

115TH CONGRESS  
1ST SESSION

# S. 297

To increase competition in the pharmaceutical industry.

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IN THE SENATE OF THE UNITED STATES

FEBRUARY 2, 2017

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

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## A BILL

To increase competition in the pharmaceutical industry.

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 “Increasing Competition  
5       in Pharmaceuticals Act”.

6       **SEC. 2. FINDINGS.**

7       Congress finds the following:

8               (1) As part of the Food and Drug Administra-  
9       tion’s mission to protect the public health, the Food  
10       and Drug Administration approves generic drugs  
11       that help establish competitive markets for treat-

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

3               (2) Rising health care costs, including prescrip-  
4       tion drug costs, continue to be a major concern for  
5       patients in the United States.

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

9               (4) Studies suggest that generic drugs account  
10      for only 28 percent of total prescription drug spend-  
11      ing and were responsible for \$1,680,000,000,000 in  
12      estimated savings over the period of 2005 to 2014.

13              (5) Increasing generic competition can be an ef-  
14      fective way to help keep prescription drug costs low  
15      for patients, the health care system, and Federal  
16      and State government.

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

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

1       been used widely for decades, for which there is no  
2       generic drug competitor, also affects access to af-  
3       fordable prescriptions for patients and the overall  
4       cost of health care in the United States.

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

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

14 **TITLE I—REMOVING REGU-**  
15 **LATORY BARRIERS TO COM-**  
16 **PETITION**

17 **SEC. 101. IMPROVING GENERIC ACCESS.**

18       Section 505(j) of the Federal Food, Drug, and Cos-  
19      metic Act (21 U.S.C. 355(j)) is amended by adding at the  
20      end the following:

21       “(11)(A) The Secretary shall prioritize the review,  
22      and act not later than 150 calendar days after the date  
23      of the submission of an application, on an application that  
24      has been submitted for review under this subsection, or

1 on a supplement to such an application, that is for a drug  
2 that—

3 “(i) has been introduced into interstate com-  
4 merce by not more than one manufacturer or spon-  
5 sor, as applicable, in the last 3 months and with re-  
6 spect to which tentative approval under paragraph  
7 (5) has been granted for not more than 2 applica-  
8 tions; or

9 “(ii) has been included on the list under section  
10 506E.

11 “(B) The fees pursuant to section 744B(a)(3) shall  
12 be waived with respect to an application described in sub-  
13 paragraph (A), unless such application contains a certifi-  
14 cation under paragraph (2)(A)(vii)(IV).

15 “(C) The Secretary may expedite an inspection or re-  
16 inspection under section 704 of an establishment that pro-  
17 poses to manufacture a drug described in subparagraph  
18 (A).”.

19 **SEC. 102. REPORTING ON PENDING GENERIC DRUG APPLI-**  
20 **CATIONS.**

21 Not later than 90 calendar days after the date of en-  
22 actment of this Act, and every 90 calendar days thereafter  
23 until October 1, 2022, the Secretary of Health and  
24 Human Services shall submit to the Committee on Health,  
25 Education, Labor, and Pensions of the Senate, the Special

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

4 (1) the number of applications that were filed  
5 under section 505(j) of the Federal Food, Drug, and  
6 Cosmetic Act (21 U.S.C. 355(j)) prior to October 1,  
7 2015, that are pending at the time the report is sub-  
8 mitted;

9 (2) the average and median total time such ap-  
10 plications have been pending;

11 (3) the number of such applications that con-  
12 tain certifications under section  
13 505(j)(2)(A)(vii)(IV) of such Act; and

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

## 16 **TITLE II—INCENTIVIZING** 17 **COMPETITION**

### 18 **SEC. 201. GENERIC PRIORITY REVIEW VOUCHER.**

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

#### 22 **“SEC. 506H. GENERIC PRIORITY REVIEW VOUCHER.**

23 “(a) DEFINITIONS.—In this section:

24 “(1) The term ‘priority review’ with respect to  
25 an application under section 505(j) means review

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

4 “(2) The term ‘priority review voucher’ means  
5 a voucher for priority review for an application  
6 under section 505(j). Such voucher shall be awarded  
7 upon the approval of the application described in  
8 505(j)(11)(A), unless such application contains a  
9 certification under subclauses (III) and (IV) of sec-  
10 tion 505(j)(2)(A)(vii).

11 “(b) GENERIC PRIORITY REVIEW VOUCHERS, IN  
12 GENERAL.—The Secretary shall award a priority review  
13 voucher to the sponsor of an application described in  
14 505(j)(11)(A) upon approval by the Secretary of such ap-  
15 plication.

16 “(c) TRANSFERABILITY.—

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

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

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

3 “(d) NOTIFICATION.—The sponsor shall notify the  
4 Secretary not later than 30 calendar days prior to the sub-  
5 mission of a human drug application that is intended to  
6 be the subject of a priority review voucher, except in the  
7 case of such an application that was pending as of October  
8 1, 2015, in which case the sponsor of such pending appli-  
9 cation shall notify the Secretary not later than 30 days  
10 after the date on which such voucher is awarded.

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

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

17 “(g) REVOCATION.—The Secretary may revoke any  
18 priority review voucher awarded under subsection (b) if  
19 the drug for which such voucher was awarded is not mar-  
20 keted in the United States within the 365-day period be-  
21 ginning on the date of the approval of such drug.

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

1 **SEC. 202. TROPICAL DISEASE PRODUCT APPLICATION.**

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

4 (1) in clause (i), by striking “and”;

5 (2) in clause (ii), by adding “and” after the  
6 semicolon; and

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

8 “(iii) that contains reports of new  
9 clinical investigations (other than bio-  
10 availability studies) essential to the ap-  
11 proval of the application and conducted or  
12 sponsored by the applicant;”.

13 **TITLE III—STUDY ON REMS**

14 **SEC. 301. STUDY ON REMS.**

15 (a) IN GENERAL.—The Comptroller General shall  
16 conduct a review of the implementation and effectiveness  
17 of section 505–1 of the Food, Drug, and Cosmetic Act  
18 (21 U.S.C. 355–1) (referred to in this section as the  
19 “REMS program”), which section—

20 (1) authorizes the Secretary of Health and  
21 Human Services to require a risk evaluation and  
22 mitigation strategy (referred to in this section as  
23 “REMS”); and

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



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

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

7 (1) New drug applications under subsection (b)  
8 of section 505 of the Federal Food, Drug, and Cos-  
9 metic Act (21 U.S.C. 355(b)).

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

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

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

18 (5) Controlled substances as defined in section  
19 102 of the Controlled Substances Act (21 U.S.C.  
20 802).

21 (6) RISKMAPs or other risk management proc-  
22 esses employed by the Food and Drug Administra-  
23 tion.

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

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

3           (1) For each type of application, and by year,  
4 the number of REMS required, submitted, volun-  
5 tarily submitted, modified, added, approved, or re-  
6 moved, and whether those REMS included elements  
7 to assure safe use, such as restricted distribution.

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

12           (3) If and how the REMS program has im-  
13 proved drug safety, as compared to the time before  
14 the REMS program became effective, and how the  
15 Food and Drug Administration tracks such improve-  
16 ments.

17           (4) The burdens associated with REMS, includ-  
18 ing burdens on patients, health care providers, ge-  
19 neric drug manufacturers, and brand drug manufac-  
20 turers.

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

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

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

10         (d) REPORT.—Not later than May 1, 2018, the  
11 Comptroller General shall submit a report to the Com-  
12 mittee on Health, Education, Labor, and Pensions of the  
13 Senate, the Special Committee on Aging of the Senate,  
14 and the Committee on Energy and Commerce of the  
15 House of Representatives, containing the results of the re-  
16 view described in this section.

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