Public Law 102-353
102d Congress

An Act

To amend the Federal Food, Drug, and Cosmetic Act to coordinate Federal and State regulation of wholesale drug distribution, and for other purposes.

Aug. 26, 1992
[S. 3163]

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

Prescription Drug Amendments of 1992.
21 USC 301 note.

SECTION 1. SHORT TITLE AND REFERENCE.

(a) SHORT TITLE.—This Act may be cited as the "Prescription Drug Amendments of 1992".

(b) REFERENCE.—Whenever in this Act an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act.

SEC. 2. DISTRIBUTOR REGISTRATION.

(a) REQUIREMENT.—Section 503(e)(2)(A) (21 U.S.C. 353(e)(2)(A)) is amended by inserting before the period the following: "or has registered with the Secretary in accordance with paragraph (3)".

(b) REGISTRATION.—Section 503(e) (21 U.S.C. 353(e)) is amended by redesignating paragraph (3) as paragraph (4) and by inserting after paragraph (2) the following:

"(3) Any person who engages in the wholesale distribution in interstate commerce of drugs that are subject to subsection (b) in a State that does not have a program that meets the guidelines established under paragraph (2)(B) shall register with the Secretary the following:

"(A) The person's name and place of business.

"(B) The name of each establishment the person owns or operates that is engaged in the wholesale distribution of drugs in a State that does not have a program to license persons engaged in such distribution.".

(c) TECHNICAL.—Section 503(f)(1)(B) (21 U.S.C. 353(f)(1)(B)) is amended by striking out "and order" and inserting in lieu thereof "an order".

(d) SUNSET.—Effective September 14, 1994, the amendments made by subsections (a) and (b) shall no longer be in effect.

SEC. 3. PENALTY CLARIFICATION.

21 USC 353 note.

(a) SCIENTER.—Paragraph (1) of section 303(b) (21 U.S.C. 333(b)) is amended to read as follows:

"(b)(1) Notwithstanding subsection (a), any person who violates section 301(t) by—

"(A) knowingly importing a drug in violation of section 801(d)(1),

"(B) knowingly selling, purchasing, or trading a drug or drug sample or knowingly offering to sell, purchase, or trade a drug or drug sample, in violation of section 503(c)(1),

"(C) knowingly selling, purchasing, or trading a coupon, knowingly offering to sell, purchase, or trade such a coupon, or knowingly counterfeiting such a coupon, in violation of section 503(c)(2), or

"(D) knowingly distributing drugs in violation of section 503(e)(2)(A),

shall be imprisoned for not more than 10 years or fined not more than $250,000, or both.".

(b) CLARIFICATION.—Section 303 (21 U.S.C. 333) is amended—

(1) in subparagraphs (A) and (B)(i) of subsection (b)(4), by striking out "the arrest and conviction of" each time it occurs and inserting in lieu thereof "the institution of a criminal proceeding against, and conviction of,";

(2) in subparagraph (B)(i) of subsection (b)(4), by striking out "the arrest of" and inserting in lieu thereof "the institution of a criminal proceeding against";

(3) in subsection (b)(5), by striking out "the arrest and conviction of" and inserting in lieu thereof "the institution of a criminal proceeding against, and conviction of,";

(4) in subsections (c) and (d), by striking out "subsection (a) of this section" and inserting in lieu thereof "subsection (a)(1) of this section"; and

(5) in subsection (d), by striking out ", and no person" and all that follows through "mislead".

SEC. 4. DRUG SAMPLES.

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

(1) in subsection (d), by amending paragraph (1) to read as follows:

"(d)(1) Except as provided in paragraphs (2) and (3), no person may distribute any drug sample. For purposes of this subsection, the term 'distribute' does not include the providing of a drug sample to a patient by a—

"(A) practitioner licensed to prescribe such drug,

"(B) health care professional acting at the direction and under the supervision of such a practitioner, or

"(C) pharmacy of a hospital or of another health care entity that is acting at the direction of such a practitioner and that received such sample pursuant to paragraph (2) or (3).".

(2) in paragraphs (2) and (3) of subsection (d), by striking out "distributor" each place it occurs and inserting in lieu thereof "authorized distributor of record" and in subsection (d)(3) by striking out "distributors" each place it occurs and inserting in lieu thereof "authorized distributors of record";

(3) in subsection (e), by amending paragraph (1) to read as follows:

"(e)(1)(A) Each person who is engaged in the wholesale distribution of a drug subject to subsection (b) and who is not the manufacturer or an authorized distributor of record of such drug shall, before each wholesale distribution of such drug (including each distribution to an authorized distributor of record or to a retail pharmacy), provide to the person who receives the drug a statement (in such form and containing such information as the Secretary may require) identifying each prior sale, purchase, or trade of such drug (including the date of the transaction and the names and addresses of all parties to the transaction).

"(B) Each manufacturer of a drug subject to subsection (b) shall maintain at its corporate offices a current list of the authorized distributors of record of such drug."; and

(4) in subsection (e)(4) (as so redesignated by section 2(c)), by inserting before the dash the following: "and subsection (d)".

SEC. 5. TECHNICAL AMENDMENT.

Section 801(d)(1) (21 U.S.C. 381(d)(1)) is amended by striking out "person who manufactured" and inserting in lieu thereof "manufacturer of".

Approved August 26, 1992.

LEGISLATIVE HISTORY—S. 3163:

CONGRESSIONAL RECORD, Vol. 138 (1992):
Aug. 11, considered and passed Senate.
Aug. 12, considered and passed House.