

113TH CONGRESS
1ST SESSION

H. R. 1958

To prohibit wholesalers from purchasing prescription drugs from pharmacies, and to enhance information and transparency regarding drug wholesalers engaged in interstate commerce.

IN THE HOUSE OF REPRESENTATIVES

MAY 14, 2013

Mr. CUMMINGS introduced the following bill; which was referred to the
Committee on Energy and Commerce

A BILL

To prohibit wholesalers from purchasing prescription drugs from pharmacies, and to enhance information and transparency regarding drug wholesalers engaged in interstate commerce.

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 “Gray Market Drug
5 Reform and Transparency Act of 2013”.

1 **SEC. 2. PROHIBITION AGAINST WHOLESALE DISTRIBUTORS**
2 **PURCHASING PRESCRIPTION DRUGS FROM**
3 **PHARMACIES.**

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

7 “(ccc) The purchase or receipt by any person re-
8 quired to report under section 510(b)(4) (relating to
9 wholesale distributors of prescription drugs) of any drug
10 subject to section 503(b)(1) from a pharmacy or phar-
11 macist, except that this paragraph does not apply to the
12 return of a drug to the wholesale distributor from which
13 the particular drug was purchased.”.

14 (b) MISBRANDING.—Section 502 of the Federal
15 Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amend-
16 ed by adding at the end the following:

17 “(bb) If it is purchased or received in violation of sec-
18 tion 301(aaa) (prohibiting the purchase or receipt of pre-
19 scription drugs by wholesale distributors from phar-
20 macists).”.

21 **SEC. 3. REPORTING BY WHOLESALE DISTRIBUTORS OF**
22 **PRESCRIPTION DRUGS.**

23 (a) REPORTING REQUIREMENT.—

24 (1) IN GENERAL.—Section 510 of the Federal
25 Food, Drug, and Cosmetic Act (21 U.S.C. 360) is
26 amended—

1 (A) in subsection (b), by adding at the end
2 the following:

3 “(4) On or before December 31 of each year, every
4 person engaged in the wholesale distribution in interstate
5 commerce of drugs subject to section 503(b)(1) shall re-
6 port to the Secretary such person’s name, contact infor-
7 mation for such person’s principal officer (or the designee
8 thereof), such person’s places of business, such person’s
9 licensing information (including the type of license and ex-
10 piration date) for each State in which such person is so
11 engaged, and such other information as the Secretary
12 deems appropriate.”;

13 (B) in subsection (c)—

14 (i) by striking the second period at
15 the end; and

16 (ii) by adding at the end the fol-
17 lowing:

18 “Every person upon first engaging in the wholesale dis-
19 tribution in interstate commerce of drugs subject to sec-
20 tion 503(b)(1) shall immediately report to the Secretary
21 the information described in subsection (b)(4).”

22 (C) in subsection (d), by adding at the end
23 the following: “Every person duly reporting in
24 accordance with the foregoing subsections shall
25 immediately report to the Secretary with re-

1 spect to any additional establishment which the
 2 person owns or operates in any State and in
 3 which the person begins the wholesale distribu-
 4 tion in interstate commerce of drugs subject to
 5 section 503(b)(1).”.

6 (2) REPORTING NUMBER.—Subsection (e) of
 7 section 510 of the Federal Food, Drug, and Cos-
 8 metic Act (21 U.S.C. 360) is amended—

9 (A) by striking “registration number” and
 10 inserting “registration or reporting number”;
 11 and

12 (B) by inserting “or reporting in accord-
 13 ance with subsections (b)(4), (c), or (d)” after
 14 “registered in accordance with this section”.

15 (3) PUBLIC AVAILABILITY; DATABASE.—Sub-
 16 section (f) of section 510 of the Federal Food, Drug,
 17 and Cosmetic Act (21 U.S.C. 360) is amended—

18 (A) by striking “(f)” and inserting
 19 “(f)(1)”; and

20 (B) by adding at the end the following:

21 “(2)(A) The Secretary, acting directly or by entering
 22 into a contract with a private entity, shall establish and
 23 maintain a database including all information reported
 24 under subsection (b)(4), the second sentence of subsection
 25 (c), and the second sentence of subsection (d).

1 “(B) Subject to subparagraph (C), the Secretary
2 shall make the information in such database publicly avail-
3 able, including on the public Website of the Food and
4 Drug Administration.

5 “(C) The Secretary may choose to restrict the Sec-
6 retary’s disclosure of any information reported under sub-
7 section (b)(4), (c), or (d)—

8 “(i) that relates to a storage facility; and

9 “(ii) whose disclosure would, as determined by
10 the Secretary, compromise the security of such facil-
11 ity.”.

12 (4) CONFORMING AMENDMENTS.—

13 (A) Section 301(p) of the Federal Food,
14 Drug, and Cosmetic Act (21 U.S.C. 331(p)) is
15 amended by inserting “the failure to report in
16 accordance with subsection (b)(4), (c), or (d) of
17 section 510,” after “The failure to register in
18 accordance with section 510 or 905,”.

19 (B) Section 502(o) of the Federal Food,
20 Drug, and Cosmetic Act (21 U.S.C. 352(o)) is
21 amended by inserting “if it was distributed in
22 interstate commerce by a person in violation of
23 the reporting requirements of subsection (b)(4),
24 (c), or (d) of section 510,” before “if it was not
25 included”.

(C) Section 510 of the Federal Food,
Drug, and Cosmetic Act (21 U.S.C. 360) is
amended—

(i) in subsection (g)—

(I) in paragraph (3), by adding
“or” at the end;

(II) by striking paragraph (4);

(III) by redesignating paragraph
(5) as paragraph (4);

(IV) in paragraph (4) (as so re-
designated), by inserting “or report-
ing, as applicable,” after “registra-
tion”; and

(V) by striking the matter fol-
lowing paragraph (4) (as so redesign-
ated);

(ii) in subsection (h), by adding at the
end the following:

“(7) WHOLESALE DISTRIBUTORS.—Every es-
tablishment in any State used by a person required
to report under subsection (b)(4), (c), or (d) for the
wholesale distribution in interstate commerce of
drugs subject to section 503(b)(1) shall be subject to
inspection pursuant to section 704.”; and

1 (iii) in subsection (j), by adding at the
2 end the following:

3 “(5) The provisions of this subsection shall apply
4 with respect to a person required to report under sub-
5 section (b)(4), (c), or (d) for the wholesale distribution in
6 interstate commerce of drugs subject to section 503(b)(1)
7 to the same extent and in the same manner as such provi-
8 sions apply to persons required to register under sub-
9 section (b), (c), (d), or (i), except that—

10 “(A) any reference to manufacturing shall be
11 treated as a reference to wholesale distribution; and

12 “(B) any reference to a drug shall be treated as
13 a reference to a drug subject to section 503(b)(1).”;
14 and

15 (D) in subsection (p)(1), by striking “Reg-
16 istrations and listings under this section” and
17 inserting “Registrations and listings under this
18 section, and reports under subsection (b)(4),
19 (c), and (d)” before “shall be submitted”.

20 (b) INFORMATION ON STATE ACTIONS AGAINST
21 WHOLESALE DISTRIBUTORS OF PRESCRIPTION DRUGS.—
22 Paragraph (2) of section 510(f) of the Federal Food,
23 Drug, and Cosmetic Act (21 U.S.C. 360(f)), as added by
24 subsection (a)(3)(B) of this section, is amended—

1 (1) in subparagraph (A), by adding at the end
 2 of the subparagraph the following: “Such database
 3 shall also include information on actions (such as
 4 suspension or revocation of licensing) taken by
 5 States against persons engaged in wholesale dis-
 6 tribution of drugs subject to section 503(b)(1).”;
 7 and

8 (2) by adding at the end the following:

9 “(D) The Secretary shall encourage States
 10 to report the type of information described in
 11 the second sentence of subparagraph (A) to the
 12 Food and Drug Administration—

13 “(i) in a consistent manner; and

14 “(ii) on a voluntary basis.”.

15 (c) FEES FOR REPORTING.—Subchapter C of chapter
 16 VII (21 U.S.C. 379f et seq.) is amended by adding at the
 17 end the following:

18 **“PART 9—FEES RELATING TO WHOLESALE**

19 **DISTRIBUTORS OF PRESCRIPTION DRUGS**

20 **“SEC. 744K. AUTHORITY TO ASSESS AND COLLECT FEES.**

21 “(a) IN GENERAL.—For fiscal year 2013 and each
 22 subsequent fiscal year, the Secretary shall assess and col-
 23 lect fees under this section from each person that reports
 24 under section 510(b)(4) to engage in the wholesale dis-

1 tribution in interstate commerce of drugs subject to sec-
2 tion 503(b)(1).

3 “(b) ESTABLISHMENT OF AMOUNT.—

4 “(1) IN GENERAL.—Not later than 1 year after
5 the date of the enactment of the Gray Market Drug
6 Reform and Transparency Act of 2013, the Sec-
7 retary shall promulgate a final regulation estab-
8 lishing the amount of fees under this section for the
9 period of fiscal years 2014 through 2018 so as to
10 generate a total revenue amount not exceeding the
11 Secretary’s estimate of 100 percent of the costs de-
12 scribed in subsection (c) during such period.

13 “(2) CONSIDERATION.—In establishing the
14 amount of fees under this section, the Secretary
15 shall take into consideration the amount of annual
16 revenues of a person to be assessed such fees in
17 comparison with the amount of annual revenues of
18 other persons to be assessed such fees.

19 “(c) COSTS TO BE FUNDED THROUGH FEES.—The
20 fees authorized by this section shall only be collected and
21 available to pay the costs incurred by the Food and Drug
22 Administration in—

23 “(1) implementing the reporting requirement
24 under section 510(b)(4); and

1 “(2) establishing and maintaining an up-to-date
2 database of the information collected pursuant to
3 such requirement.

4 “(d) CREDITING AND AVAILABILITY FEES.—Fees
5 authorized under subsection (a) shall be collected and
6 available for obligation only to the extent and in the
7 amount provided in advance in appropriation Acts. Such
8 fees are authorized to remain available until expended.
9 Such sums as may be necessary may be transferred from
10 the Food and Drug Administration salaries and expenses
11 appropriation account without fiscal year limitation to
12 such appropriation account for salaries and expenses with
13 such fiscal year limitation. The sums transferred shall be
14 available solely for the costs described in subsection (c).

15 “(e) AUTHORIZATION OF APPROPRIATIONS.—For
16 each of the fiscal years 2014 through 2018, there is au-
17 thorized to be appropriated for fees under this section an
18 amount equal to the total revenue amount determined
19 under subsection (b) for the fiscal year.

20 “(f) OFFSET.—If the sum of the cumulative amount
21 of fees collected under this section for the fiscal years
22 2014 through 2016 and the amount of fees estimated to
23 be collected under this section for fiscal year 2017 exceeds
24 the cumulative amount appropriated pursuant to sub-
25 section (e) for the fiscal years 2014 through 2017, the

1 excess shall be credited to the appropriation account of
 2 the Food and Drug Administration as provided in sub-
 3 section (d), and shall be subtracted from the amount of
 4 fees that would otherwise be authorized to be collected
 5 under this section pursuant to appropriation Acts for fis-
 6 cal year 2018.”.

7 **SEC. 4. IDENTIFICATION OF SALES PRICE FOR DRUGS IN**
 8 **SHORTAGE.**

9 (a) IDENTIFICATION OF SALES PRICE FOR DRUGS IN
 10 SHORTAGE.—Paragraph (1) of section 503(e) of the Fed-
 11 eral Food, Drug, and Cosmetic Act (21 U.S.C. 353(e))
 12 is amended—

13 (1) in subparagraph (A), by inserting before the
 14 period at the end the following: “, the amount paid
 15 for such drug by the person receiving it if such drug
 16 is in shortage at the time of the sale, and the
 17 amount paid for such drug for any prior sale that
 18 occurred at a time when such drug was in short-
 19 age”; and

20 (2) by adding at the end the following new sub-
 21 paragraph:

22 “(C) In this paragraph, the term ‘in shortage’ means
 23 listed on the public Website of the Food and Drug Admin-
 24 istration, at the time of the sale to be identified in the

1 statement required by subparagraph (A), as being in
2 shortage.”.

3 (b) APPLICABILITY.—The amendment made by sub-
4 section (a) applies only with respect to sales of a drug
5 occurring on or after the date that is 1 year after the date
6 of the enactment of this Act.

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