Public Law 100-293
100th Congress

An Act

To amend the Federal Food, Drug, and Cosmetic Act to ban the reimportation of drugs produced in the United States, to place restrictions on the distribution of drug samples, to ban certain resales of drugs by hospitals and other health care entities, and for other purposes.

Apr. 22, 1988
[H.R. 1207]

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

Prescription Drug Marketing Act of 1987.
Commerce and trade.
21 USC 301 note.

SECTION 1. SHORT TITLE; REFERENCE.

(a) SHORT TITLE.—This Act may be cited as the "Prescription Drug Marketing Act of 1987".

(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. FINDINGS.

21 USC 353 note.

The Congress finds the following:

(1) American consumers cannot purchase prescription drugs with the certainty that the products are safe and effective.

(2) The integrity of the distribution system for prescription drugs is insufficient to prevent the introduction and eventual retail sale of substandard, ineffective, or even counterfeit drugs.

(3) The existence and operation of a wholesale submarket, commonly known as the "diversion market", prevents effective control over or even routine knowledge of the true sources of prescription drugs in a significant number of cases.

(4) Large amounts of drugs are being reimported to the United States as American goods returned. These imports are a health and safety risk to American consumers because they may have become subpotent or adulterated during foreign handling and shipping.

(5) The ready market for prescription drug reimports has been the catalyst for a continuing series of frauds against American manufacturers and has provided the cover for the importation of foreign counterfeit drugs.

(6) The existing system of providing drug samples to physicians through manufacturer's representatives has been abused for decades and has resulted in the sale to consumers of misbranded, expired, and adulterated pharmaceuticals.

(7) The bulk resale of below wholesale priced prescription drugs by health care entities, for ultimate sale at retail, helps fuel the diversion market and is an unfair form of competition to wholesalers and retailers that must pay otherwise prevailing market prices.

(8) The effect of these several practices and conditions is to create an unacceptable risk that counterfeit, adulterated, mis-

branded, subpotent, or expired drugs will be sold to American consumers.

SEC. 3. REIMPORTATION.

Section 801 (21 U.S.C. 381) is amended by redesignating subsection (d) as subsection (e) and by inserting after subsection (c) the following:

"(d)(1) Except as provided in paragraph (2), no drug subject to section 503(b) which is manufactured in a State and exported may be imported into the United States unless the drug is imported by the person who manufactured the drug.

"(2) The Secretary may authorize the importation of a drug the importation of which is prohibited by paragraph (1) if the drug is required for emergency medical care.".

SEC. 4. SALES RESTRICTIONS.

Section 503 (21 U.S.C. 353) is amended by adding at the end the following:

"(c)(1) No person may sell, purchase, or trade or offer to sell, purchase, or trade any drug sample. For purposes of this paragraph and subsection (d), the term 'drug sample' means a unit of a drug, subject to subsection (b), which is not intended to be sold and is intended to promote the sale of the drug. Nothing in this paragraph shall subject an officer or executive of a drug manufacturer or distributor to criminal liability solely because of a sale, purchase, trade, or offer to sell, purchase, or trade in violation of this paragraph by other employees of the manufacturer or distributor.

"(2) No person may sell, purchase, or trade, offer to sell, purchase, or trade, or counterfeit any coupon. For purposes of this paragraph, the term 'coupon' means a form which may be redeemed, at no cost or at a reduced cost, for a drug which is prescribed in accordance with section 503(b).

"(3)(A) No person may sell, purchase, or trade, or offer to sell, purchase, or trade, any drug—

"(i) which is subject to subsection (b), and

"(ii)(I) which was purchased by a public or private hospital or other health care entity, or

"(II) which was donated or supplied at a reduced price to a charitable organization described in section 501(c)(3) of the Internal Revenue Code of 1954.

"(B) Subparagraph (A) does not apply to—

"(i) the purchase or other acquisition by a hospital or other health care entity which is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or health care entities which are members of such organization,

"(ii) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by an organization described in subparagraph (A)(ii)(II) to a nonprofit affiliate of the organization to the extent otherwise permitted by law,

"(iii) a sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities which are under common control,

"(iv) a sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons, or

"(v) a sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription executed in accordance with section 503(b).

For purposes of this paragraph, the term 'entity' does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law and the term 'emergency medical reasons' includes transfers of a drug between health care entities or from a health care entity to a retail pharmacy undertaken to alleviate temporary shortages of the drug arising from delays in or interruptions of regular distribution schedules.".

SEC. 5. DISTRIBUTION OF DRUG SAMPLES.

Section 503 (as amended by section 4 of this Act) is amended by adding at the end thereof the following:

"(d)(1) Except as provided in paragraphs (2) and (3), no representative of a drug manufacturer or distributor may distribute any drug sample.

"(2)(A) The manufacturer or distributor of a drug subject to subsection (b) may, in accordance with this paragraph, distribute drug samples by mail or common carrier to practitioners licensed to prescribe such drugs or, at the request of a licensed practitioner, to pharmacies of hospitals or other health care entities. Such a distribution of drug samples may only be made— Mail. Health care professionals.

"(i) in response to a written request for drug samples made on a form which meets the requirements of subparagraph (B), and

"(ii) under a system which requires the recipient of the drug sample to execute a written receipt for the drug sample upon its delivery and the return of the receipt to the manufacturer or distributor.

"(B) A written request for a drug sample required by subparagraph (A)(i) shall contain—

"(i) the name, address, professional designation, and signature of the practitioner making the request,

"(ii) the identity of the drug sample requested and the quantity requested,

"(iii) the name of the manufacturer of the drug sample requested, and

"(iv) the date of the request.

"(C) Each drug manufacturer or distributor which makes distributions by mail or common carrier under this paragraph shall maintain, for a period of 3 years, the request forms submitted for such distributions and the receipts submitted for such distributions and shall maintain a record of distributions of drug samples which identifies the drugs distributed and the recipients of the distributions. Forms, receipts, and records required to be maintained under this subparagraph shall be made available by the drug manufacturer or distributor to Federal and State officials engaged in the regulation of drugs and in the enforcement of laws applicable to drugs. Mail. Records. State and local governments.

"(3) The manufacturer or distributor of a drug subject to subsection (b) may, by means other than mail or common carrier, distribute drug samples only if the manufacturer or distributor makes the distributions in accordance with subparagraph (A) and carries out the activities described in subparagraphs (B) through (F) as follows:

"(A) Drug samples may only be distributed— Health care professionals.

"(i) to practitioners licensed to prescribe such drugs if they make a written request for the drug samples, or

"(ii) at the written request of such a licensed practitioner, to pharmacies of hospitals or other health care entities. A written request for drug samples shall be made on a form which contains the practitioner's name, address, and professional designation, the identity of the drug sample requested, the quantity of drug samples requested, the name of the manufacturer or distributor of the drug sample, the date of the request and signature of the practitioner making the request.

"(B) Drug manufacturers or distributors shall store drug samples under conditions that will maintain their stability, integrity, and effectiveness and will assure that the drug samples will be free of contamination, deterioration, and adulteration.

Records. "(C) Drug manufacturers or distributors shall conduct, at least annually, a complete and accurate inventory of all drug samples in the possession of representatives of the manufacturer or distributor. Drug manufacturers or distributors shall maintain lists of the names and address of each of their representatives who distribute drug samples and of the sites where drug samples are stored. Drug manufacturers or distributors shall maintain records for at least 3 years of all drug samples distributed, destroyed, or returned to the manufacturer or distributor, of all inventories maintained under this subparagraph, of all thefts or significant losses of drug samples, and of all requests made under subparagraph (A) for drug samples. Records and lists maintained under this subparagraph shall be made available by the drug manufacturer or distributor to the Secretary upon request.

"(D) Drug manufacturers or distributors shall notify the Secretary of any significant loss of drug samples and any known theft of drug samples.

Reports. "(E) Drug manufacturers or distributors shall report to the Secretary any conviction of their representatives for violations of section 503(c)(1) or a State law because of the sale, purchase, or trade of a drug sample or the offer to sell, purchase, or trade a drug sample.

"(F) Drug manufacturers or distributors shall provide to the Secretary the name and telephone number of the individual responsible for responding to a request for information respecting drug samples.".

SEC. 6. WHOLESALE DISTRIBUTORS.

Section 503 (as amended by section 5 of this Act) is amended by adding at the end the following:

"(e)(1) Each person who is engaged in the wholesale distribution of drugs subject to subsection (b) and who is not an authorized distributor of record of such drugs shall provide to each wholesale distributor of such drugs a statement identifying each sale of the drug (including the date of the sale) before the sale to such wholesale

Records. distributor. Each manufacturer shall maintain at its corporate offices a current list of such authorized distributors.

"(2)(A) No person may engage in the wholesale distribution in interstate commerce of drugs subject to subsection (b) in a State unless such person is licensed by the State in accordance with the guidelines issued under subparagraph (B).

Regulations. "(B) The Secretary shall by regulation issue guidelines establishing minimum standards, terms, and conditions for the licensing of persons to make wholesale distributions in interstate commerce of

drugs subject to subsection (b). Such guidelines shall prescribe requirements for the storage and handling of such drugs and for the establishment and maintenance of records of the distributions of such drugs. Records.

"(3) For the purposes of this subsection—

"(A) the term 'authorized distributors of record' means those distributors with whom a manufacturer has established an ongoing relationship to distribute such manufacturer's products, and

"(B) the term 'wholesale distribution' means distribution of drugs subject to subsection (b) to other than the consumer or patient but does not include intracompany sales and does not include distributions of drugs described in subsection (c)(3)(B).".

SEC. 7. PENALTIES.

(a) PROHIBITED ACTS.—Section 301 (21 U.S.C. 331) is amended by adding at the end the following:

"(t) The importation of a drug in violation of section 801(d)(1), the sale, purchase, or trade of a drug or drug sample or the offer to sell, purchase, or trade a drug or drug sample in violation of section 503(c), the sale, purchase, or trade of a coupon, the offer to sell, purchase, or trade such a coupon, or the counterfeiting of such a coupon in violation of section 503(c)(2), the distribution of a drug sample in violation of section 503(d) or the failure to otherwise comply with the requirements of section 503(d), or the distribution of drugs in violation of section 503(e) or the failure to otherwise comply with the requirements of section 503(e).".

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

(1) by inserting "(1)" after "(a)",

(2) by redesignating subsection (b) as paragraph (2) and by striking out "subsection (a)" in such subsection and inserting in lieu thereof "paragraph (1)", and

(3) by inserting after subsection (a) the following:

"(b)(1) Notwithstanding subsection (a), any person who violates section 301(t) because of an importation of a drug in violation of section 801(d)(1), because of a sale, purchase, or trade of a drug or drug sample or the offer to sell, purchase, or trade a drug or drug sample in violation of section 503(c), because of the sale, purchase, or trade of a coupon, the offer to sell, purchase, or trade such a coupon, or the counterfeiting of such a coupon in violation of section 503(c)(2), or the distribution of 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.

"(2) Any manufacturer or distributor who distributes drug samples by means other than the mail or common carrier whose representative, during the course of the representative's employment or association with that manufacturer or distributor, violated section 301(t) because of a violation of section 503(c)(1) or violated any State law prohibiting the sale, purchase, or trade of a drug sample subject to section 503(b) or the offer to sell, purchase, or trade such a drug sample shall, upon conviction of the representative for such violation, be subject to the following civil penalties:

"(A) A civil penalty of not more than $50,000 for each of the first two such violations resulting in a conviction of any representative of the manufacturer or distributor in any 10-year period.

"(B) A civil penalty of not more than $1,000,000 for each violation resulting in a conviction of any representative after the second conviction in any 10-year period.

For the purposes of this paragraph, multiple convictions of one or more persons arising out of the same event or transaction, or a related series of events or transactions, shall be considered as one violation.

"(3) Any manufacturer or distributor who violates section 301(t) because of a failure to make a report required by section 503(d)(3)(E) shall be subject to a civil penalty of not more than $100,000.

"(4)(A) If a manufacturer or distributor or any representative of such manufacturer or distributor provides information leading to the arrest and conviction of any representative of that manufacturer or distributor for a violation of section 301(t) because of a sale, purchase, or trade or offer to purchase, sell, or trade a drug sample in violation of section 503(c)(1) or for a violation of State law prohibiting the sale, purchase, or trade or offer to sell, purchase, or trade a drug sample, the conviction of such representative shall not be considered as a violation for purposes of paragraph (2).

"(B) If, in an action brought under paragraph (2) against a manufacturer or distributor relating to the conviction of a representative of such manufacturer or distributor for the sale, purchase, or trade of a drug or the offer to sell, purchase, or trade a drug, it is shown, by clear and convincing evidence—

"(i) that the manufacturer or distributor conducted, before the arrest of such representative for the violation which resulted in such conviction, an investigation of events or transactions which would have led to the reporting of information leading to the arrest and conviction of such representative for such purchase, sale, or trade or offer to purchase, sell, or trade, or

"(ii) that, except in the case of the conviction of a representative employed in a supervisory function, despite diligent implementation by the manufacturer or distributor of an independent audit and security system designed to detect such a violation, the manufacturer or distributor could not reasonably have been expected to have detected such violation,

the conviction of such representative shall not be considered as a conviction for purposes of paragraph (2).

"(5) If a person provides information leading to the arrest and conviction of a person for a violation of section 301(t) because of the sale, purchase, or trade of a drug sample or the offer to sell, purchase, or trade a drug sample in violation of section 503(c)(1), such person shall be entitled to one-half of the criminal fine imposed and collected for such violation but not more than $125,000.".

21 USC 353 note.

SEC. 8. EFFECTIVE DATE.

(a) GENERAL RULE.—Except as provided in subsection (b), this Act and the amendments made by this Act shall take effect upon the expiration of 90 days after the date of the enactment of this Act.

(b) EXCEPTION.—

(1) Section 503(d) of the Federal Food, Drug, and Cosmetic Act (as added by section 5 of this Act) shall take effect upon the expiration of 180 days after the date of the enactment of this Act.

Regulations.

(2) The Secretary of Health and Human Services shall by regulation issue the guidelines required by section 503(e)(2)(B) of

the Federal Food, Drug, and Cosmetic Act (as added by section 6 of this Act) not later than 180 days after the date of the enactment of this Act. Section 503(e)(2)(A) of such Act shall take effect upon the expiration of 2 years after the date such regulations are promulgated and take effect.

Approved April 22, 1988.

LEGISLATIVE HISTORY—H.R. 1207:

HOUSE REPORTS: No. 100-76 (Comm. on Energy and Commerce).
SENATE REPORTS: No. 100-303 (Comm. on Finance).
CONGRESSIONAL RECORD:
Vol. 133 (1987): May 4, considered and passed House.
Vol. 134 (1988): Mar. 31, considered and passed Senate.
WEEKLY COMPILATION OF PRESIDENTIAL DOCUMENTS, Vol. 24 (1988):
Apr. 22, Presidential statement.