Union Calendar No. 520

114TH CONGRESS
2D SESSION

H. R. 3250

[Report No. 114–672]

To amend the Federal Food, Drug, and Cosmetic Act to prevent the abuse of dextromethorphan, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JULY 28, 2015

Mr. JOHNSON of Ohio (for himself and Ms. MATSUI) introduced the following bill; which was referred to the Committee on Energy and Commerce

JULY 8, 2016

Additional sponsors: Mr. LOEBSACK, Mr. TONKO, Mr. BURGESS, Mr. GUTHRIE, Mr. KINZINGER of Illinois, Mr. BARLETTA, Ms. BROWNLEY of California, Ms. CLARKE of New York, Ms. NORTON, Mr. HUFFMAN, Mr. KATKO, Mr. OLSON, Mr. HASTINGS, Mr. KIND, Mr. PAULSEN, Mr. COSTELLO of Pennsylvania, Mr. MEEHAN, Mr. DESAULNIER, and Mr. FITZPATRICK

JULY 8, 2016

Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to prevent the abuse of dextromethorphan, and for other purposes.

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

SECTION 1. SHORT TITLE.

This Act may be cited as the ''DXM Abuse Prevention Act of 2015''.

SEC. 2. SALES OF OVER-THE-COUNTER DRUGS CONTAINING DEXTROMETHORPHAN.

(a) PROHIBITED ACT.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following:

''(ddd) The failure of a retailer to implement a verification system as required by section 506G (relating to sales of over-the-counter drugs containing dextromethorphan).''.

(b) VERIFICATION SYSTEM.—The Federal Food, Drug, and Cosmetic Act is amended by inserting after section 506F of such Act (21 U.S.C. 356f) the following:

''SEC. 506G. SALES OF OVER-THE-COUNTER DRUGS CONTAINING DEXTROMETHORPHAN.

''(a) VERIFICATION SYSTEM.—Any retailer selling or offering for sale in interstate commerce dextromethorphan shall implement a verification system to ensure compliance with this section. Such a system may ensure such compliance by means of—

''(1) an electronic point-of-sale system coded to prompt for verification of the age of all purchasers of drugs described in subsection (b) and deny sales to those under the age of 18;

''(2) training manuals or materials instructing employees to verify the age of all purchasers of such drugs and deny sales to those under the age of 18;

''(3) signage in and around the sales counter outlining the age restriction on sales of such drugs;

''(4) designating one on-duty employee to approve all sales of such drugs; or

''(5) any other verification measure deemed valid by the Secretary.

''(b) PROHIBITION.—Except as provided in subsection (c), each retailer shall verify that no individual is under 18 years of age who purchases any drug that—

''(1) contains dextromethorphan; and

''(2) is not subject to section 503(b)(1).

''(c) EXCEPTIONS.—

''(1) INDIVIDUALS OVER 26.—Subsection (b) does not require verification of the age of any individual over the age of 26.

''(2) VALID PRESCRIPTION.—Subsection (b) does not apply to any sale made pursuant to a validly issued prescription.

''(3) VALID MILITARY IDENTIFICATION CARD.—Subsection (b) does not apply to any sale to an individual under 18 years of age if such individual supplies proof at the time of such sale that such individual is actively enrolled in the military and presents a valid military identification card.

''(d) AFFIRMATIVE DEFENSE.—It shall be an affirmative defense to an alleged violation of subsection (b) that the individual selling a drug containing dextromethorphan—

''(1) examined the purchaser's identification card; and

''(2) based on that examination, reasonably concluded that the identification was valid and indicated that the purchaser was not less than 18 years of age.

''(e) DEFINITION.—In this paragraph, the term 'identification card' means an identification card that—

''(1) includes a photograph and the date of birth of the individual; and

''(2) is issued by a State or the Federal Government or is considered acceptable for purposes of sections 274a.2(b)(1)(v)(A) and 274a.2(b)(1)(v)(B)(1) of title 8, Code of Federal Regulations (including any successor regulations).''.

(c) CIVIL PENALTIES.—Section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333) is amended by adding at the end the following:

''(h) Notwithstanding subsection (a), the following provisions shall apply to violations of section 301(ddd):

''(1) A person who violates section 301(ddd) shall—

''(A) receive a violation notification from the Secretary for the first such violation; and

''(B) be subject to a civil penalty in an amount—

''(i) not more than $1,000 for the second such violation by a person;

''(ii) not more than $2,000 for the third such violation by a person; and

''(iii) not more than $5,000 for the fourth such violation, or a subsequent such violation, by a person.

''(2) In determining the amount of a civil penalty under this subsection for a person who is a retailer, the Secretary shall consider whether the retailer has taken appropriate steps to prevent subsequent violations, such as the establishment and administration of a documented employee training program to ensure all employees are familiar with and

abiding by the provisions of section 301(ddd), where such program includes—

''(A) educating employees regarding products containing dextromethorphan;

''(B) instruction on the correct method of checking a purchaser's identification card; and

''(C) notifying employees of the civil penalties under this subsection.

''(3) If a person who is a retailer transacts sales of products containing dextromethorphan at more than one physical location, for purposes of determining the number of violations by that person under this subsection, each individual physical location operated by that retailer shall be considered a separate person.

''(4) The Secretary shall notify persons found to have violated section 301(ddd) as soon as practicable after the Secretary discovers such violation. Such notification shall include the date and time when the violation was observed to occur.

''(5) Notwithstanding any other provision of this subsection or section 301(ddd), an employee shall not be subject to penalties under this subsection unless such employee knowingly and willfully participates in a conspiracy to violate section

301(ddd). For purposes of this paragraph, a conspiracy shall consist of an agreement between two or more persons with the intent to violate section 301(ddd) and the commission of at least one overt act in furtherance of the agreement.

''(6) In this subsection—

''(A) the term 'employee' means an individual who is employed by a retailer in a clerical or other non-managerial position; and

''(B) the term 'retailer' means a grocery store, general merchandise store, drug store, pharmacy, convenience store, or other entity or person whose activities as a distributor relating to products containing dextromethorphan are limited almost exclusively to sales for personal use, both in number of sales and volume of sales, including any sales made by the Internet or other means.''.

SEC. 3. RESTRICTIONS ON DISTRIBUTION OF BULK DEXTROMETHORPHAN.

The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.) is amended—

(1) in section 501, by inserting at the end the following:

''(k) If it is unfinished dextromethorphan and is possessed, received, or distributed in violation of section 506H.''; and

(2) by inserting after section 506F the following:

''SEC. 506H. RESTRICTIONS ON THE DISTRIBUTION OF BULK DEXTROMETHORPHAN.

''(a) IN GENERAL.—No person shall—

''(1) possess or receive unfinished dextromethorphan, unless the person is registered under section 510 or otherwise registered, licensed, or approved pursuant to Federal or State law to engage in the practice of pharmacy, pharmaceutical production, or manufacture or distribution of drug ingredients; or

''(2) distribute unfinished dextromethorphan to any person other than a person registered under section 510 or otherwise registered, licensed, or approved pursuant to Federal or State law to engage in the practice of pharmacy, pharmaceutical production, or manufacture or distribution of drug ingredients.

''(b) EXCEPTION FOR COMMON CARRIERS.—This section does not apply to a common carrier that possesses, receives, or distributes unfinished dextromethorphan for

purposes of distributing such unfinished dextromethorphan between persons described in subsection (a) as registered, licensed, or approved.

''(c) DEFINITIONS.—In this section:

''(1) The term 'common carrier' means any person that holds itself out to the general public as a provider for hire of the transportation by water, land, or air of merchandise, whether or not the person actually operates the vessel, vehicle, or aircraft by which the transportation is provided, between a port or place and a port or place in the United States.

''(2) The term 'unfinished dextromethorphan' means dextromethorphan that is not contained in a drug that is in finished dosage form.''; and

(3) by amending section 303, as amended by section 2(b), by adding at the end the following:

''(i) Notwithstanding subsection (a), a person who violates section 506H shall be subject to a civil penalty of not more than $100,000.''.

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