

105TH CONGRESS  
1ST SESSION

# H. R. 3070

To amend the Federal Food, Drug, and Cosmetic Act to provide for improved public health and food safety through enhanced enforcement, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 13, 1997

Mr. PALLONE (for himself, Mr. BROWN of Ohio, Mr. STUPAK, Ms. ESHOO, and Ms. DELAURO) introduced the following bill; which was referred to the Committee on Commerce

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide for improved public health and food safety through enhanced enforcement, and for other purposes.

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 “Food Safety Enforce-  
5 ment Enhancement Act of 1997”.

1 **SEC. 2. AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND**  
2 **COSMETIC ACT.**

3 (a) IN GENERAL.—The Federal, Food, Drug, and  
4 Cosmetic Act (21 U.S.C. 301 et seq.) is amended by add-  
5 ing after section 413 the following new sections:

6 **“SEC. 414. NOTIFICATION AND RECALL.**

7 “(a) NOTICE TO SECRETARY OF ADULTERATION OR  
8 MISBRANDING.—Any person (other than a household  
9 consumer or other individual who is the intended  
10 consumer of an article of food) that has a reasonable basis  
11 for believing that any article of food introduced into or  
12 in interstate commerce, or held for sale (whether or not  
13 the first sale) after shipment in interstate commerce, may  
14 be adulterated or misbranded shall immediately notify the  
15 Secretary, in such manner and by such means as the Sec-  
16 retary may by regulation prescribe, of the identity and lo-  
17 cation of such article.

18 “(b) RECALL AND CONSUMER NOTIFICATION.—

19 “(1) VOLUNTARY PROCEDURES.—If the Sec-  
20 retary finds, upon such notification or otherwise,  
21 that any article of food is adulterated or misbranded  
22 when introduced into or while in interstate com-  
23 merce or while held for sale (whether or not the first  
24 sale) after shipment in interstate commerce and  
25 there is a reasonable probability that such article, if  
26 consumed, would present a threat to public health,

1 as determined by the Secretary, the Secretary shall  
2 provide the appropriate persons (including the man-  
3 ufacturers, importers, distributors, or retailers) with  
4 an opportunity to—

5 “(A) cease distribution of such article,

6 “(B) notify all persons—

7 “(i) producing, manufacturing, pack-  
8 ing, processing, preparing, treating, pack-  
9 aging, distributing, or holding such article,  
10 or

11 “(ii) to which such article has been  
12 distributed, transported, or sold,

13 to immediately cease distribution of such arti-  
14 cle,

15 “(C) recall such article,

16 “(D) provide, in consultation with the Sec-  
17 retary, notice to consumers to whom such arti-  
18 cle was, or may have been, distributed, or

19 “(E) take any combination of the above  
20 measures, as appropriate in the circumstances.

21 “(2) PRE-HEARING ORDER TO CEASE DISTRIBU-  
22 TION AND GIVE NOTICE.—If such person refuses to  
23 or does not voluntarily cease distribution, make noti-  
24 fication, recall such article, or provide notice to con-  
25 sumers, as applicable, within the time and in the

1 manner prescribed by the Secretary, the Secretary  
2 shall, by order, require, as the Secretary deems nec-  
3 essary, such person to—

4 “(A) immediately cease distribution of  
5 such article,

6 “(B) immediately notify all persons—

7 “(i) producing, manufacturing, pack-  
8 ing, processing, preparing, treating, pack-  
9 aging, distributing, or holding such article,  
10 or

11 “(ii) to which such article has been  
12 distributed, transported, or sold,

13 to immediately cease distribution of such arti-  
14 cle, or

15 “(C) immediately take the actions specified  
16 in both subparagraphs (A) and (B).

17 “(3) NOTIFICATION OF CONSUMERS BY SEC-  
18 RETARY.—The Secretary shall, as the Secretary  
19 deems necessary, provide notice to consumers to  
20 whom such article was, or may have been, distrib-  
21 uted.

22 “(c) HEARING ON ORDER.—The Secretary shall pro-  
23 vide any person subject to an order under subsection (b)  
24 with an opportunity for a hearing, to be held as soon as  
25 possible but not later than 2 days after the issuance of

1 the order, on the actions required by the order and on  
2 why the article that is the subject of the order should not  
3 be recalled.

4 “(d) POST-HEARING RECALL ORDER.—

5 “(1) AMENDMENT OF ORDER.—If, after provid-  
6 ing opportunity for a hearing under subsection (c),  
7 the Secretary determines that there is a reasonable  
8 probability that the article that is the subject of an  
9 order under subsection (b), if consumed, presents a  
10 threat to public health, the Secretary, as the Sec-  
11 retary deems necessary, may—

12 “(A) amend the order to require recall of  
13 such article or other appropriate action,

14 “(B) specify a timetable in which the recall  
15 shall occur,

16 “(C) require periodic reports to the Sec-  
17 retary describing the progress of the recall, and

18 “(D) provide notice to consumers to whom  
19 such article was, or may have been, distributed.

20 “(2) VACATION OF ORDER.—If, after such a  
21 hearing, the Secretary determines that adequate  
22 grounds do not exist to continue the actions required  
23 by the order, the Secretary shall vacate the order.

1       “(e) REMEDIES NOT EXCLUSIVE.—The remedies  
2 provided in this section shall be in addition to and not  
3 exclusive of other remedies that may be available.

4 **“SEC. 418. CIVIL PENALTIES.**

5       “(a) IN GENERAL.—

6           “(1) ACTS SUBJECT TO PENALTY; PENALTY  
7 AMOUNT.—Any person that commits an act prohib-  
8 ited by section 301 with respect to food may be as-  
9 sessed a civil penalty by the Secretary of not more  
10 than \$100,000 for each such act. Each such act and  
11 each day during which such act continues shall be  
12 a separate offense.

13           “(2) NOTICE AND HEARING.—No penalty shall  
14 be assessed by the Secretary under this section un-  
15 less such person is given notice and opportunity for  
16 a hearing on the record before the Secretary in ac-  
17 cordance with sections 554 and 556 of title 5, Unit-  
18 ed States Code.

19           “(3) OTHER REQUIREMENTS.—The amount of  
20 such civil penalty shall be assessed by the Secretary  
21 by written order, taking into account the gravity of  
22 the violation, degree of culpability, size and type of  
23 business, and any history of prior offenses; and may  
24 be reviewed only as provided in subsection (b).

1           “(b) JUDICIAL REVIEW.—An order assessing a civil  
2 penalty under subsection (a) shall be final and conclusive  
3 unless the person files, within 30 days from the effective  
4 date of the order, an application for judicial review in the  
5 Court of Appeals of the United States for the circuit in  
6 which such person resides or has its principal place of  
7 business or in the United States Court of Appeals for the  
8 District of Columbia Circuit by filing a notice of appeal  
9 in such court and by simultaneously sending a copy of  
10 such notice by certified mail to the Secretary. The Sec-  
11 retary shall promptly file in such court a certified copy  
12 of the record upon which such penalty was assessed. The  
13 findings of the Secretary shall be set aside only if found  
14 to be unsupported by substantial evidence on the record  
15 as a whole.

16           “(c) COLLECTION ACTIONS.—If any person fails to  
17 pay an assessment of a civil penalty after it has become  
18 a final and unappealable order, or after the appropriate  
19 court of appeals has entered final judgment in favor of  
20 the Secretary, the Secretary shall refer the matter to the  
21 Attorney General, who shall institute a civil action to re-  
22 cover the amount assessed in an appropriate district court  
23 of the United States. In such collection action, the validity  
24 and appropriateness of the Secretary’s order imposing the  
25 civil penalty shall not be subject to review.

1       “(d) PENALTIES PAID INTO TREASURY.—All pen-  
2 alties collected under authority of this section shall be paid  
3 into the Treasury of the United States.

4       “(e) SECRETARY’S DISCRETION TO PROSECUTE.—  
5 Nothing in this Act shall be construed as requiring the  
6 Secretary to report for prosecution, or for the institution  
7 of libel or injunction proceedings, violations of this Act  
8 whenever the Secretary believes that the public interest  
9 will be adequately served by assessment of civil penalties.

10       “(f) REMEDIES NOT EXCLUSIVE.—The remedies  
11 provided in this section shall be in addition to and not  
12 exclusive of other remedies that may be available.”.

13       (b) CONFORMING AMENDMENT; PROHIBITED ACT.—  
14 Section 301 of the Federal Food, Drug, and Cosmetic Act  
15 (21 U.S.C. 331) is amended by adding at the end the fol-  
16 lowing new subsection:

17       “(x) The failure or refusal to comply with an order  
18 issued under section 414(b)(2) or 414(d).”.

19 **SEC. 3. WHISTLEBLOWER PROTECTION.**

20       (a) IN GENERAL.—No employee or other person may  
21 be harassed, prosecuted, held liable, or discriminated  
22 against in any way because that person—

23               (1) has commenced, caused to be commenced,  
24               or is about to commence a proceeding, testified or is  
25               about to testify at a proceeding, or assisted or par-

1       ticipated or is about to assist or participate in any  
2       manner in such a proceeding or in any other action  
3       to carry out the purposes, functions, or responsibil-  
4       ities of the Federal Food, Drug, and Cosmetic Act,  
5       or of the Department of Agriculture; or

6               (2) is refusing to violate or assist in violation  
7       of law, rule, or regulation.

8       (b) PROCEDURES AND PENALTIES.—The process and  
9       procedures with respect to prohibited discrimination under  
10       subsection (a) shall be governed by the applicable provi-  
11       sions of section 31105 of title 49, United States Code,  
12       unless the party bringing an action under this subsection  
13       chooses alternative dispute resolution procedures such as  
14       mediation or arbitration.

15       (c) BURDENS OF PROOF.—The legal burdens of proof  
16       with respect to prohibited discrimination under subsection  
17       (a) shall be governed by the applicable provisions of sec-  
18       tions 1214 and 1221 of title 5, United States Code.

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