

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

# A BILL

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

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

### 3 SECTION 1. SHORT TITLE.

4        This Act may be cited as the “DXM Abuse Preven-  
5        tion Act of 2019”.

## 6 SEC. 2. SALES OF OVER-THE-COUNTER DRUGS CONTAINING

## DEXTROMETHORPHAN.

8 (a) PROHIBITED ACTS.—

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

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

22                   “(2) the established name of each active ingre-  
23                   dient of the covered drug within the first panel of  
24                   the drug facts labeling required by section 201.66(c)  
25                   of title 21, Code of Federal Regulations (or any suc-

1 cessor regulations), in no smaller than 6-point  
2 type.”.

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

6 **“SEC. 506H. SALES OF OVER-THE-COUNTER DRUGS CON-**

7 **TAINING DEXTROMETHORPHAN.**

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

15 “(b) MEANS USED TO ENSURE COMPLIANCE.—A  
16 verification system under subsection (a) may ensure com-  
17 pliance with this section by any of, or any combination  
18 of, the following means:

19 “(1) An electronic point-of-sale system that is  
20 coded—

21 “(A) to prompt for verification of the age  
22 of purchasers of covered drugs; and

23 “(B) to deny sales of covered drugs to  
24 those under the age of 18.

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

3           “(A) to verify the age of purchasers of cov-  
4        ered drugs; and

5           “(B) to deny sales of covered drugs to  
6        those under the age of 18.

7           “(3) Signage in and around the sales counter  
8        outlining the age restriction on sales of covered  
9        drugs.

10          “(4) Designating one on-duty employee to ap-  
11        prove sales of covered drugs.

12          “(5) Any other verification measure adopted by  
13        a retailer that is designed to ensure that a purchaser  
14        of a covered drug is not under 18 years of age if,  
15        based on an examination of the purchaser’s identi-  
16        fication card, the retailer reasonably concludes the  
17        identification card is valid and indicates the pur-  
18        chaser is not under 18 years of age.

19          “(c) EXCEPTIONS.—

20          “(1) INDIVIDUALS OVER 26.—A verification sys-  
21        tem under subsection (a) need not require  
22        verification of the age of any individual over the age  
23        of 26.

24          “(2) VALID PRESCRIPTION.—A verification sys-  
25        tem under subsection (a) need not apply to any sale

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

3           “(3) VALID MILITARY IDENTIFICATION CARD.—  
4       A verification system under subsection (a) need not  
5       apply to any sale to an individual who supplies proof  
6       at the time of such sale that such individual is ac-  
7       tively enrolled in the military and presents a valid  
8       military identification card.

9           “(d) ENFORCEMENT.—In carrying out this section,  
10      the Secretary shall coordinate with State entities that reg-  
11      ulate retailers, as designated by the State, to perform ac-  
12      tivities to ensure compliance with this section, including  
13      providing for appropriate investigation of complaints re-  
14      lated to violations of this section.

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

23           “(f) DEFINITIONS.—In this section:

24            “(1) The term ‘covered drug’—

25              “(A) means a drug that—

1                         “(i) contains dextromethorphan; and  
2                         “(ii) is not subject to section  
3                         503(b)(1); and

4                         “(B) excludes any drug that is packaged in  
5                         packets or pouches and contains 2 or fewer  
6                         maximum adult doses of dextromethorphan as  
7                         allowable under section 341.74 of title 21, Code  
8                         of Federal Regulations (or any successor regu-  
9                         lations).

10                        “(2) The term ‘identification card’ means an  
11                         identification card that—

12                        “(A) includes a photograph and the date of  
13                         birth of the individual; and

14                        “(B) is issued by a State or the Federal  
15                         Government or is considered acceptable for pur-  
16                         poses of sections 274a.2(b)(1)(v)(A) and  
17                         274a.2(b)(1)(v)(B)(1) of title 8, Code of Fed-  
18                         eral Regulations (including any successor regu-  
19                         lations).

20                        “(3) The term ‘retailer’ means—

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

1           use, both in number and volume of sales, in-  
2           cluding any sales made by the Internet or other  
3           means; and

4           “(B) excludes any entity listed in subpara-  
5           graph (A) that does not sell any covered drug  
6           described in paragraph (1)(A).”.

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

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

13           “(1) If the Secretary finds that a retailer fails  
14           to have a verification system in violation of section  
15           301(fff)—

16           “(A) upon the first such finding, the Sec-  
17           retary shall issue a formal notice of violation  
18           and give the retailer a period of at least 30  
19           days (beginning on the receipt of such notice)  
20           to correct the violation;

21           “(B) upon the second such finding, the re-  
22           tailer shall be subject to a civil penalty of not  
23           more than \$1,000;

1                   “(C) upon the third such finding, the re-  
2                   tailer shall be subject to a civil penalty of not  
3                   more than \$2,000; and

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

7                   “(2) In determining the amount of a civil pen-  
8                   alty under this subsection for a retailer, the Sec-  
9                   retary shall consider whether the retailer has taken  
10                   appropriate steps to prevent subsequent violations,  
11                   such as the establishment and administration of a  
12                   documented employee training program to ensure all  
13                   employees are familiar with, and abiding by, the re-  
14                   tailer’s verification system established pursuant to  
15                   section 506H, where such program includes—

16                   “(A) educating employees regarding cov-  
17                   ered drugs;

18                   “(B) instruction on the correct method of  
19                   checking a purchaser’s identification card; and

20                   “(C) notifying employees of the civil pen-  
21                   alties under this subsection.

22                   “(3) If a retailer transacts sales of covered  
23                   drugs at more than one physical location, for pur-  
24                   poses of determining the number of violations by  
25                   that retailer under this subsection, each individual

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

3           “(4) The Secretary shall notify retailers found  
4       to have violated section 301(fff) as soon as prac-  
5       ticable after the Secretary discovers such violation.  
6       Such notification shall include the date and time  
7       when the failure to have a verification system as re-  
8       quired by such section was observed to occur.

9           “(5) In this subsection, the terms ‘covered  
10      drug’ and ‘retailer’ have the meanings given such  
11      terms in section 506H.”.

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

16       (e) SENSE OF CONGRESS REGARDING COMMUNICA-  
17      TION BY ORGANIZATIONS NOMINATED BY MANUFACTUR-  
18      ERS.—It is the sense of Congress that organizations nomi-  
19      nated by manufacturers of covered drugs (as defined in  
20      section 506H of the Federal Food, Drug, and Cosmetic  
21      Act, as added by subsection (c)) should make reasonable  
22      efforts to communicate to retailers (as defined in such sec-  
23      tion 506H) the requirements of such section 506H, includ-  
24      ing by making available upon request materials (which  
25      may include signage, manuals, materials, or programs) to

1 assist with educating employees regarding such covered  
2 drugs.

3 **SEC. 3. RESTRICTIONS ON DISTRIBUTION OF BULK DEX-**

4 **TROMETHORPHAN.**

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

7 (1) in section 301 (21 U.S.C. 331) (as amended  
8 by section 2(a)) by adding at the end the following:  
9 “(hhh) The possession, receipt, or distribution of un-  
10 finished dextromethorphan in violation of section 506I.”;  
11 (2) by inserting after section 506H (as added  
12 by section 2(b)) the following:

13 **“SEC. 506I. RESTRICTIONS ON THE DISTRIBUTION OF BULK**

14 **DEXTROMETHORPHAN.**

15 “(a) IN GENERAL.—No person shall—

16 “(1) possess or receive unfinished dextrome-  
17 thorphan, unless the person is registered under sec-  
18 tion 510 or otherwise registered, licensed, or ap-  
19 proved pursuant to Federal or State law to engage  
20 in—

21 “(A) the practice of pharmacy; or  
22 “(B) drug or drug ingredient discovery,  
23 production, manufacture, or distribution; or

1           “(2) distribute unfinished dextromethorphan to  
2       any person other than a person described in para-  
3       graph (1).

4           “(b) EXCEPTION FOR COMMON CARRIERS.—This  
5       section does not apply to a common carrier that possesses,  
6       receives, or distributes unfinished dextromethorphan for  
7       purposes of distributing such unfinished dextromethor-  
8       phan between persons described in subsection (a).

9           “(c) DEFINITIONS.—In this section:

10           “(1) The term ‘common carrier’ means any per-  
11       son that holds itself out to the general public as a  
12       provider for hire of the transportation by water,  
13       land, or air of merchandise, whether or not the per-  
14       son actually operates the vessel, vehicle, or aircraft  
15       by which the transportation is provided, between a  
16       port or place and a port or place in the United  
17       States.

18           “(2) The term ‘unfinished dextromethorphan’  
19       means dextromethorphan that is not contained in a  
20       drug that is in finished dosage form.”; and

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

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

1 be subject to a civil penalty in an amount of not more  
2 than \$100,000.”.

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

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