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116TH CONGRESS
1ST SESSION

H. R. 863

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 30, 2019

Ms. MATSUI (for herself and Mr. JOHNSON of Ohio) 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 ''DXM Abuse Prevention Act of 2019''.

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

(a) PROHIBITED ACTS.—

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

''(fff) The failure of a retailer (as defined in section 506H) that offers for sale in interstate commerce covered drugs (as defined in section 506H) to have a verification system as required by section 506H (relating to sales of over-the-counter drugs containing dextromethorphan).''.

(2) IDENTIFIER FOR ELECTRONIC POINT OF SALE SYSTEM; ACTIVE INGREDIENTS.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331), as amended by paragraph (1), is further amended by adding at the end the following:

''(ggg) The introduction or delivery for introduction into interstate commerce of any covered drug (as defined in section 506H) whose labeling does not include—

''(1) a universal product code, universal product number, bar code, or similar identifier to allow an electronic point of sale system to recognize that the sale of the covered drug is prohibited to those under the age of 18; and

''(2) the established name of each active ingredient of the covered drug within the first panel of the drug facts labeling required by section 201.66(c) of title 21, Code of Federal Regulations (or any suc-

cessor regulations), in no smaller than 6-point type.''.

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

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

''(a) VERIFICATION SYSTEM.—Any retailer selling or offering for sale in interstate commerce a covered drug shall have a verification system in accordance with this section that is intended to ensure that no individual who purchases a covered drug from the retailer is under 18 years of age. Such a system shall be set up to prompt a retailer to examine a purchaser's identification card.

''(b) MEANS USED TO ENSURE COMPLIANCE.—A verification system under subsection (a) may ensure compliance with this section by any of, or any combination of, the following means:

''(1) An electronic point-of-sale system that is coded—

''(A) to prompt for verification of the age of purchasers of covered drugs; and

''(B) to deny sales of covered drugs to those under the age of 18.

''(2) Training manuals, materials, or programs that instruct employees—

''(A) to verify the age of purchasers of covered drugs; and

''(B) to deny sales of covered drugs to those under the age of 18.

''(3) Signage in and around the sales counter outlining the age restriction on sales of covered drugs.

''(4) Designating one on-duty employee to approve sales of covered drugs.

''(5) Any other verification measure adopted by a retailer that is designed to ensure that a purchaser of a covered drug is not under 18 years of age if, based on an examination of the purchaser's identification card, the retailer reasonably concludes the identification card is valid and indicates the purchaser is not under 18 years of age.

''(c) EXCEPTIONS.—

''(1) INDIVIDUALS OVER 26.—A verification system under subsection (a) need not require verification of the age of any individual over the age of 26.

''(2) VALID PRESCRIPTION.—A verification system under subsection (a) need not apply to any sale

made by a retailer that is a pharmacy pursuant to a validly issued prescription.

''(3) VALID MILITARY IDENTIFICATION CARD.—A verification system under subsection (a) need not apply to any sale to an individual who 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) ENFORCEMENT.—In carrying out this section, the Secretary shall coordinate with State entities that regulate retailers, as designated by the State, to perform activities to ensure compliance with this section, including providing for appropriate investigation of complaints related to violations of this section.

''(e) COMPLIANCE WITH STATE SYSTEM.—If a State has a law under which a retailer in the State is required to have a system that ensures that no individual who purchases a covered drug from the retailer is under 18 years of age, the Secretary shall treat any such retailer in the State that is in compliance with such law as having a verification system as required by this section, including for purposes of sections 301(fff) and 303(h).

''(f) DEFINITIONS.—In this section:

''(1) The term 'covered drug'—

''(A) means a drug that—

''(i) contains dextromethorphan; and

''(ii) is not subject to section 503(b)(1); and

''(B) excludes any drug that is packaged in packets or pouches and contains 2 or fewer maximum adult doses of dextromethorphan as allowable under section 341.74 of title 21, Code of Federal Regulations (or any successor regulations).

''(2) 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 (including any successor regulations).

''(3) The term 'retailer' means—

''(A) a grocery store, general merchandise store, drug store, pharmacy, convenience store, or other entity whose activities as a seller of covered drugs containing dextromethorphan are limited almost exclusively to sales for personal

use, both in number and volume of sales, including any sales made by the Internet or other means; and

''(B) excludes any entity listed in subparagraph (A) that does not sell any covered drug described in paragraph (1)(A).''.

(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) A retailer that violates section 301(fff) shall not be subject to subsection (a) or any civil monetary penalty under this Act for such violation except as follows:

''(1) If the Secretary finds that a retailer fails to have a verification system in violation of section 301(fff)—

''(A) upon the first such finding, the Secretary shall issue a formal notice of violation and give the retailer a period of at least 30 days (beginning on the receipt of such notice) to correct the violation;

''(B) upon the second such finding, the retailer shall be subject to a civil penalty of not more than $1,000;

''(C) upon the third such finding, the retailer shall be subject to a civil penalty of not more than $2,000; and

''(D) upon the fourth and any subsequent such finding, the retailer shall be subject to a civil penalty of not more than $5,000.

''(2) In determining the amount of a civil penalty under this subsection for 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 retailer's verification system established pursuant to section 506H, where such program includes—

''(A) educating employees regarding covered drugs;

''(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 retailer transacts sales of covered drugs at more than one physical location, for purposes of determining the number of violations by that retailer under this subsection, each individual

physical location operated by that retailer shall be considered a separate retailer.

''(4) The Secretary shall notify retailers found to have violated section 301(fff) as soon as practicable after the Secretary discovers such violation. Such notification shall include the date and time when the failure to have a verification system as required by such section was observed to occur.

''(5) In this subsection, the terms 'covered drug' and 'retailer' have the meanings given such terms in section 506H.''.

(d) APPLICABILITY.—The amendments made by subsections (a), (b), and (c) shall apply with respect to drugs sold or offered for sale on or after the date that is one year after the date of enactment of this Act.

(e) SENSE OF CONGRESS REGARDING COMMUNICATION BY ORGANIZATIONS NOMINATED BY MANUFACTURERS.—It is the sense of Congress that organizations nominated by manufacturers of covered drugs (as defined in section 506H of the Federal Food, Drug, and Cosmetic Act, as added by subsection (c)) should make reasonable efforts to communicate to retailers (as defined in such section 506H) the requirements of such section 506H, including by making available upon request materials (which may include signage, manuals, materials, or programs) to

assist with educating employees regarding such covered drugs.

SEC. 3. RESTRICTIONS ON DISTRIBUTION OF BULK DEXTROMETHORPHAN.

(a) IN GENERAL.—The Federal Food, Drug, and Cosmetic Act is amended—

(1) in section 301 (21 U.S.C. 331) (as amended by section 2(a)) by adding at the end the following:

''(hhh) The possession, receipt, or distribution of unfinished dextromethorphan in violation of section 506I.'';

(2) by inserting after section 506H (as added by section 2(b)) the following:

''SEC. 506I. 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—

''(A) the practice of pharmacy; or

''(B) drug or drug ingredient discovery, production, manufacture, or distribution; or

''(2) distribute unfinished dextromethorphan to any person other than a person described in paragraph (1).

''(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).

''(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(c), by adding at the end the following:

''(i) A person that violates section 301(hhh) shall not be subject to subsection (a) or any civil monetary penalty under this Act for such violation except such person shall

be subject to a civil penalty in an amount of not more than $100,000.''.

(b) APPLICABILITY.—The amendments made by this section apply beginning on the date of enactment of this Act.

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