

117TH CONGRESS  
2D SESSION

# H. R. 6834

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

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IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 25, 2022

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

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## 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 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Recall Unsafe Drugs  
5 Act of 2022”.

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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