

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.

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## IN THE HOUSE OF REPRESENTATIVES

MAY 14, 2013

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

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## 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”.

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,” after “registra-  
13                tion”; and

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

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

19                “(7) WHOLESALE DISTRIBUTORS.—Every es-  
20                tablishment in any State used by a person required  
21                to report under subsection (b)(4), (c), or (d) for the  
22                wholesale distribution in interstate commerce of  
23                drugs subject to section 503(b)(1) shall be subject to  
24                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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