

Suspend the Rules and Pass the Bill, H.R. 3250, with An Amendment

(The amendment strikes all after the enacting clause and inserts a new text)

114TH CONGRESS
2^D SESSION

H. R. 3250

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

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 2016”.

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

3 (a) PROHIBITED ACTS.—

4 (1) VERIFICATION SYSTEM.—Section 301 of the
5 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
6 331) is amended by adding at the end the following:
7 “(eee) The failure of a retailer (as defined in section
8 506G) that offers for sale in interstate commerce covered
9 drugs (as defined in section 506G) to have a verification
10 system as required by section 506G (relating to sales of
11 over-the-counter drugs containing dextromethorphan).”.

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

17 “(fff) The introduction or delivery for introduction
18 into interstate commerce of any covered drug (as defined
19 in section 506G) whose labeling does not include—

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

25 “(2) the established name of each active ingre-
26 dient of the covered drug within the first panel of

1 the drug facts labeling required by section 201.66(c)
2 of title 21, Code of Federal Regulations (or any suc-
3 cessor regulations) in no smaller than 6-point type.”.

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

7 **“SEC. 506G. SALES OF OVER-THE-COUNTER DRUGS CON-**
8 **TAINING DEXTROMETHORPHAN.**

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

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

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

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

24 “(B) to deny sales of covered drugs to
25 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(eee) 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(eee) 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(eee)—

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 506G, 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(eee) 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 506G.”.

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 506G 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 506G) the requirements of such section 506G, 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**
4 **DEXTROMETHORPHAN.**

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 “(ggg) The possession, receipt, or distribution of un-
10 finished dextromethorphan in violation of section 506H.”;

11 (2) by inserting after section 506G (as added
12 by section 2(b)) the following:

13 **“SEC. 506H. RESTRICTIONS ON THE DISTRIBUTION OF**
14 **BULK DEXTROMETHORPHAN.**

15 “(a) IN GENERAL.—No person shall—

16 “(1) possess or receive unfinished
17 dextromethorphan, unless the person is registered
18 under section 510 or otherwise registered, licensed,
19 or approved pursuant to Federal or State law to en-
20 gage 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
8 dextromethorphan between persons described in sub-
9 section (a).

10 “(c) DEFINITIONS.—In this section:

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

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

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

24 “(i) A person that violates section 301(fff) shall not
25 be subject to subsection (a) or any civil monetary penalty

1 under this Act for such violation except such person shall
2 be subject to a civil penalty in an amount of not more
3 than \$100,000.”.

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