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TITLE: PRESCRIPTION DRUG AMENDMENTS OF 1992

SPEAKER: Mr. DANNEMEYER; MR. DINGELL; Mr. WAXMAN

TEXT: Text that appears in UPPER CASE identifies statements or insertions which are not spoken by a Member of the House on the floor.

[*H8107] Mr. WAXMAN. Mr. Speaker, I ask unanimous consent to take from the Speaker's table the Senate bill (S. 3163) to amend the Federal Food, Drug, and Cosmetic Act to coordinate Federal and State regulation of wholesale drug distribution, and for other purposes, and ask for its immediate consideration in the House.

The Clerk read the title of the Senate bill.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from California?

Mr. DANNEMEYER. Mr. Speaker, reserving the right to object, I yield to my colleague, the gentleman from California [Mr. Waxman], to explain briefly what this bill would do.

Mr. WAXMAN. Mr. Speaker, I thank the gentleman for yielding.

Mr. Speaker, this legislation will extend the deadline for States to comply with the Prescription Drug Marketing Act, and in the interim establish a substitute registration system at the Food and Drug Administration. It will also clarify the legal requirements concerning the level of knowledge required for a criminal prosecution.

The Prescription Drug Marketing Act set a September 14, 1992, deadline for States to license prescription drug wholesaler. As of this month, most States are in full compliance with this requirement, but it is clear that some States have not adopted the registration system. An extension of the original deadline is needed to guarantee continued access to the full range of prescription drugs for all Americans. Otherwise, prescription drug wholesalers in States that have not yet met the legislative requirements of the PDMA will be subject to civil and criminal penalties.

Congressman Dingell and I have worked with industry groups and the administration in drafting this amendment. The bill includes a sunset provision, so that the PDMA deadline is extended by only 2 years. This gives States the time they need to legislate and implement their registration programs. In the interim, companies in States that have not yet established registration programs will be required to register at the Food and Drug Administration.

Following this statement, I have included a section-by-section analysis of the bill.

S. 3163 was adopted unanimously by other body. I urge my colleagues to support this legislation.

SECTION-BY-SECTION ANALYSIS

SEC. 1. SHORT TITLE

The short title of the bill is the Prescription Drug Amendments of 1992.

SEC. 2. DISTRIBUTOR REGISTRATION

Section 2 establishes a temporary (2 year) registration program with the Food and Drug Administration ("FDA") for wholesale distributors of prescription drugs in interstate commerce in states that do not license such persons in accordance with existing requirements of the Federal Food, Drug and Cosmetic Act ("FDC Act").

Section 503(e)(2)(A) of the current law is intended to ensure that any person engaging in the wholesale distribution of prescription drugs in interstate commerce shall be licensed in the state in which it does business and that state licensing requirements meet certain minimum requirements as contained in regulations promulgated by the Secretary of the Department of Health and Human Services ("HHS"). The effective date for subparagraph 503(e)(2)(A) is September 14, 1992.

While many states have taken steps to meet the licensing requirements and are expected to meet the deadline, current data indicate that some states may not enact prescription drug wholesaler licensing requirements by September 14, 1992. Therefore, the amendments to section 503(e) provide for a temporary registration program within HHS for persons engaging in the wholesale distribution of prescription drugs in states that have not yet adopted licensing programs. This temporary registration provision is not intended to create a federalized registration program and will expire without extension on September 14, 1994. Ultimate responsibility for licensing wholesale distributors shall remain with the states.

The bill's sponsors understand the FDA has the discretion to implement this provision in a manner that is consistent with its resources.

SEC. 3. PENALTY CLARIFICATION

Section 3 adds a "knowingly" standard to the felony provision of the Prescription Drug Marketing Act ("PDMA"). In its present form, the Act provides severe punishment for criminal violations without expressly requiring any scienter on the part of the offender.

Addition of the word "knowingly" in Section 303(b)(1) of the FDC Act is intended to clarify that the offenses described in that section require an element of knowledge. The amendment conforms with prosecutorial experience and practice.

Section 303(b)(1) is intended to clarify that the offenses described in that section require an element of knowledge. The provision conforms with prosecutorial experience and practice.

The offenses described in section 303(b)(1) are treated differently from other offenses in the FDC Act. In general, a violation of the FDC Act is punishable as a misdemeanor without proof of consciousness of wrongdoing (Section 303(a)(1); UNITED STATES V. PARK, 421 U.S. 658 (1975)), or as a three-year felony when the violation is second offense, or when it is committed with the intent to defraud or mislead. Section 303(b)(2). The precription drug marketing offenses described in section 303(b)(1) of the FDC Act are excepted from this scheme, carrying only a felony penalty.

As originally enacted, section 303(b)(1) stated no mental element for the offenses it described. This silence potentially could create confusion about what kind of conduct Congress was addressing. Indicia of Congress' intent are available in other parts of the statute and the legislative history. For example, Congress provided that a pharmaceutical

company would not be criminally responsible for every drug diversion perpetrated by a company employee 303(c)(1); House Report 1000-76 at 12. This is strong evidence that 303(b)(1) was not intended to create a strict liability offense under the FDC Act. In the absence of specific language describing the intended mental element of the offense, however, the statute might be subject to conflicting or erroneous interpretation by the courts.

The present amendment makes clear that the offenses described in section 303(b)(1) are committed when an individual "knowingly" commits acts that are proscribed by the PDMA (for example selling a presecription drug sample, importing a prescription drug, or selling a drug that had been purchased by a health care entity). This knowledge extends only to the prohibited act; it would not be necessary in a prosecution for the government to prove that the defendant knew that the act was a violation of any law. Thus, for example, an offense under amended section 303(b)(1)(B) would be committed when an individual sold a prescription drug that had been purchased by a health care entity, if he or she were aware of these circumstances, whether or not he or she also knew that the sale of the drug was a violation of section 503(c)(3).

Section 3 also sbustitutes the words "institution of criminal proceeding" for "arrest" or "arrest of" in current law, because there are rarely arrests in connection with criminal proceedings under the PDMA.

Finally, section 3 revises section 303(c) and (d) to conform with section 303 (a) and (b) as amended by the PDMA, and corrects subsection (d).

SEC. 4 DRUG SAMPLES

Section 4 clarifies the prohibition against the distribution of drug samples by anyone other than the manufacturer or the manufacturer's authorized distributor. It also makes clear that providing a drug sample to a patient by (or in very limited circumstances at the discretion of) a licensed practitioner is not prohibited.

Section 4 also makes clear that any wholesale distribution of a prescription drug (any sale to anyone other than a consumer or patient, including any sale to an authorized distributor of record to a retail pharmacy) by anyone other than the manufacturer or authorized distributor of record must be preceded by a statement identifying each prior sale of the drug. The identifying statement must in all cases include the dates of each transaction involving the drug and the names and addresses of all parties to the transaction, and must contain such other information as the Secretary of HHS may require.

SEC. 5 TECHNICAL AMENDMENT

Section 5 makes a technical amendment to section 801(d)(1) of current law.

Mr. DANNEMEYER. Mr. Speaker, further reserving the right to object, if we do not adopt this bill very soon, there are certain sellers of prescription drugs that may be in violation inadvertently of State laws, and this is the reason that I think the legislation should be adopted.

MR. DINGELL. MR. SPEAKER, I RISE IN SUPPORT OF S. 3163, A BILL THAT PROVIDES FOR THE TEMPORARY LICENSING WITH THE FOOD AND DRUG ADMINISTRATION OF PRESCRIPTION DRUG WHOLESALERS IN STATES THAT HAVE YET TO ESTABLISH A STATE LICENSING SYSTEM AS REQUIRED BY EXISTING LAW.

THE PURPOSE OF THIS TECHNICAL AMENDMENT IS TO PREVENT NEEDLESS DISRUPTION IN THE DISTRIBUTION OF DRUGS BY WHOLESALERS IN THE UNITED STATES.

THE BILL AMENDS THE PRESCRIPTION DRUG MARKETING ACT, WHICH WAS SIGNED INTO LAW IN APRIL 1988. THIS LAW REQUIRES STATES TO LICENSE WHOLESALE DISTRIBUTORS OF PRESCRIPTION DRUGS IN CONFORMANCE WITH MINIMUM STANDARDS PUBLISHED BY THE FDA.

THE STATUTE GAVE THE [*H8108] STATES 2 YEARS TO ACCOMPLISH THIS TASK. WHILE MANY STATES HAVE COMPLIED, A NUMBER OF OTHER STATES HAVE NOT. ON SEPTEMBER 15, 1992, ANY WHOLESALER THAT SELLS PRESCRIPTION DRUGS IN A STATE THAT HAS NOT COMPLIED WITH THE LICENSING REQUIREMENT WILL BE COMMITTING A FELONY.

THE NATIONAL WHOLESALE DRUGGISTS ASSOCIATION HAS INFORMED THE ENERGY AND COMMERCE COMMITTEE THAT, AS OF THE END OF JULY 22 STATES AND THE COMMONWEALTH OF PUERTO RICO WERE NOT IN COMPLIANCE. WHILE SEVERAL OF THESE STATES MAY COME INTO COMPLIANCE BY SEPTEMBER 15, IT IS CLEAR THAT SOME WILL NOT. THE NWDA HAS TOLD THE COMMITTEE THAT THEIR MEMBERS IN THOSE STATES WILL BE FORCED TO CEASE SALES IN INTERSTATE COMMERCE FOR FEAR OF VIOLATING THE LAW.

TO PREVENT THIS DISRUPTIVE AND COSTLY OUTCOME, THIS LEGISLATION ALLOWS WHOLESALERS IN NONCOMPLYING STATES TO REGISTER INSTEAD WITH THE FDA. THIS TEMPORARY ALTERNATIVE REGISTRATION SYSTEM, WHICH ONLY APPLIES TO STATES WITHOUT REGISTRATION SYSTEMS THAT MEET THE FDA STANDARD, WILL SUNSET AFTER 2 YEARS.

THE PROVISIONS OF THIS BILL HAVE BEEN WORKED OUT WITH ALL PARTIES, INCLUDING AFFECTED ELEMENTS IN THE PHARMACEUTICAL INDUSTRY, THE ADMINISTRATION AND, OF COURSE, MY REPUBLICAN COLLEAGUES. I WOULD ESPECIALLY LIKE TO THANK MY GOOD FRIENDS IN THE SENATE, CHAIRMAN KENNEDY AND SENATOR HATCH, AND THEIR STAFFS, FOR THEIR LEADERSHIP AND THEIR HARD WORK IN PASSING THIS LEGISLATION. THANKS ARE ALSO DUE FOR CHAIRMAN WAXMAN AND THE STAFF OF HIS SUBCOMMITTEE FOR THEIR HELPFUL ROLE IN FACILITATING THE PASSAGE OF THIS BILL.

MR. SPEAKER, I URGE MY COLLEAGUES TO VOTE IN FAVOR OF THIS IMPORTANT PIECE OF LEGISLATION.

Mr. DANNEMEYER. Mr. Speaker, I withdraw my reservation of objection.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from California?

There was no objection.

The Clerk read the Senate bill, as follows:

S. 3163

BE IT ENACTED BY THE SENATE AND HOUSE OF REPRESENTATIVES OF THE UNITED STATES OF AMERICA IN CONGRESS ASSEMBLED,

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. DISTRIBUTION 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.

(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 records";

(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".

The Senate bill was ordered to be read a third time, was read the third time, and passed, and a motion to reconsider was laid on the table.

SUBJECT: PRESCRIPTION DRUGS (91%); WHOLESALERS (90%); PHARMACEUTICALS WHOLESALERS (89%); LEGISLATION (79%); LEGISLATORS (59%); PRESCRIPTION DRUG POLICY (59%); LICENSES & PERMITS (59%);