I

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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Gray Market Drug Reform and Transparency Act of 2012".

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

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

''(aaa) The purchase or receipt by any person required to report under section 510(b)(3) (relating to wholesale distributors of prescription drugs) of any drug subject to section 503(b)(1) from a pharmacy or pharmacist, except that this paragraph does not apply to the return of a drug to the wholesale distributor from which the particular drug was purchased.''.

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

''(aa) If it is purchased or received in violation of section 301(aaa) (prohibiting the purchase or receipt of prescription drugs by wholesale distributors from pharmacists).''.

SEC. 3. REPORTING BY WHOLESALE DISTRIBUTORS OF PRESCRIPTION DRUGS.

(a) REPORTING REQUIREMENT.—

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

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

"(3) On or before December 31 of each year, every person engaged in the wholesale distribution in interstate commerce of drugs subject to section 503(b)(1) shall report to the Secretary such person's name, contact information for such person's principal officer (or the designee thereof), such person's places of business, such person's licensing information (including the type of license and expiration date) for each State in which such person is so engaged, and such other information as the Secretary deems appropriate.";

(B) in subsection (c), by adding at the end: "Every person upon first engaging in the wholesale distribution in interstate commerce of drugs subject to section 503(b)(1) shall immediately report to the Secretary the information described in subsection (b)(3)."; and

(C) in subsection (d), by adding at the end the following: "Every person duly reporting in accordance with the foregoing subsections shall immediately report to the Secretary with respect to any additional establishment which the person owns or operates in any State and in which the person begins the wholesale distribution in interstate commerce of drugs subject to section 503(b)(1).''.

(2) REPORTING NUMBER.—Subsection (e) of section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360) is amended—

(A) by striking ''registration number'' and inserting ''registration or reporting number''; and

(B) by inserting ''or reporting in accordance with subsections (b)(3), (c), or (d)'' after ''registered in accordance with this section''.

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

(A) by striking ''(f)'' and inserting ''(f)(1)''; and

(B) by adding at the end the following:

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

''(B) Subject to subparagraph (C), the Secretary shall make the information in such database publicly available, including on the public Website of the Food and Drug Administration.

"(C) The Secretary may choose to restrict the Secretary's disclosure of any information reported under subsection (b)(3), (c), or (d)—

"(i) that relates to a storage facility; and

"(ii) whose disclosure would, as determined by the Secretary, compromise the security of such facility.".

(4) CONFORMING AMENDMENTS.—

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

(B) Section 502(o) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(o)) is amended by inserting "if it was distributed in interstate commerce by a person in violation of the reporting requirements of subsection (b)(3), (c), or (d) of section 510," before "if it was not 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 redesignated), by inserting ''or reporting, as applicable,''; and

(V) by striking the matter following paragraph (4) (as so redesignated);

(ii) in subsection (h), by adding at the end the following: ''Every establishment in any State used by a person required to report under subsection (b)(3), (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

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

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

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

''(B) any reference to a drug shall be treated as a reference to a drug subject to section 503(b)(1).''; and

(D) in subsection (p), by inserting ''and reports under subsection (b)(3), (c), and (d)'' before ''shall be submitted''.

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

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

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

(2) by adding at the end the following:

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

''(i) in a consistent manner; and

''(ii) on a voluntary basis.''.

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

''PART 7—FEES RELATING TO WHOLESALE DISTRIBUTORS OF PRESCRIPTION DRUGS

''SEC. 744. AUTHORITY TO ASSESS AND COLLECT FEES.

''(a) IN GENERAL.—For fiscal year 2013 and each subsequent fiscal year, the Secretary shall assess and collect fees under this section from each person that reports under section 510(b)(3) to engage in the wholesale distribution in interstate commerce of drugs subject to section 503(b)(1).

''(b) ESTABLISHMENT OF AMOUNT.—

''(1) IN GENERAL.—Not later than 1 year after the date of the enactment of the Gray Market Drug Reform and Transparency Act of 2012, the Secretary shall promulgate a final regulation establishing the amount of fees under this section for the period of fiscal years 2013 through 2017 so as to generate a total revenue amount not exceeding the Secretary's estimate of 100 percent of the costs described in subsection (c) during such period.

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

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

"(1) implementing the reporting requirement under section 510(b)(3); and

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

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

"(e) AUTHORIZATION OF APPROPRIATIONS.—For each of the fiscal years 2013 through 2017, there is authorized to be appropriated for fees under this section an amount equal to the total revenue amount determined under subsection (b) for the fiscal year.

"(f) OFFSET.—If the sum of the cumulative amount of fees collected under this section for the fiscal years 2013 through 2015 and the amount of fees estimated to be collected under this section for fiscal year 2016 exceeds the cumulative amount appropriated pursuant to subsection (e) for the fiscal years 2013 through 2016, the excess shall be credited to the appropriation account of the Food and Drug Administration as provided in subsection (d), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for fiscal year 2017.".

SEC. 4. IDENTIFICATION OF SALES PRICE FOR DRUGS IN SHORTAGE.

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

(1) in subparagraph (A), by inserting before the period at the end the following: ", the amount paid for such drug by the person receiving it if such drug is in shortage at the time of the sale, and the amount paid for such drug for any prior sale that occurred at a time when such drug was in shortage"; and

(2) by adding at the end the following new subparagraph:

"(C) In this paragraph, the term 'in shortage' means listed on the public Website of the Food and Drug Administration, at the time of the sale to be identified in the statement required by subparagraph (A), as being in shortage.".

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

○