

Mark F. Bennett
S.L.C.

AMENDMENT NO. Bennet Amendment #3 Calendar No. _____

Purpose: To provide for mandatory recall authority for drugs.

IN THE SENATE OF THE UNITED STATES—112th Cong., 2d Sess.

(no.) _____

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Mr. Bennett

Viz:

1 At the end of title VII, insert the following:

2 **SEC. 718. MANDATORY RECALL AUTHORITY FOR DRUGS.**

3 (a) MANDATORY RECALL AUTHORITY.—

4 (1) IN GENERAL.—Chapter V (21 U.S.C. 351
5 et seq.) is amended by inserting after section 506C
6 the following:

7 **“SEC. 507. MANDATORY RECALL AUTHORITY FOR DRUGS.**

8 “(a) ORDER TO CEASE DISTRIBUTION; NOTIFICA-
9 TION; PROCESS.—

10 “(1) ORDER TO CEASE DISTRIBUTION; NOTIFI-
11 CATION.—If the Secretary finds that there is a rea-

1 sonable probability that a drug intended for human
2 use would cause serious, adverse health con-
3 sequences or death, the Secretary shall issue an
4 order requiring the appropriate person (including
5 the manufacturers, importers, distributors, or retail-
6 ers of the drug)—

7 “(A) to immediately cease distribution of
8 such drug; and

9 “(B) to immediately notify health profes-
10 sionals and hospitals and other health care fa-
11 cilities of the order and to instruct such profes-
12 sionals and facilities to cease use of such drug.

13 “(2) PROCESS.—The order under paragraph
14 (1) shall provide the person subject to the order with
15 an opportunity for an informal hearing, to be held
16 not later than 10 days after the date of the issuance
17 of the order, on the actions required by the order
18 and on whether the order should be amended to re-
19 quire a recall of such drug. If, after providing an op-
20 portunity for such a hearing, the Secretary deter-
21 mines that inadequate grounds exist to support the
22 actions required by the order, the Secretary shall va-
23 cate the order.

24 “(b) ORDER TO RECALL.—

1 “(1) IN GENERAL.—If, after providing an op-
2 portunity for an informal hearing under subsection
3 (a), the Secretary determines that the order should
4 be amended to include a recall of the drug with re-
5 spect to which the order was issued, the Secretary
6 shall, except as provided in paragraph (2), amend
7 the order to require a recall. The Secretary shall
8 specify a timetable in which the drug recall will
9 occur and shall require periodic reports to the Sec-
10 retary describing the progress of the recall.

11 “(2) AMENDED ORDER.—An amended order
12 under paragraph (1)—

13 “(A) shall—

14 “(i) not include recall of a drug from
15 individuals; and

16 “(ii) not include recall of a drug from
17 hospitals and other health care facilities if
18 the Secretary determines that the risk of
19 recalling such drug from the facilities pre-
20 sents a greater health risk than the health
21 risk of not recalling the drug from use;
22 and

23 “(B) shall provide for notice to individuals
24 subject to the risks associated with the use of
25 such drug.

1 “(3) ASSISTANCE.—In providing the notice re-
2 quired by paragraph (2), the Secretary may use the
3 assistance of health professionals who prescribed or
4 used such a drug for individuals. If a significant
5 number of such individuals cannot be identified, the
6 Secretary shall notify such individuals pursuant to
7 section 705(b).’.

8 “(4) REGULATIONS.—Until the date that the
9 Secretary of Health and Human Services issues a
10 final regulation to implement section 507 of the
11 Federal Food, Drug, and Cosmetic Act (as added by
12 paragraph (1)), the regulations on medical device re-
13 call authority in part 810 of title 21, Code of Fed-
14 eral Regulations, shall apply to any recall of a drug
15 under such section 507.”.

16 (2) PROHIBITED ACTS.—Section 301 of the
17 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
18 331), as amended by section 712, is further amend-
19 ed by adding at the end the following:

20 “(bbb) The failure to comply with an order issued
21 under section 507.”.