II

114TH CONGRESS
2D SESSION

S. 2615

To increase competition in the pharmaceutical industry.

IN THE SENATE OF THE UNITED STATES

MARCH 1, 2016

Ms. COLLINS (for herself and Mrs. MCCASKILL) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To increase competition in the pharmaceutical industry.

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 ''Increasing Competition in Pharmaceuticals Act''.

SEC. 2. FINDINGS.

Congress finds the following:

(1) As part of the Food and Drug Administration's mission to protect the public health, the Food and Drug Administration approves generic drugs that help establish competitive markets for treat-

ments that improve the lives of millions of patients in the United States.

(2) Rising health care costs, including prescription drug costs, continue to be a major concern for patients in the United States.

(3) Eighty-eight percent of prescription drugs dispensed in the United States, or nearly 9 out of every 10 prescriptions dispensed, are generic drugs.

(4) Studies suggest that generic drugs account for only 28 percent of total prescription drug spending and were responsible for $1,680,000,000,000 in estimated savings over the period of 2005 to 2014.

(5) Increasing generic competition can be an effective way to help keep prescription drug costs low for patients, the health care system, and Federal and State government.

(6) Despite enactment of the Generic Drug User Fee Amendments of 2012 (21 U.S.C. 379j–41 et seq.), which was established to provide the Food and Drug Administration with industry funding to ensure a more consistent timeline for generic drug approvals, a significant backlog of abbreviated new drug applications for generic drugs remains.

(7) The sudden, aggressive price hikes for a variety of recently acquired off-patent drugs that have

been used widely for decades, for which there is no generic drug competitor, also affects access to affordable prescriptions for patients and the overall cost of health care in the United States.

(8) Improving the review of abbreviated new drug applications and the approval of generic drugs would help to improve competition and lower prices for patients.

(9) Establishing a clear timeframe for the Food and Drug Administration to expedite the review of certain applications for generic drugs would also help keep drug prices down and improve timely access for patients.

TITLE I—REMOVING REGULATORY BARRIERS TO COMPETITION

SEC. 101. IMPROVING GENERIC ACCESS.

Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) is amended by adding at the end the following:

''(11)(A) The Secretary shall prioritize the review, and act not later than 150 calendar days after the date of the submission of an application, on an application that has been submitted and accepted for review under this

subsection, or on a supplement to such an application, that is for a drug that—

''(i) has been introduced into interstate commerce by not more than one manufacturer or sponsor, as applicable, in the last 3 months and with respect to which tentative approval under paragraph (5) has been granted for not more than 2 applications; or

''(ii) has been included on the list under section 506E.

''(B) The fees pursuant to section 744B(a)(3) shall be waived with respect to an application described in subparagraph (A), unless such application contains a certification under paragraph (2)(A)(vii)(IV).

''(C) The Secretary may expedite an inspection or reinspection under section 704 of an establishment that proposes to manufacture a drug described in subparagraph (A).''.

SEC. 102. REPORTING ON PENDING GENERIC DRUG APPLICATIONS.

Not later than 90 calendar days after the date of enactment of this Act, and every 90 calendar days thereafter until October 1, 2022, the Secretary of Health and Human Services shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate, the Special

Committee on Aging of the Senate, and the Committee on Energy and Commerce of the House of Representatives a report that provides—

(1) the number of applications that were filed under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) prior to October 1, 2015, that are pending at the time the report is submitted;

(2) the average and median total time such applications have been pending;

(3) the number of such applications that contain certifications under section 505(j)(2)(A)(vii)(IV) of such Act; and

(4) the number of such applications that are subject to priority review.

TITLE II—INCENTIVIZING COMPETITION

SEC. 201. GENERIC PRIORITY REVIEW VOUCHER.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 506F the following:

"SEC. 506G. GENERIC PRIORITY REVIEW VOUCHER.

''(a) DEFINITIONS.—In this section:

''(1) The term 'priority review' with respect to an application under section 505(j) means review

and action by the Secretary on such application by the Secretary not later than 150 calendar days after such application has been submitted and accepted for review.

''(2) The term 'priority review voucher' means a voucher for priority review for an application under section 505(j). Such voucher shall be awarded upon the approval of the application described in 505(j)(11)(A), unless such application contains a certification under section 505(j)(2)(A)(vii)(IV).

''(b) GENERIC PRIORITY REVIEW VOUCHERS, IN GENERAL.—The Secretary shall award a priority review voucher to the sponsor of an application described in 505(j)(11)(A) upon approval by the Secretary of such application.

''(c) TRANSFERABILITY.—

''(1) IN GENERAL.—The recipient of a priority review voucher under subsection (a) may transfer (including by sale) the entitlement to such voucher. There is no limit on the number of times a priority review voucher may be transferred before such voucher is used.

''(2) NOTIFICATION TO THE SECRETARY.—Each person to whom a voucher is transferred shall notify the Secretary of such change in ownership of

such voucher not later than 30 calendar days after such transfer.

''(d) NOTIFICATION.—The sponsor shall notify the Secretary not later than 30 calendar days prior to the submission of a human drug application that is intended to be the subject of a priority review voucher, except in the case of such an application that was pending as of October 1, 2015, in which case the sponsor of such pending application shall notify the Secretary not later than 30 days after the date on which such voucher is awarded.

''(e) FEES.—The sponsor of an application that is the subject of a priority review voucher shall be subject to the fees required under section 744A.

''(f) CLARIFICATION.—Nothing in this section affects any period of exclusivity under this Act or the protection of any patent.

''(g) REVOCATION.—The Secretary may revoke any priority review voucher awarded under subsection (b) if the drug for which such voucher was awarded is not marketed in the United States within the 365-day period beginning on the date of the approval of such drug.

''(h) SUNSET.—The authority of the Secretary to carry out the generic priority review voucher program under this section shall terminate on October 1, 2022.''.

SEC. 202. TROPICAL DISEASE PRODUCT APPLICATION.

Section 524(a)(4)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360n(a)(4)(A)) is amended—

(1) in clause (i), by striking ''and'';

(2) in clause (ii), by adding ''and'' after the semicolon; and

(3) by adding at the end the following:

''(iii) that contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant;''.

TITLE III—STUDY ON REMS

SEC. 301. STUDY ON REMS.

(a) IN GENERAL.—The Comptroller General shall conduct a review of the implementation and effectiveness of section 505–1 of the Food, Drug, and Cosmetic Act (21 U.S.C. 355–1) (referred to in this section as the ''REMS program''), which section—

(1) authorizes the Secretary of Health and Human Services to require a risk evaluation and mitigation strategy (referred to in this section as ''REMS''); and

(2) codifies and expands regulations issued by the Food and Drug Administration under which the Food and Drug Administration may impose restric-

tions on distribution necessary to ensure a drug is safely used.

(b) CONTENTS OF STUDY.—In conducting the review under subsection (a), the Comptroller General shall examine each relevant element described in subsection (c) with respect to each of the following categories:

(1) New drug applications under subsection (b) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)).

(2) Abbreviated new drug applications under subsection (j) of such section.

(3) Applications for the license of a biological product under section 351 of the Public Health Service Act (42 U.S.C. 262).

(4) Single, shared system REMS, as described in section 505–1(i) of the Food, Drug, and Cosmetic Act (21 U.S.C. 355–1(i)).

(5) Controlled substances as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802).

(6) RISKMAPs or other risk management processes employed by the Food and Drug Administration.

(c) ELEMENTS UNDER REVIEW.—In conducting the review under subsection (a), the Comptroller General shall

examine each of the following elements with respect to each relevant category described in subsection (b).

(1) For each type of application, and by year, the number of REMS required, submitted, voluntarily submitted, modified, added, approved, or removed, and whether those REMS included elements to assure safe use, such as restricted distribution.

(2) For each type of application, the number of REMS in effect at the time of the review and the number of years that each such REMS has been in effect at such time.

(3) If and how the REMS program has improved drug safety, as compared to the time before the REMS program became effective, and how the Food and Drug Administration tracks such improvements.

(4) The burdens associated with REMS, including burdens on patients, health care providers, generic drug manufacturers, and brand drug manufacturers.

(5) In the case of a REMS program for a drug containing a controlled substance, the coordination between the Food and Drug Administration and the Drug Enforcement Administration.

(6) The impact of additional risk mitigation strategies, including non-REMS restricted distribution systems, imposed by companies outside of what is required under the REMS program.

(7) The standards and policies applied by the Food and Drug Administration to require, modify, add, or remove, a REMS, and how those standards and policies have changed since the REMS program became effective.

(d) REPORT.—Not later than May 1, 2017, the Comptroller General shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate, the Special Committee on Aging of the Senate, and the Committee on Energy and Commerce of the House of Representatives, containing the results of the review described in this section.

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