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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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. NOTIFICATION, NONDISTRIBUTION, AND RECALL OF ADULTERATED OR MISBRANDED DRUGS.

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

''(uu) The failure to comply with—

''(1) the notification requirement under section 568(a);

''(2) an order issued under paragraph (1) of section 568(c), following a hearing, if requested, under paragraph (2)(C) of such section;

''(3) an order amended under paragraph (2) or paragraph (3) of section 568(c); or

''(4) an emergency order issued under section 568(d).''.

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

''SEC. 568. NOTIFICATION, NONDISTRIBUTION, AND RECALL OF CERTAIN ADULTERATED OR MISBRANDED DRUGS.

''(a) NOTIFICATION REGARDING CERTAIN ADULTERATED OR MISBRANDED DRUGS.—

''(1) IN GENERAL.—Any person required to register 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—

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

for sale (regardless of whether the first sale) after shipment in interstate commerce, is adulterated or misbranded; and

''(B) there is a reasonable probability that the use or consumption of, or exposure to, the drug (or an ingredient or component used in any such drug) will cause a threat of serious adverse health consequences or death to humans or animals.

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

''(b) VOLUNTARY RECALL.—The Secretary may request that any person who distributes a drug that the Secretary has reason to believe is adulterated, misbranded, or otherwise in violation of this Act voluntarily—

''(1) recall such drug; and

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

''(c) ORDER TO CEASE DISTRIBUTION AND RECALL DRUG AND RELATED PROCEDURES.—

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

or exposure to, a drug (or an ingredient or component used in any such drug) may cause serious adverse health consequences or death to humans or animals, the Secretary shall have the authority to issue an order requiring any person who distributes such drug—

''(A) to immediately cease distribution of such drug; and

''(B) to provide for notice, including to individuals as appropriate, to persons who may be affected by such cessation of distribution.

''(2) ACTION FOLLOWING ORDER.—

''(A) CEASE DISTRIBUTION AND NOTIFICATION.—Any person who is subject to an order under paragraph (1) shall immediately cease distribution of such drug and provide notification as required by such order.

''(B) APPEAL.— Any person who is subject to an order under paragraph (1) may appeal within 24 hours of issuance such order to the Secretary. Such appeal may include a request for an informal hearing and a description of any efforts to recall such drug undertaken voluntarily by the person, including after a request under subsection (b).

''(C) INFORMAL HEARING.—Except as provided in subsection (d), if an appeal made under subparagraph (B) contains a request for an informal hearing, such hearing shall be held as soon as practicable, but not later than 5 calendar days, or less as determined by the Secretary, after such an appeal is filed, unless the parties jointly agree to an extension.

''(D) DETERMINATION.—After affording an opportunity for an informal hearing, the Secretary shall determine—

''(i) whether—

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

''(II) inadequate grounds exist to support the actions required by the order; or

''(ii) that the order under paragraph (1) was appropriate as issued.

''(E) AMENDMENT OR VACATION OF ORDER.—

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

order made under paragraph (1) accordingly.

''(ii) VACATION.—In the case of a determination made under subparagraph (D)(i)(II), the Secretary shall vacate the order made under paragraph (1).

''(3) ORDER TO RECALL.—

''(A) AMENDMENT.—Except as provided under subsection (d), if after providing an opportunity for an informal hearing under paragraph (2)(C), the Secretary determines that the order should be amended to include a recall of the drug with respect to which the order was issued, the Secretary shall amend the order to require a recall.

''(B) CONTENTS.—An amended order under subparagraph (A) shall—

''(i) specify a timetable in which the recall will occur;

''(ii) require periodic reports to the Secretary describing the progress of the recall; and

''(iii) provide for notice, including to individuals as appropriate, to persons who 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 amended order under this paragraph shall be ordered by the Secretary or an official designated by the Secretary. An official may not be so designated unless the official is the director of the district under this Act in which the drug involved is located, or is an official senior to such director.

''(d) EMERGENCY RECALL ORDER.—

''(1) IN GENERAL.—If the Secretary has credible evidence or information that a drug subject to an order under subsection (c)(1) presents an imminent threat of serious adverse health consequences or death to humans or animals, the Secretary may issue an order requiring any person who distributes such drug—

''(A) to immediately recall such drug; and

''(B) to provide for notice, including to individuals as appropriate, to persons who may be affected by the recall.

''(2) ACTION FOLLOWING ORDER.—

''(A) RECALL AND NOTIFICATION.—Any person who is subject to an emergency recall order under this subsection shall immediately recall such drug and provide notification as required by such order.

''(B) APPEAL.—

''(i) TIMING.—Any person who is subject to an emergency recall order under this subsection may appeal within 24 hours after issuance such order to the Secretary.

''(ii) CONTINUATION OF RECALL.—The person subject to an emergency recall order shall conduct the recall notwithstanding the pendency of any appeal of such order.

''(C) INFORMAL HEARING.—An informal hearing shall be held as soon as practicable but not later than 5 calendar days, or less as determined by the Secretary, after an appeal under subparagraph (B) is filed, unless the parties jointly agree to an extension.

''(D) DETERMINATION.—After affording an opportunity for an informal hearing, the Secretary shall determine—

''(i) whether—

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

''(II) inadequate grounds exist to support the actions required by the order; or

''(ii) that the order under paragraph (1) was appropriate as issued.

''(E) AMENDMENT OR VACATION OF ORDER.—

''(i) AMENDMENT.—In the case of a determination made under subparagraph (D)(i)(I), the Secretary shall amend the order made under paragraph (1) accordingly.

''(ii) VACATION.—In the case of a determination made under subparagraph (D)(i)(II), the Secretary shall vacate the order made under paragraph (1).

''(3) NONDELEGATION.—An order under this subsection shall be issued by the Commissioner of Food and Drugs, the Principal Deputy Commissioner, or the Associate Commissioner for Regulatory Affairs of the Food and Drug Administration.

''(e) NOTICE TO CONSUMERS AND HEALTH OFFICIALS.—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.

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

''(1) the authority of the Secretary to issue an order to cease distribution of, or to recall, a drug under any other provision of this Act or the Public 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.''.

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