

103^D CONGRESS
2^D SESSION

S. 2168

To amend the Federal Food, Drug, and Cosmetic Act to prohibit the distribution of samples of prescription drugs.

IN THE SENATE OF THE UNITED STATES

JUNE 8 (legislative day, JUNE 7), 1994

Mrs. KASSEBAUM 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 prohibit the distribution of samples of prescription drugs.

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 AND REFERENCE.**

4 (A) SHORT TITLE.—This Act may be cited as the
5 “Prescription Drug Marketing Reform Act of 1994”.

6 (b) REFERENCE.—Whenever in this Act an amend-
7 ment or repeal is expressed in terms of an amendment
8 to, or repeal of, a section or other provision, the reference
9 shall be considered to be made to a section or other provi-
10 sion of the Federal Food, Drug, and Cosmetic Act.

1 **SEC. 2. PROHIBITION OF DRUG SAMPLES.**

2 Section 503 (21 U.S.C. 353) is amended—

3 (1) in the first sentence of subsection (c)(1), by
4 inserting “distribute,” after “No person may”,

5 (2) in the second sentence of such subsection,
6 by striking “and subsection (d)”,

7 (3) by inserting after the second sentence of
8 such subsection the following: “For purposes of this
9 subsection, the term ‘distribute’ does not include
10 providing a drug sample to enable a practitioner li-
11 censed to prescribe a drug subject to subsection (b)
12 or a health care professional acting under the direc-
13 tion and supervision of such a practitioner to provide
14 for the dispensing of or to dispense a sample of such
15 drug if the sample is made available to a patient in
16 accordance with regulations of the Secretary specify-
17 ing conditions under which such drug is necessary
18 for medical care.”,

19 (4) in paragraph (2), by inserting “distribute,”
20 after “No person may”,

21 (5) by redesignating paragraph (3) as para-
22 graph (4) and by adding after paragraph (2) the
23 following:

24 “(3) Nothing in paragraphs (1) and (2) precludes dis-
25 tribution of a drug subject to subsection (b) at no cost
26 or nominal cost pursuant to a program established by the

1 manufacturer or distributor of such drug to provide it to
2 specific identified patients who, for financial reasons,
3 would not otherwise have access to such drug. The Sec-
4 retary shall promulgate regulations to specify the docu-
5 mentation and record keeping required for such a pro-
6 gram.”, and

7 (6) by repealing subsection (d) and redesignat-
8 ing subsections (e), (f), and (g) as subsections (d),
9 (e), and (f), respectively.

10 **SEC. 3. ENFORCEMENT.**

11 (a) PROHIBITED ACT.—Section 301(t) (21 U.S.C.
12 331(t)) is amended to read as follows:

13 “(t) the importation of a drug in violation of section
14 801(d)(1), the distribution, sale, purchase, or trade of a
15 drug or drug sample or the offer to distribute, sell, pur-
16 chase, or trade a drug or drug sample in violation of sec-
17 tion 503(c), the distribution, sale, purchase, or trade of
18 a coupon or the offer to distribute, sell, purchase, or trade
19 such a coupon in violation of section 503(c)(2), or the dis-
20 tribution of drugs in violation of section 503(d) or the fail-
21 ure to otherwise comply with the requirements of section
22 503(d).”.

23 (b) PENALTY.—Section 303(b) (21 U.S.C. 333(b)) is
24 amended—

1 (1) in subparagraph (B), by inserting “distrib-
2 ute,” after “knowingly”,

3 (2) in subparagraph (C), by inserting “distrib-
4 uting,” after “knowingly”,

5 (3) in subparagraph (D), by striking
6 “503(e)(2)(A)” and inserting “503(d)(2)(A)”,

7 (4) in paragraph (5), by striking “because of
8 the sale” through “503(c)(1)” and inserting “of a
9 violation of section 503(c)”, and

10 (5) by striking paragraphs (2), (3), and (4) and
11 redesignating paragraph (5) as paragraph (2).

12 **SEC. 4. EFFECTIVE DATE AND REGULATIONS.**

13 The amendments made by this Act shall take effect
14 upon the expiration of 180 days after the date of the en-
15 actment of this Act. During such 180 day period the Sec-
16 retary of Health and Human Services shall promulgate
17 regulations to implement the amendments made by this
18 Act. If final regulations are not promulgated before the
19 expiration of such 180 days, the Secretary may not take
20 any action to prevent a program, established before the
21 expiration of such days, from providing a drug or a coupon
22 for a drug to patients who would not otherwise be able
23 financially to use such drug.

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