

112TH CONGRESS
2D SESSION

S. 3376

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

IN THE SENATE OF THE UNITED STATES

JULY 11, 2012

Mr. CASEY (for himself and Ms. MURKOWSKI) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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 2012” or the “PACT Act”.

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

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

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

11 “(B) If a person fails to request identification from
12 an individual under 18 years of age and sells a product
13 containing dextromethorphan to that individual, that per-
14 son shall be deemed to have known that the individual was
15 under 18 years of age.

16 “(C) It shall be an affirmative defense to an alleged
17 violation of clause (A) that the person selling a product
18 containing dextromethorphan examined the purchaser’s
19 identification card and, based on that examination, that
20 person reasonably concluded that the identification was
21 valid and indicated that the purchaser was not less than
22 18 years of age.

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

25 “(B) This paragraph shall not apply to the sale or
26 offering for sale of a drug containing dextromethorphan

1 to an individual under 18 years of age if such individual
 2 supplies proof at the time of such sale that such indi-
 3 vidual—

4 “(i) is married;

5 “(ii) is the parent of a child; or

6 “(iii) is actively enrolled in the military.

7 “(3) In this paragraph, the term ‘identification card’
 8 mean an identification card that—

9 “(A) includes a photograph and the date of
 10 birth of the individual; and

11 “(B) is issued by a State or the Federal Gov-
 12 ernment or is considered acceptable for purposes of
 13 sections 274a.2(b)(1)(v)(A) and
 14 274a.2(b)(1)(v)(B)(1) of title 8, Code of Federal
 15 Regulations (as in effect on or after the date of the
 16 enactment of the Preventing Abuse of Cough Treat-
 17 ments Act of 2012).”.

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

21 “(h)(1) Notwithstanding subsection (a), a person who
 22 violates section 301(aaa) shall be subject to a civil penalty
 23 in an amount—

24 “(A) not more than \$1,000 for the first such
 25 violation by a person;

1 “(B) not more than \$2,000 for the second such
2 violation by a person; and

3 “(C) not more than \$5,000 for the third such
4 violation, or a subsequent such violation, by a per-
5 son.

6 “(2) In determining the amount of a civil penalty
7 under this subsection for a person who is a retailer, the
8 Secretary shall consider whether the retailer has taken ap-
9 propriate steps to prevent subsequent violations, such as—

10 “(A) the establishment and administration of a
11 documented employee training program to ensure all
12 employees are familiar with and abiding by the pro-
13 visions of this section; or

14 “(B) other actions taken by a retailer to ensure
15 compliance with this section.

16 “(3) If a person who is a retailer transacts sales of
17 products containing dextromethorphan at more than one
18 physical location, for purposes of determining the number
19 of violations by that person under this subsection, each
20 individual physical location operated by that retailer shall
21 be considered a separate person.

22 “(4) In this subsection, the term ‘retailer’ means a
23 grocery store, general merchandise store, drug store, phar-
24 macy, convenience store, or other entity or person whose
25 activities as a distributor relating to products containing

1 dextromethorphan are limited almost exclusively to sales
 2 for personal use, both in number of sales and volume of
 3 sales, either directly to walk-in customers or in face-to-
 4 face transactions by direct sales.”.

5 **SEC. 3. RESTRICTIONS ON DISTRIBUTION OF BULK**
 6 **DEXTROMETHORPHAN.**

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

9 (1) in section 501, by inserting at the end the
 10 following:

11 “(j) If it is unfinished dextromethorphan and is pos-
 12 sessed, received, or distributed in violation of section
 13 506D.”;

14 (2) by inserting after section 506C the fol-
 15 lowing:

16 **“SEC. 506D. RESTRICTIONS ON THE DISTRIBUTION OF**
 17 **BULK DEXTROMETHORPHAN.**

18 “(a) IN GENERAL.—No person shall—

19 “(1) possess or receive unfinished dextrome-
 20 thorphan, unless the person is registered under sec-
 21 tion 510 or otherwise registered, licensed, or ap-
 22 proved pursuant to Federal or State law to engage
 23 in the practice of pharmacy, pharmaceutical produc-
 24 tion, or manufacture or distribution of drug ingredi-
 25 ents; or

1 “(2) distribute unfinished dextromethorphan to
2 any person other than a person registered under sec-
3 tion 510 or otherwise registered, licensed, or ap-
4 proved pursuant to Federal or State law to engage
5 in the practice of pharmacy, pharmaceutical produc-
6 tion, or manufacture or distribution of drug ingredi-
7 ents.

8 “(b) EXCEPTION FOR COMMON CARRIERS.—This
9 section does not apply to a common carrier that possesses,
10 receives, or distributes unfinished dextromethorphan for
11 purposes of distributing such unfinished dextromethor-
12 phan between persons described in subsection (a) as reg-
13 istered, licensed, or approved.

14 “(c) DEFINITIONS.—In this section:

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

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

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

3 “(i) Notwithstanding subsection (a), a person who
4 violates section 506D shall be subject to a civil penalty
5 of not more than \$100,000.”.

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