

111TH CONGRESS  
2D SESSION

# S. 3697

To amend the Federal Food, Drug, and Cosmetic Act to improve the priority review voucher incentive program relating to tropical and rare pediatric diseases.

---

## IN THE SENATE OF THE UNITED STATES

AUGUST 4, 2010

Mr. BROWNBACK (for himself, Mr. BROWN of Ohio, and Mr. FRANKEN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

---

## A BILL

To amend the Federal Food, Drug, and Cosmetic Act to improve the priority review voucher incentive program relating to tropical and rare pediatric diseases.

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; REFERENCES.**

4 (a) SHORT TITLE.—This Act may be cited as the  
5 “Creating Hope Act of 2010”.

6 (b) REFERENCES.—Wherever in this Act an amend-  
7 ment is expressed in terms of an amendment to a section  
8 or other provision, the reference shall be considered to be

1 made to a section or other provision of the Federal Food,  
2 Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

3 **SEC. 2. IMPROVEMENT OF THE TROPICAL DISEASE VOUCH-**  
4 **ER PROGRAM.**

5 (a) **HEADING.**—The heading of section 524 (21  
6 U.S.C. 360n) is amended to read as follows: “**PRIORITY**  
7 **REVIEW TO ENCOURAGE INNOVATIVE TREATMENTS**  
8 **FOR TROPICAL DISEASES AND RARE PEDIATRIC**  
9 **DISEASES**”.

10 (b) **DEFINITIONS.**—Section 524(a) (21 U.S.C.  
11 360n(a)) is amended—

12 (1) by redesignating paragraphs (3) and (4) as  
13 paragraphs (6) and (7), respectively;

14 (2) by redesignating paragraphs (1) and (2) as  
15 paragraphs (2) and (3), respectively;

16 (3) by inserting after “In this section:”, the fol-  
17 lowing:

18 “(1) **INNOVATIVE TREATMENT.**—The term ‘in-  
19 novative treatment’ means—

20 “(A) a human drug that is the subject of  
21 an application submitted under section  
22 505(b)(1), if that drug contains no active ingre-  
23 dient (including any ester or salt of the active  
24 ingredient) that has been previously approved  
25 in any other application under section

1           505(b)(1), 505(b)(2), or 505(j) or section 351  
2           of the Public Health Service Act; or

3           “(B) a biological product that is the sub-  
4           ject of an application submitted under section  
5           351(a) of the Public Health Service Act, if that  
6           biological product—

7                   “(i) does not have the same structure  
8                   as a biological product that has been pre-  
9                   viously licensed in any other application  
10                  under subsection (a) or (k) of section 351  
11                  of the Public Health Service Act or ap-  
12                  proved under section 505 of this Act; and

13                   “(ii) is not biosimilar, within the  
14                   meaning of section 351(i) of the Public  
15                   Health Service Act, to a biological product  
16                   that has been previously licensed in any  
17                   other application under subsection (a) or  
18                   (k) of section 351 of the Public Health  
19                   Service Act or approved under section 505  
20                   of this Act.”;

21           (4) in paragraph (3), as so redesignated, by in-  
22           serting “or rare pediatric disease product applica-  
23           tion” after “tropical disease product application”  
24           each place that phrase appears;

1           (5) by inserting after paragraph (3) the fol-  
2           lowing:

3           “(4) RARE PEDIATRIC DISEASE.—The term  
4           ‘rare pediatric disease’ means a disease that meets  
5           each of the following criteria:

6                   “(A) The disease is recognized in the med-  
7                   ical community as affecting a pediatric popu-  
8                   lation.

9                   “(B) The disease is a rare disease or con-  
10                  dition, within the meaning of section 526.

11           “(5) RARE PEDIATRIC DISEASE PRODUCT AP-  
12           PLICATION.—The term ‘rare pediatric disease prod-  
13           uct application’ means a human drug application, as  
14           defined in section 735(1)—

15                   “(A) for prevention or treatment of a rare  
16                   pediatric disease;

17                   “(B) that the Secretary deems eligible for  
18                   priority review;

19                   “(C) that is for an innovative treatment;

20                   “(D) that relies on clinical data derived  
21                   from studies examining a pediatric population  
22                   and dosages of the drug intended for that popu-  
23                   lation; and

1 “(E) that does not seek approval for an  
2 adult indication in the original rare pediatric  
3 disease product application.”;

4 (6) in paragraph (6), as so redesignated—

5 (A) by redesignating subparagraph (Q) as  
6 subparagraph (R); and

7 (B) by inserting after subparagraph (P)  
8 the following:

9 “(Q) Chagas Disease.”; and

10 (7) by amending paragraph (7), as so redesignated,  
11 to read as follows:

12 “(7) TROPICAL DISEASE PRODUCT APPLICA-  
13 TION.—The term ‘tropical disease product applica-  
14 tion’ means a human drug application, as defined in  
15 section 735(1)—

16 “(A) for prevention or treatment of a tropi-  
17 cal disease;

18 “(B) that the Secretary deems eligible for  
19 priority review;

20 “(C) that is for an innovative treatment;  
21 and

22 “(D) that is for a drug that has not been  
23 approved for commercial marketing for any  
24 tropical disease indication by a government au-  
25 thority outside of the United States for more

1           than 24 months before the tropical disease  
2           product application is submitted.”.

3           (c) RULES REGARDING USE AND TRANSFER OF PRI-  
4   ORITY REVIEW VOUCHERS.—Section 524(b) (21 U.S.C.  
5   360n(b)) is amended—

6           (1) in paragraph (1), by inserting “or rare pe-  
7   diatric disease product application” after “tropical  
8   disease product application” each place that phrase  
9   appears;

10          (2) by amending paragraph (2) to read as fol-  
11   lows:

12          “(2) TRANSFERABILITY.—

13               “(A) IN GENERAL.—The sponsor of a trop-  
14   ical disease product application or rare pediatric  
15   disease product application that receives a pri-  
16   ority review voucher under this section may  
17   transfer (including by sale) the entitlement to  
18   such voucher. There is no limit on the number  
19   of times a priority review voucher may be trans-  
20   ferred before such voucher is used.

21               “(B) CONDITIONS OF TRANSFER.—If a  
22   sponsor transfers a priority review voucher  
23   after such sponsor has provided notification to  
24   the Secretary under paragraph (4)(A) of the in-  
25   tent of such sponsor to use the voucher, the

1 transfer shall be subject to the provisions of  
2 subparagraphs (B) and (C) of paragraph (4).

3 “(C) NOTIFICATION OF TRANSFER.—The  
4 person to whom a voucher is transferred under  
5 paragraph (4)(B)(i) shall notify the Secretary  
6 of such change in ownership of the voucher not  
7 later than 30 days after such transfer.”;

8 (3) by amending paragraph (3) to read as fol-  
9 lows:

10 “(3) LIMITATION FOR PRIOR APPLICATIONS.—

11 “(A) TROPICAL DISEASE PRODUCT APPLI-  
12 CATIONS.—A sponsor of a tropical disease prod-  
13 uct application may not receive a priority review  
14 voucher under this section if the tropical dis-  
15 ease product application was submitted to the  
16 Secretary prior to September 27, 2007.

17 “(B) RARE PEDIATRIC DISEASE PRODUCT  
18 APPLICATIONS.—A sponsor of a rare pediatric  
19 disease product application may not receive a  
20 priority review voucher under this section if the  
21 rare pediatric disease product application was  
22 submitted to the Secretary prior to the date  
23 that is 90 days after the date of enactment of  
24 the Creating Hope Act of 2010.”; and

1 (4) by amending paragraph (4) to read as fol-  
2 lows:

3 “(4) NOTIFICATION.—

4 “(A) TIMING.—At least 90 days before the  
5 date on which a human drug application for  
6 which the sponsor intends to use a priority re-  
7 view voucher is submitted, the sponsor of such  
8 human drug application shall notify the Sec-  
9 retary of the intent of such sponsor to submit  
10 the human drug application.

11 “(B) TRANSFER OF VOUCHER AFTER NO-  
12 TIFICATION.—

13 “(i) IN GENERAL.—The sponsor of a  
14 human drug application that provides noti-  
15 fication of the intent of such sponsor to  
16 use the voucher for the human drug appli-  
17 cation may transfer the voucher within 1  
18 year after such notification is provided, if  
19 such sponsor has not yet submitted the  
20 human drug application described in the  
21 notification.

22 “(ii) EXCEPTION.—The person to  
23 whom a voucher is transferred under  
24 clause (i) (referred to in this paragraph as  
25 the ‘transferee’) shall give notification of



1 the intent of such transferee to use the  
2 voucher in accordance with this subsection,  
3 unless—

4 “(I) the transferee uses the  
5 voucher for a human drug application  
6 featuring the same indications as the  
7 human drug application described in  
8 the transferor’s notification; and

9 “(II) the transferee notifies the  
10 Secretary within 30 days of the trans-  
11 fer of the intent of such transferee to  
12 use the voucher for such purpose.

13 “(iii) INTERNAL TRANSFER.—If the  
14 sponsor transfers a voucher internally for  
15 use with a drug application that includes  
16 one or more indications that were not in-  
17 cluded in the drug application that was the  
18 subject of the notification of such sponsor,  
19 the sponsor shall notify the Secretary of  
20 the transfer in accordance with this sub-  
21 section.

22 “(C) FEE DUE UPON NOTIFICATION; CRED-  
23 IT FOR TRANSFERRED VOUCHER.—

24 “(i) DUE UPON NOTIFICATION.—The  
25 notification under this subsection shall be

1 a legally binding commitment to pay for  
2 the user fee to be assessed in accordance  
3 with this section. Such fee shall be payable  
4 by the sponsor upon the submission by  
5 such sponsor of such notification.

6 “(ii) CREDIT.—If a sponsor pays a  
7 user fee upon providing notification of the  
8 intent of such sponsor to use a priority re-  
9 view voucher, but later transfers the vouch-  
10 er for which such sponsor gave notifica-  
11 tion, the Secretary shall credit the user  
12 fees paid to the next human drug applica-  
13 tion for which a sponsor provides notifica-  
14 tion of the intent of such sponsor to use  
15 the same transferred voucher.

16 “(iii) DIFFERENCE IN FEE.—The Sec-  
17 retary may require a sponsor using a  
18 transferred voucher to pay the difference  
19 between the credit associated with the  
20 transferred voucher and the user fee pre-  
21 vailing at the time the sponsor submits no-  
22 tification of the intent of such sponsor to  
23 use the transferred voucher. This provision  
24 does not apply in cases where a transferee

1 is exempted from submitting notification  
2 under this paragraph.”.

3 (d) PAYMENT.—Section 524(c)(4) (21 U.S.C.  
4 360n(c)(4)) is amended—

5 (1) in subparagraph (A), by striking “submis-  
6 sion of a human drug application under section  
7 505(b)(1) or section 351 of the Public Health Serv-  
8 ices Act for which the priority review voucher is  
9 used.” and inserting “notification by a sponsor of  
10 the intent of such sponsor to use the voucher, as  
11 specified in subsection (b)(4)(A). All other user fees  
12 associated with the human drug application shall be  
13 due as required by the Secretary or under applicable  
14 law.”; and

15 (2) in subparagraph (C), by striking the period  
16 at the end and inserting “, except as specified in  
17 subsection (b)(4)(C).”.

18 (e) DESIGNATION PROCESS; PRODUCT IMPLEMENTA-  
19 TION REQUIREMENT.—Section 524 (21 U.S.C. 360n) is  
20 amended by adding at the end the following new sub-  
21 sections:

22 “(e) DESIGNATION PROCESS.—

23 “(1) DESIGNATION OF RARE PEDIATRIC DIS-  
24 EASES.—

1           “(A) IN GENERAL.—Upon the request of  
2           the manufacturer or the sponsor of a new drug,  
3           the Secretary may designate that the new drug  
4           is for a rare pediatric disease. Such a request  
5           for designation, if sought, shall be made when  
6           requesting designation of orphan disease status  
7           under section 526 or fast-track designation  
8           under section 506. Requesting designation of  
9           rare pediatric disease status under this para-  
10          graph is not a prerequisite to receiving a pri-  
11          ority review voucher.

12           “(B) DETERMINATION BY SECRETARY.—  
13          Not later than 60 days after a request is sub-  
14          mitted under subparagraph (A), the Secretary  
15          shall determine whether the disease or condition  
16          that is the subject of such request is a rare pe-  
17          diatric disease.

18          “(2) DESIGNATION OF INNOVATIVE TREAT-  
19          MENTS.—

20           “(A) IN GENERAL.—Upon the request of  
21           the manufacturer or the sponsor of a new drug,  
22           the Secretary may designate that a new drug is  
23           an innovative treatment. Such a request for  
24           designation, if sought, shall be made when re-  
25           questing fast-track designation under section

1           506. Requesting designation that a new drug is  
2           an innovative treatment is not a prerequisite to  
3           receiving a priority review voucher.

4           “(B) DETERMINATION BY SECRETARY.—  
5           Not later than 60 days after a request is sub-  
6           mitted under subparagraph (A), the Secretary  
7           shall determine whether the new drug that is  
8           the subject of such request is an innovative  
9           treatment.

10          “(f) PRODUCT IMPLEMENTATION FOR RARE PEDI-  
11          ATRIC DISEASE PRODUCTS.—

12           “(1) IN GENERAL.—The Secretary shall deem a  
13           rare pediatric disease product application incomplete  
14           if such application does not contain a description of  
15           the plan of the sponsor of such application to mar-  
16           ket the product in the United States.

17           “(2) GOOD FAITH INTENT TO MARKET.—

18           “(A) GOOD FAITH INTENT REQUIRED.—  
19           The Secretary may refuse to issue a priority re-  
20           view voucher upon the approval of a rare pedi-  
21           atric disease product application if the Sec-  
22           retary finds that the sponsor of such applica-  
23           tion lacks a good faith intention to produce and  
24           distribute the product. The Secretary may con-  
25           sider any fact relevant to this determination, in-

1 including the history of such sponsor of producing  
2 rare pediatric disease products for which such  
3 sponsor received a priority review voucher, or-  
4 phan drugs for which the sponsor received ex-  
5 clusivity under section 527, or pediatric drugs  
6 for which the sponsor received an additional 6  
7 months of exclusivity under section 505A.

8 “(B) PRESUMPTION.—The sponsor may  
9 establish a presumption of good faith by dem-  
10 onstrating that such sponsor has allocated suffi-  
11 cient resources or otherwise arranged for the  
12 production of the rare pediatric disease product  
13 in a manner sufficient to meet the expected de-  
14 mand for the product during the 5-year period  
15 following approval of the application.

16 “(3) PRODUCTION REPORT.—

17 “(A) REPORT REQUIRED.—The sponsor of  
18 an approved rare pediatric disease product shall  
19 submit a report to the Secretary not later than  
20 5 years after the approval of the applicable rare  
21 pediatric disease product application. Such re-  
22 port shall provide the following information,  
23 with respect to each of the first 4 years after  
24 approval of such product:

1                   “(i) The estimated population in the  
2                   United States suffering from the rare pedi-  
3                   atric disease.

4                   “(ii) The estimated demand in the  
5                   United States for such rare pediatric dis-  
6                   ease product.

7                   “(iii) The actual amount of such rare  
8                   pediatric disease product distributed in the  
9                   United States.

10                  “(B) PUBLICATION UPON FAILURE TO  
11                  DEMONSTRATE GOOD FAITH EFFORT TO MAR-  
12                  KET.—The Secretary may publish the results of  
13                  a report submitted under subparagraph (A) in  
14                  the Federal Register if the Secretary finds that  
15                  the sponsor that submitted such report has not  
16                  made a good faith effort to meet the demand in  
17                  the United States for the product that is the  
18                  subject of such report during each of the first  
19                  4 years after approval of such product.

20                  “(g) PRODUCTION REPORT FOR TROPICAL DISEASE  
21                  PRODUCTS.—

22                  “(1) REPORT REQUIRED.—The sponsor of an  
23                  approved tropical disease product shall submit a re-  
24                  port to the Secretary not later than 5 years after the  
25                  approval of the applicable rare tropical disease prod-

1       uct application. Such report shall provide the fol-  
2       lowing information, with respect to each of the first  
3       4 years after approval of such product:

4               “(A) The estimated global population suf-  
5       fering from the tropical disease.

6               “(B) The estimated global demand for  
7       such tropical disease product.

8               “(C) The actual amount of such tropical  
9       disease product distributed globally.

10              “(2) PUBLICATION UPON FAILURE TO DEM-  
11       ONSTRATE GOOD FAITH EFFORT TO MARKET.—The  
12       Secretary may publish the results of a report sub-  
13       mitted under paragraph (1) in the Federal Register  
14       if the Secretary finds that the sponsor that sub-  
15       mitted such report has not made a good faith effort  
16       to meet the global demand for the product that is  
17       the subject of such report during each of the first  
18       4 years after approval of such product.

19              “(h) NOTICE OF ISSUANCE AND USE OF VOUCHER.—  
20       The Secretary shall publish a notice in the Federal Reg-  
21       ister and on the Web site of the Food and Drug Adminis-  
22       tration not later than 30 days after the occurrence of each  
23       of the following:

24              “(1) The Secretary issues a priority review  
25       voucher under this section.



1           “(2) A sponsor submits a human drug applica-  
2           tion for which such sponsor uses a priority review  
3           voucher.

4           “(i) ELIGIBILITY FOR OTHER PROGRAMS.—A spon-  
5           sor who seeks a priority review voucher under this section  
6           may participate in any other incentive program, including  
7           the programs the Secretary has implemented under this  
8           Act, if the sponsor meets the applicable criteria of such  
9           other incentive program.

10          “(j) RELATION TO OTHER PROVISIONS.—This provi-  
11          sions of this section shall supplement, not supplant, any  
12          other provisions of this Act or the Public Health Service  
13          Act that encourage the development of drugs for tropical  
14          diseases and rare pediatric diseases.”.

15          (f) CONFORMING AMENDMENT.—Section 740(b) of  
16          the Agricultural, Rural Development, Food and Drug Ad-  
17          ministration, and Related Agencies Appropriations Act,  
18          2010 (21 U.S.C. 360aa(b)) is amended by striking  
19          “(a)(3)” and inserting “(a)(6)”.

20          **SEC. 3. EFFECTIVE DATE.**

21          This Act (and the amendments made by this Act)  
22          shall take effect on the date that is 90 days after the date  
23          of enactment of this Act.

○