

112TH CONGRESS
2D SESSION

H. R. 5853

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 22, 2012

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 2012”.

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 “(aaa) The purchase or receipt by any person re-
8 quired to report under section 510(b)(3) (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 “(aa) 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 “(3) 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), by adding at the end:

14 “Every person upon first engaging in the whole-
15 sale distribution in interstate commerce of
16 drugs subject to section 503(b)(1) shall imme-
17 diately report to the Secretary the information
18 described in subsection (b)(3).”; and

19 (C) in subsection (d), by adding at the end

20 the following: “Every person duly reporting in
21 accordance with the foregoing subsections shall
22 immediately report to the Secretary with re-
23 spect to any additional establishment which the
24 person owns or operates in any State and in
25 which the person begins the wholesale distribu-

1 tion in interstate commerce of drugs subject to
2 section 503(b)(1).”.

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

6 (A) by striking “registration number” and
7 inserting “registration or reporting number”;
8 and

9 (B) by inserting “or reporting in accord-
10 ance with subsections (b)(3), (c), or (d)” after
11 “registered in accordance with this section”.

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

15 (A) by striking “(f)” and inserting
16 “(f)(1)”; and

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

18 “(2)(A) The Secretary, acting directly or by entering
19 into a contract with a private entity, shall establish and
20 maintain a database including all information reported
21 under subsection (b)(3), the second sentence of subsection
22 (c), and the second sentence of subsection (d).

23 “(B) Subject to subparagraph (C), the Secretary
24 shall make the information in such database publicly avail-

1 able, including on the public Website of the Food and
2 Drug Administration.

3 “(C) The Secretary may choose to restrict the Sec-
4 retary’s disclosure of any information reported under sub-
5 section (b)(3), (c), or (d)—

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

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

10 (4) CONFORMING AMENDMENTS.—

11 (A) Section 301(p) of the Federal Food,
12 Drug, and Cosmetic Act (21 U.S.C. 331(p)) is
13 amended by inserting “the failure to report in
14 accordance with subsection (b)(3), (c), or (d) of
15 section 510,” after “The failure to register in
16 accordance with section 510 or 905,”.

17 (B) Section 502(o) of the Federal Food,
18 Drug, and Cosmetic Act (21 U.S.C. 352(o)) is
19 amended by inserting “if it was distributed in
20 interstate commerce by a person in violation of
21 the reporting requirements of subsection (b)(3),
22 (c), or (d) of section 510,” before “if it was not
23 included”.

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

4 (i) in subsection (g)—

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

7 (II) by striking paragraph (4);

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

10 (IV) in paragraph (4) (as so re-
11 designated), by inserting “or report-
12 ing, as applicable,”; and

13 (V) by striking the matter fol-
14 lowing paragraph (4) (as so redesign-
15 nated);

16 (ii) in subsection (h), by adding at the
17 end the following: “Every establishment in
18 any State used by a person required to re-
19 port under subsection (b)(3), (c), or (d) for
20 the wholesale distribution in interstate
21 commerce of drugs subject to section
22 503(b)(1) shall be subject to inspection
23 pursuant to section 704.”; and

24 (iii) in subsection (j), by adding at the
25 end the following:

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

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

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

13 (D) in subsection (p), by inserting “and re-
 14 ports under subsection (b)(3), (c), and (d)” be-
 15 fore “shall be submitted”.

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

21 (1) in subparagraph (A), by adding at the end
 22 of the subparagraph the following: “Such database
 23 shall also include information on actions (such as
 24 suspension or revocation of licensing) taken by
 25 States against persons engaged in wholesale dis-

1 tribution of drugs subject to section 503(b)(1).”;
 2 and

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

4 “(D) The Secretary shall encourage States
 5 to report the type of information described in
 6 the second sentence of subparagraph (A) to the
 7 Food and Drug Administration—

8 “(i) in a consistent manner; and

9 “(ii) on a voluntary basis.”.

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

13 **“PART 7—FEES RELATING TO WHOLESALE**

14 **DISTRIBUTORS OF PRESCRIPTION DRUGS**

15 **“SEC. 744. AUTHORITY TO ASSESS AND COLLECT FEES.**

16 “(a) IN GENERAL.—For fiscal year 2013 and each
 17 subsequent fiscal year, the Secretary shall assess and col-
 18 lect fees under this section from each person that reports
 19 under section 510(b)(3) to engage in the wholesale dis-
 20 tribution in interstate commerce of drugs subject to sec-
 21 tion 503(b)(1).

22 “(b) ESTABLISHMENT OF AMOUNT.—

23 “(1) IN GENERAL.—Not later than 1 year after
 24 the date of the enactment of the Gray Market Drug
 25 Reform and Transparency Act of 2012, the Sec-

1 retary shall promulgate a final regulation estab-
2 lishing the amount of fees under this section for the
3 period of fiscal years 2013 through 2017 so as to
4 generate a total revenue amount not exceeding the
5 Secretary's estimate of 100 percent of the costs de-
6 scribed in subsection (c) during such period.

7 “(2) CONSIDERATION.—In establishing the
8 amount of fees under this section, the Secretary
9 shall take into consideration the amount of annual
10 revenues of a person to be assessed such fees in
11 comparison with the amount of annual revenues of
12 other persons to be assessed such fees.

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

17 “(1) implementing the reporting requirement
18 under section 510(b)(3); and

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

22 “(d) CREDITING AND AVAILABILITY FEES.—Fees
23 authorized under subsection (a) shall be collected and
24 available for obligation only to the extent and in the
25 amount provided in advance in appropriation Acts. Such

1 fees are authorized to remain available until expended.
2 Such sums as may be necessary may be transferred from
3 the Food and Drug Administration salaries and expenses
4 appropriation account without fiscal year limitation to
5 such appropriation account for salaries and expenses with
6 such fiscal year limitation. The sums transferred shall be
7 available solely for the costs described in subsection (c).

8 “(e) AUTHORIZATION OF APPROPRIATIONS.—For
9 each of the fiscal years 2013 through 2017, there is au-
10 thorized to be appropriated for fees under this section an
11 amount equal to the total revenue amount determined
12 under subsection (b) for the fiscal year.

13 “(f) OFFSET.—If the sum of the cumulative amount
14 of fees collected under this section for the fiscal years
15 2013 through 2015 and the amount of fees estimated to
16 be collected under this section for fiscal year 2016 exceeds
17 the cumulative amount appropriated pursuant to sub-
18 section (e) for the fiscal years 2013 through 2016, the
19 excess shall be credited to the appropriation account of
20 the Food and Drug Administration as provided in sub-
21 section (d), and shall be subtracted from the amount of
22 fees that would otherwise be authorized to be collected
23 under this section pursuant to appropriation Acts for fis-
24 cal year 2017.”.

1 **SEC. 4. IDENTIFICATION OF SALES PRICE FOR DRUGS IN**
2 **SHORTAGE.**

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

7 (1) in subparagraph (A), by inserting before the
8 period at the end the following: “, the amount paid
9 for such drug by the person receiving it if such drug
10 is in shortage at the time of the sale, and the
11 amount paid for such drug for any prior sale that
12 occurred at a time when such drug was in short-
13 age”; and

14 (2) by adding at the end the following new sub-
15 paragraph:

16 “(C) In this paragraph, the term ‘in shortage’ means
17 listed on the public Website of the Food and Drug Admin-
18 istration, at the time of the sale to be identified in the
19 statement required by subparagraph (A), as being in
20 shortage.”.

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

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