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113TH CONGRESS
2D SESSION

H. R. 3969

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

IN THE HOUSE OF REPRESENTATIVES

JANUARY 29, 2014

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

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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 ''Preventing Abuse of Cough Treatments Act of 2014'' or the ''PACT Act''.

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)(1)(A) Except as provided in subparagraph (2), the sale or offering for sale of a drug containing dextromethorphan to an individual under 18 years of age, including any such sale using the Internet, provided the drug is not subject to section 503(b)(1).

''(B) If a person fails to request identification from an individual under 18 years of age and sells a product containing dextromethorphan to that individual, that person shall be deemed to have known that the individual was under 18 years of age, unless from the individual's outward appearance the person making the sale would reasonably presume the individual to be 25 years of age or older.

''(C) It shall be an affirmative defense to an alleged violation of clause (A) that the person selling a product containing dextromethorphan examined the purchaser's identification card and, based on that examination, that person reasonably concluded that the identification was valid and indicated that the purchaser was not less than 18 years of age.

''(2)(A) This paragraph shall not apply to any sale made pursuant to a validly issued prescription.

''(B) This paragraph shall not apply to the sale or offering for sale of a drug containing dextromethorphan 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.

''(3) In this paragraph, the term 'identification card' means an identification card that—

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

''(B) 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 (as in effect on or after the date of the enactment of the Preventing Abuse of Cough Treatments Act of 2014).''.

(b) 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 warning letter 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 de-

termining 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 details of the violation, such as—

''(A) the date and time of the sale;

''(B) a sales receipt or credit card receipt documenting the sale; and

''(C) the name or description of the employee involved in the sale.

''(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, either directly to walk-in customers or in face-to-face transactions by direct sales.''.

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 506G.'';

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

"SEC. 506G. 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 506G shall be subject to a civil penalty of not more than $100,000.''.

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