

105TH CONGRESS
2D SESSION

S. 1767

To amend the Federal Food, Drug, and Cosmetic Act to require notification of recalls of drugs and devices, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MARCH 16, 1998

Mr. DODD introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to require notification of recalls of drugs and devices, 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 “Drug and Device Re-
5 call Reporting Act of 1998”.

6 **SEC. 2. RECALLS.**

7 Subchapter E of chapter V of the Federal Food,
8 Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.) is
9 amended by adding at the end the following:

1 **“SEC. 564. NOTIFICATION OF RECALLS.**

2 “(a) NOTIFICATION TO CUSTOMERS.—A pharmacy
3 that receives notice from a recalling firm regarding a Class
4 I or Class II recall of a drug or device shall provide notifi-
5 cation about the recall to customers that received the drug
6 or device as follows:

7 “(1) In the case of a drug or device dispensed
8 by the pharmacy to customers on the prescription of
9 a licensed practitioner, by providing, at a minimum,
10 written notification to each of the customers.

11 “(2) In the case of another drug or device, by
12 public display in the pharmacy of a notice regarding
13 the recall.

14 “(b) CIVIL PENALTY.—Any pharmacy that violates
15 subsection (a) shall be liable to the United States for a
16 civil penalty in an amount not to exceed \$10,000 for each
17 such violation.

18 “(c) DEFINITIONS.—In this section:

19 “(1) CLASS I OR CLASS II.—The term ‘Class I’
20 or ‘Class II’ refers to the corresponding designation
21 given recalls in subpart A of part 7 of title 21, Code
22 of Federal Regulations, or a successor regulation.

23 “(2) RECALL.—The term ‘recall’ means—

24 “(A) a recall, as defined in subpart A of
25 part 7 of title 21, Code of Federal Regulations,
26 or a successor regulation; and

1 “(B) a recall under section 518(e).

2 “(3) RECALLING FIRM.—The term ‘recalling
3 firm’ means—

4 “(A) a recalling firm, as defined in subpart
5 A of part 7 of title 21, Code of Federal Regula-
6 tions, or a successor regulation; and

7 “(B) a person subject to an order issued
8 under section 518(e)(1).”.

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