

111TH CONGRESS
1ST SESSION

H. R. 841

To authorize the Secretary of Health and Human Services to order a mandatory recall of any product that is regulated by the Food and Drug Administration, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 3, 2009

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

A BILL

To authorize the Secretary of Health and Human Services to order a mandatory recall of any product that is regulated by the Food and Drug Administration, 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 “Protect Consumers Act
5 of 2009”.

6 **SEC. 2. AUTHORITY TO IMPLEMENT MANDATORY RECALL.**

7 (a) IN GENERAL.—If the Secretary of Health and
8 Human Services determines that it is necessary to imple-

1 ment a mandatory recall of any product that is regulated
2 by the Food and Drug Administration, the Secretary shall
3 issue an order requiring the appropriate person (including
4 the manufacturers, importers, distributors, or retailers of
5 the product)—

6 (1) to immediately cease distribution, manufac-
7 ture, and sale of such product,

8 (2) to immediately provide for notice to individ-
9 uals subject to the risks associated with the use of
10 such product, and

11 (3) to implement an immediate recall of such
12 product.

13 The order shall provide the person subject to the order
14 with an opportunity for an informal hearing, to be held
15 not later than 10 days after the date of the issuance of
16 the order, on the actions required by the order. If, after
17 providing an opportunity for such a hearing or holding
18 such a hearing, the Secretary determines there are inad-
19 equate grounds to support the actions required by the
20 order, the Secretary shall vacate the order. If, after pro-
21 viding an opportunity for an informal hearing or holding
22 such a hearing, the Secretary determines there are ade-
23 quate grounds to support the actions required by the
24 order, the order shall remain in effect until such a time
25 the Secretary finds otherwise. In the case of an informal

1 hearing, the order shall remain in effect pending a decision
2 by the Secretary.

3 (b) ENFORCEMENT.—The failure to comply with an
4 order issued by the Secretary of Health and Human Serv-
5 ices under subsection (a) shall be treated as a violation
6 of section 301 of the Federal Food, Drug, and Cosmetic
7 Act (21 U.S.C. 331) for the purpose of sections 302 and
8 303 of such Act.

9 **SEC. 3. STUDY ON EFFECTIVENESS OF RECALLS.**

10 (a) STUDY.—The Secretary of Health and Human
11 Services, in consultation with manufacturers, distributors,
12 retailers, public health groups, consumer groups, and
13 other affected organizations, shall conduct a study to de-
14 termine new procedures for implementing voluntary and
15 mandatory recalls and enhancing their effectiveness.

16 (b) REPORT.—Not later than 180 days after the date
17 of the enactment of this Act, the Secretary shall submit
18 to the Congress a report describing findings and rec-
19 ommendations made as a result of carrying out subsection
20 (a).

21 (c) REGULATIONS.—Not later than 180 days after
22 submitting to the Congress the report described in sub-
23 section (b), the Secretary shall issue regulations imple-
24 menting the recommendations described in such report.

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