

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

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 “Preventing Abuse of
5 Cough Treatments Act of 2014” or the “PACT Act”.

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

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

1 “(ddd)(1)(A) Except as provided in subparagraph
2 (2), the sale or offering for sale of a drug containing dex-
3 tromethorphan to an individual under 18 years of age, in-
4 cluding any such sale using the Internet, provided the
5 drug is not subject to section 503(b)(1).

6 “(B) If a person fails to request identification from
7 an individual under 18 years of age and sells a product
8 containing dextromethorphan to that individual, that per-
9 son shall be deemed to have known that the individual was
10 under 18 years of age, unless from the individual’s out-
11 ward appearance the person making the sale would rea-
12 sonably presume the individual to be 25 years of age or
13 older.

14 “(C) It shall be an affirmative defense to an alleged
15 violation of clause (A) that the person selling a product
16 containing dextromethorphan examined the purchaser’s
17 identification card and, based on that examination, that
18 person reasonably concluded that the identification was
19 valid and indicated that the purchaser was not less than
20 18 years of age.

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

23 “(B) This paragraph shall not apply to the sale or
24 offering for sale of a drug containing dextromethorphan
25 to an individual under 18 years of age if such individual

1 supplies proof at the time of such sale that such individual
2 is actively enrolled in the military and presents a valid
3 military identification card.

4 “(3) In this paragraph, the term ‘identification card’
5 means an identification card that—

6 “(A) includes a photograph and the date of
7 birth of the individual; and

8 “(B) is issued by a State or the Federal Gov-
9 ernment or is considered acceptable for purposes of
10 sections 274a.2(b)(1)(v)(A) and
11 274a.2(b)(1)(v)(B)(1) of title 8, Code of Federal
12 Regulations (as in effect on or after the date of the
13 enactment of the Preventing Abuse of Cough Treat-
14 ments Act of 2014).”.

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

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

20 “(1) A person who violates section 301(ddd)
21 shall—

22 “(A) receive a warning letter from the Sec-
23 retary for the first such violation; and

24 “(B) be subject to a civil penalty in an
25 amount—

1 “(i) not more than \$1,000 for the sec-
2 ond such violation by a person;

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

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

8 “(2) In determining the amount of a civil pen-
9 alty under this subsection for a person who is a re-
10 tailer, the Secretary shall consider whether the re-
11 tailer has taken appropriate steps to prevent subse-
12 quent violations, such as the establishment and ad-
13 ministration of a documented employee training pro-
14 gram to ensure all employees are familiar with and
15 abiding by the provisions of section 301(ddd), where
16 such program includes—

17 “(A) educating employees regarding prod-
18 ucts containing dextromethorphan;

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

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

23 “(3) If a person who is a retailer transacts
24 sales of products containing dextromethorphan at
25 more than one physical location, for purposes of de-

1 termining the number of violations by that person
2 under this subsection, each individual physical loca-
3 tion operated by that retailer shall be considered a
4 separate person.

5 “(4) The Secretary shall notify persons found
6 to have violated section 301(ddd) as soon as prac-
7 ticable after the Secretary discovers such violation.
8 Such notification shall include details of the viola-
9 tion, such as—

10 “(A) the date and time of the sale;

11 “(B) a sales receipt or credit card receipt
12 documenting the sale; and

13 “(C) the name or description of the em-
14 ployee involved in the sale.

15 “(5) Notwithstanding any other provision of
16 this subsection or section 301(ddd), an employee
17 shall not be subject to penalties under this sub-
18 section unless such employee knowingly and willfully
19 participates in a conspiracy to violate section
20 301(ddd). For purposes of this paragraph, a con-
21 spiracy shall consist of an agreement between two or
22 more persons with the intent to violate section
23 301(ddd) and the commission of at least one overt
24 act in furtherance of the agreement.

25 “(6) In this subsection—

1 “(A) the term ‘employee’ means an indi-
2 vidual who is employed by a retailer in a cler-
3 ical or other non-managerial position; and

4 “(B) the term ‘retailer’ means a grocery
5 store, general merchandise store, drug store,
6 pharmacy, convenience store, or other entity or
7 person whose activities as a distributor relating
8 to products containing dextromethorphan are
9 limited almost exclusively to sales for personal
10 use, both in number of sales and volume of
11 sales, either directly to walk-in customers or in
12 face-to-face transactions by direct sales.”.

13 **SEC. 3. RESTRICTIONS ON DISTRIBUTION OF BULK**
14 **DEXTROMETHORPHAN.**

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

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

19 “(k) If it is unfinished dextromethorphan and is pos-
20 sessed, received, or distributed in violation of section
21 506G.”;

22 (2) by inserting after section 506F the fol-
23 lowing:

1 **“SEC. 506G. RESTRICTIONS ON THE DISTRIBUTION OF**
2 **BULK DEXTROMETHORPHAN.**

3 “(a) IN GENERAL.—No person shall—

4 “(1) possess or receive unfinished dextrome-
5 thorphan, unless the person is registered under sec-
6 tion 510 or otherwise registered, licensed, or ap-
7 proved pursuant to Federal or State law to engage
8 in the practice of pharmacy, pharmaceutical produc-
9 tion, or manufacture or distribution of drug ingredi-
10 ents; or

11 “(2) distribute unfinished dextromethorphan to
12 any person other than a person registered under sec-
13 tion 510 or otherwise registered, licensed, or ap-
14 proved pursuant to Federal or State law to engage
15 in the practice of pharmacy, pharmaceutical produc-
16 tion, or manufacture or distribution of drug ingredi-
17 ents.

18 “(b) EXCEPTION FOR COMMON CARRIERS.—This
19 section does not apply to a common carrier that possesses,
20 receives, or distributes unfinished dextromethorphan for
21 purposes of distributing such unfinished dextromethor-
22 phan between persons described in subsection (a) as reg-
23 istered, licensed, or approved.

24 “(c) DEFINITIONS.—In this section:

25 “(1) The term ‘common carrier’ means any per-
26 son that holds itself out to the general public as a

1 provider for hire of the transportation by water,
2 land, or air of merchandise, whether or not the per-
3 son actually operates the vessel, vehicle, or aircraft
4 by which the transportation is provided, between a
5 port or place and a port or place in the United
6 States.

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

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

12 “(i) Notwithstanding subsection (a), a person who
13 violates section 506G shall be subject to a civil penalty
14 of not more than \$100,000.”.

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