or guidance.
13	"(b) Voluntary Recall.—The Secretary may re-
14	quest that any person who distributes a drug that the Sec-
15	retary has reason to believe is adulterated, misbranded,
16	or otherwise in violation of this Act voluntarily—
17	"(1) recall such drug; and
18	"(2) provide for notice, including to individuals
19	as appropriate, to persons who may be affected by
20	the recall.
21	"(c) Order To Cease Distribution and Recall
22	Drug and Related Procedures.—
23	"(1) Issuance of order.—If the Secretary
24	has reason to believe that the use or consumption of,
25	or exposure to, a drug (or an ingredient or compo-

1	nent used in any such drug) may cause serious ad-
2	verse health consequences or death to humans or
3	animals, the Secretary shall have the authority to
4	issue an order requiring any person who distributes
5	such drug—
6	"(A) to immediately cease distribution of
7	such drug; and
8	"(B) to provide for notice, including to in-
9	dividuals as appropriate, to persons who may be
10	affected by such cessation of distribution.
11	"(2) Action following order.—
12	"(A) CEASE DISTRIBUTION AND NOTIFICA-
13	TION.—Any person who is subject to an order
14	under paragraph (1) shall immediately cease
15	distribution of such drug and provide notifica-
16	tion as required by such order.
17	"(B) APPEAL.—Any person who is subject
18	to an order under paragraph (1) may appeal
19	within 24 hours of issuance such order to the
20	Secretary. Such appeal may include a request
21	for an informal hearing and a description of
22	any efforts to recall such drug undertaken vol-
23	untarily by the person, including after a request
24	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.

In providing for such notice, the Secretary may allow for the assistance of health professionals, State or local officials, or other individuals designated by the Secretary.

"(C) NONDELEGATION.—An 5 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 in22 dividuals as appropriate, to persons who may be
23 affected by the recall.

24 "(2) Action following order.—

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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.

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

"(2) the ability of the Secretary to request any
person to perform a voluntary activity related to any
drug subject to this Act or the Public Health Service
Act.".

17 (c) EFFECTIVE DATE.—The amendments made by18 this section shall take effect one year period after the date19 of the enactment of this Act.