

118TH CONGRESS
1ST SESSION

H. R. 3688

To provide for the mandatory recall of drugs regulated by the Food and Drug Administration.

IN THE HOUSE OF REPRESENTATIVES

MAY 25, 2023

Ms. DELAURO introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To provide for the mandatory recall of drugs regulated by the Food and Drug Administration.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SEC. 1. SHORT TITLE.**

4 This Act may be cited as the “Recall Unsafe Drugs
5 Act of 2023”.

6 **SEC. 2. NOTIFICATION, NONDISTRIBUTION, AND RECALL**
7 **OF ADULTERATED OR MISBRANDED DRUGS.**

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

1 “(fff) The failure to comply with—

2 “(1) the notification requirement under section
3 569D(a);

4 “(2) an order issued under paragraph (1) of
5 section 569D(c), following a hearing, if requested,
6 under paragraph (2)(C) of such section;

7 “(3) an order amended under paragraph (2) or
8 paragraph (3) of section 569D(c); or

9 “(4) an emergency order issued under section
10 569D(d).

11 “(ggg) The failure to have in effect a recall plan
12 under section 569(g).”.

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

18 **“SEC. 569E. NOTIFICATION, NONDISTRIBUTION, AND RE-**
19 **CALL OF CERTAIN ADULTERATED OR MIS-**
20 **BRANDED DRUGS.**

21 “(a) NOTIFICATION REGARDING CERTAIN ADULTER-
22 ATED OR MISBRANDED DRUGS.—

23 “(1) IN GENERAL.—Any person required to reg-
24 ister under section 510 shall, as soon as practicable,

1 notify the Secretary of the identity and location of
2 a drug, if such person has reason to believe—

3 “(A) that such drug, when introduced into
4 or while in interstate commerce, or while held
5 for sale (regardless of whether the first sale)
6 after shipment in interstate commerce, is adul-
7 terated or misbranded; and

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

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

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

22 “(1) recall such drug; and

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

1 “(c) ORDER TO CEASE DISTRIBUTION AND RECALL
2 DRUG AND RELATED PROCEDURES.—

3 “(1) ISSUANCE OF ORDER.—If the Secretary
4 has reason to believe that the use or consumption of,
5 or exposure to, a drug (or an ingredient or compo-
6 nent used in any such drug) may cause serious ad-
7 verse health consequences or death to humans or
8 animals, the Secretary shall have the authority to
9 issue an order requiring any person who distributes
10 such drug—

11 “(A) to immediately cease distribution of
12 such drug; and

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

16 “(2) ACTION FOLLOWING ORDER.—

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

22 “(B) APPEAL.—Any person who is subject
23 to an order under paragraph (1) may appeal
24 within 24 hours of issuance such order to the
25 Secretary. Such appeal may include a request

1 for an informal hearing and a description of
2 any efforts to recall such drug undertaken vol-
3 untarily by the person, including after a request
4 under subsection (b).

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

13 “(D) DETERMINATION.—After affording
14 an opportunity for an informal hearing, the
15 Secretary shall determine—

16 “(i) whether—

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

20 “(II) inadequate grounds exist to
21 support the actions required by the
22 order; or

23 “(ii) that the order under paragraph
24 (1) was appropriate as issued.

1 “(E) AMENDMENT OR VACATION OF
2 ORDER.—

3 “(i) AMENDMENT.—In the case of a
4 determination made under subparagraph
5 (D)(i)(I), the Secretary shall amend the
6 order made under paragraph (1) accord-
7 ingly.

8 “(ii) VACATION.—In the case of a de-
9 termination made under subparagraph
10 (D)(i)(II), the Secretary shall vacate the
11 order made under paragraph (1).

12 “(3) ORDER TO RECALL.—

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

21 “(B) CONTENTS.—An amended order
22 under subparagraph (A) shall—

23 “(i) specify a timetable in which the
24 recall will occur;

1 “(ii) require periodic reports to the
2 Secretary describing the progress of the re-
3 call; and

4 “(iii) provide for notice, including to
5 individuals as appropriate, to persons who
6 may be affected by the recall.

7 In providing for such notice, the Secretary may
8 allow for the assistance of health professionals,
9 State or local officials, or other individuals des-
10 ignated by the Secretary.

11 “(C) NONDELEGATION.—An amended
12 order under this paragraph shall be ordered by
13 the Secretary or an official designated by the
14 Secretary. An official may not be so designated
15 unless the official is the director of the district
16 under this Act in which the drug involved is lo-
17 cated, or is an official senior to such director.

18 “(d) EMERGENCY RECALL ORDER.—

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

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

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

5 “(2) ACTION FOLLOWING ORDER.—

6 “(A) RECALL AND NOTIFICATION.—Any
7 person who is subject to an emergency recall
8 order under this subsection shall immediately
9 recall such drug and provide notification as re-
10 quired by such order.

11 “(B) APPEAL.—

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

16 “(ii) CONTINUATION OF RECALL.—
17 The person subject to an emergency recall
18 order shall conduct the recall notwith-
19 standing the pendency of any appeal of
20 such order.

21 “(C) INFORMAL HEARING.—An informal
22 hearing shall be held as soon as practicable but
23 not later than 5 calendar days, or less as deter-
24 mined by the Secretary, after an appeal under

1 subparagraph (B) is filed, unless the parties
2 jointly agree to an extension.

3 “(D) DETERMINATION.—After affording
4 an opportunity for an informal hearing, the
5 Secretary shall determine—

6 “(i) whether—

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

10 “(II) inadequate grounds exist to
11 support the actions required by the
12 order; or

13 “(ii) that the order under paragraph
14 (1) was appropriate as issued.

15 “(E) AMENDMENT OR VACATION OF
16 ORDER.—

17 “(i) AMENDMENT.—In the case of a
18 determination made under subparagraph
19 (D)(i)(I), the Secretary shall amend the
20 order made under paragraph (1) accord-
21 ingly.

22 “(ii) VACATION.—In the case of a de-
23 termination made under subparagraph
24 (D)(i)(II), the Secretary shall vacate the
25 order made under paragraph (1).

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

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

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

14 “(1) the authority of the Secretary to issue an
15 order to cease distribution of, or to recall, a drug
16 under any other provision of this Act or the Public
17 Health Service Act; or

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

22 “(g) RECALL PLAN.—Any person required to register
23 under section 510 shall have in effect a recall plan con-
24 sistent with the requirements of this section.”.

1 (c) DELAYED APPLICABILITY.—The amendments
2 made by this section apply beginning on the date that is
3 one year after the date of the enactment of this Act.

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