

114TH CONGRESS  
1ST SESSION

# S. 2041

To promote the development of safe drugs for neonates.

---

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 16, 2015

Mr. CASEY (for himself, Mr. CASSIDY, and Mr. MENENDEZ) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

---

## A BILL

To promote the development of safe drugs for neonates.

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 “Promoting Life-Saving  
5       New Therapies for Neonates Act of 2015”.

6       **SEC. 2. PROMOTING THE DEVELOPMENT OF SAFE AND EF-**  
7       **FFECTIVE THERAPIES FOR NEONATES.**

8       Subchapter B of chapter V of the Federal Food,  
9       Drug, and Cosmetic Act (21 U.S.C. 360aa et seq.) is  
10      amended by inserting after section 529 the following:

1 **“SEC. 530. EXCLUSIVITY TO ENCOURAGE DEVELOPMENT OF**  
2 **SAFE AND EFFECTIVE THERAPIES FOR NEO-**  
3 **NATES.**

4 “(a) DEFINITIONS.—In this section:

5 “(1) NEONATAL DRUG.—The term ‘neonatal  
6 drug’ means a drug for the prevention or treatment  
7 of a disease or condition of a preterm or full-term  
8 neonate.

9 “(2) NEONATAL DRUG APPLICATION.—The  
10 term ‘neonatal drug application’ means a human  
11 drug application, as defined in section 735(1),  
12 that—

13 “(A) is for a drug or biological product—

14 “(i) that is for the prevention or  
15 treatment of a disease or condition listed  
16 on the Priority List of Critical Needs for  
17 Neonates described in subsection (c); and

18 “(ii) that contains no active ingredient  
19 (including any ester or salt of the active  
20 ingredient) that has been previously ap-  
21 proved in any other application under sec-  
22 tion 505(b)(1), 505(b)(2), or 505(j) of this  
23 Act or section 351(a) or 351(k) of the  
24 Public Health Service Act;

1           “(B) is submitted under section 505(b)(1)  
2 of this Act or section 351(a) of the Public  
3 Health Service Act;

4           “(C) the Secretary determines to be eligi-  
5 ble for a neonatal drug exclusivity voucher, in  
6 accordance with subsection (b);

7           “(D) relies on clinical data derived from  
8 studies examining a neonatal population and  
9 dosages of the drug intended for that popu-  
10 lation; and

11           “(E) is approved after the date of the en-  
12 actment of the Promoting Life-Saving New  
13 Therapies for Neonates Act of 2015.

14           “(3) NEONATAL DRUG EXCLUSIVITY VOUCH-  
15 ER.—The term ‘neonatal drug exclusivity voucher’  
16 means a voucher issued by the Secretary to the  
17 sponsor of a neonatal drug application that entitles  
18 the holder of such voucher to one year of transfer-  
19 able extension of all existing patents and marketing  
20 exclusivities, including any extensions, for a single  
21 human drug with respect to an application sub-  
22 mitted under section 505(b)(1) or for a single  
23 human biologic product with respect to an applica-  
24 tion submitted under section 351(a) of the Public  
25 Health Service Act, including the 6-month period de-

1 scribed in section 505A, the 4- and 5-year periods  
2 described in subsections (c)(3)(E)(ii) and  
3 (j)(5)(F)(ii) of section 505, the 3-year periods de-  
4 scribed in clauses (iii) and (iv) of subsection  
5 (c)(3)(E) and clauses (iii) and (iv) of subsection  
6 (j)(5)(F) of section 505, the 7-year period described  
7 in section 527, the 5-year period described in section  
8 505E, and the 12-year period described in section  
9 351(k)(7).

10 “(b) NEONATAL DRUG EXCLUSIVITY VOUCHER.—

11 “(1) IN GENERAL.—The Secretary shall award  
12 a neonatal drug exclusivity voucher to the sponsor of  
13 a neonatal drug application upon approval by the  
14 Secretary of such neonatal drug application.

15 “(2) TRANSFERABILITY.—

16 “(A) IN GENERAL.—The sponsor of a neo-  
17 natal drug application that receives a neonatal  
18 drug exclusivity voucher under this section may  
19 transfer (including by sale) the voucher to a  
20 sponsor of a human drug for which an applica-  
21 tion under section 505(b)(1) or section 351 of  
22 the Public Health Service Act has been ap-  
23 proved, will be submitted, or has been sub-  
24 mitted.

1           “(B) NONTRANSFERABILITY.—A neonatal  
2 exclusivity voucher may not be transferred to,  
3 or used for, a drug with respect to which all  
4 patents and exclusivities have expired as of the  
5 date of the transfer.

6           “(C) NOTIFICATION OF TRANSFER.—Each  
7 person to whom a voucher is transferred shall  
8 notify the Secretary of such change in owner-  
9 ship of the voucher not later than 30 calendar  
10 days after such transfer.

11           “(D) PROHIBITION ON ADDITIONAL  
12 FEES.—The Secretary shall not apply a fee for  
13 the exercise of a voucher under this section.  
14 The preceding sentence shall not affect the au-  
15 thority of the Secretary to apply fees with re-  
16 spect to a neonatal drug application that are  
17 otherwise applicable under law.

18           “(E) REVOCATION OF VOUCHER.—The  
19 Secretary may revoke any neonatal exclusivity  
20 voucher if the neonatal drug product for which  
21 such voucher was awarded is not marketed in  
22 the United States within the 365-day period be-  
23 ginning on the date of the approval of such  
24 drug under section 505 of this Act or section  
25 351 of the Public Health Service Act.

1 “(3) LIMITATIONS.—

2 “(A) NO AWARD FOR PRIOR APPROVED AP-  
3 PPLICATION.—A sponsor of a neonatal drug may  
4 not receive a voucher under this section if the  
5 neonatal drug application was submitted to the  
6 Secretary prior to the date of enactment of this  
7 section.

8 “(B) REQUIRED PEDIATRIC RESEARCH.—  
9 The Secretary shall limit grants of exclusivity  
10 under this section to drugs that are not re-  
11 quired to complete neonatal studies under sec-  
12 tion 505B.

13 “(C) NO COMBINING VOUCHERS.—A spon-  
14 sor may not use a neonatal exclusivity voucher  
15 on a product for which the sponsor also intends  
16 to use a voucher obtained or purchased pursu-  
17 ant to section 524 or section 529.

18 “(4) NOTIFICATION OF INTENT TO USE VOUCH-  
19 ER.—

20 “(A) NOTIFICATION BY SPONSOR.—The  
21 sponsor of a human drug application intending  
22 to use a voucher awarded or transferred under  
23 this section shall notify the Secretary not later  
24 than 15 months prior to loss of patent and  
25 exclusivities on the drug for which the voucher

1 will be redeemed, in such form as the Secretary  
2 may require.

3 “(B) NOTIFICATION BY SECRETARY.—  
4 Within 30 calendar days of such notification to  
5 the Secretary, the Secretary shall notify the  
6 sponsor of its eligibility to redeem a voucher for  
7 the intended drug.

8 “(c) PRIORITY LIST OF CRITICAL NEEDS FOR NEO-  
9 NATES.—

10 “(1) IN GENERAL.—The Secretary, in consulta-  
11 tion with the Pediatric Advisory Committee, the Na-  
12 tional Institutes of Health, the International Neo-  
13 natal Consortium sponsored by Critical Path Insti-  
14 tute, and other stakeholders, shall, within one year  
15 of the date of enactment of the Promoting Life-Sav-  
16 ing New Therapies for Neonates Act of 2015—

17 “(A) develop and publish a list of critical  
18 research priorities related to specific diseases or  
19 conditions common to the neonatal population  
20 (referred to as the ‘Priority List of Critical  
21 Needs for Neonates’);

22 “(B) issue guidance specific to the neo-  
23 natal drug exclusivity voucher program; and

24 “(C) perform other activities necessary to  
25 support neonatal drug applications.

1           “(2) PUBLIC COMMENT.—The Secretary shall  
2 provide a period of public notice and comment on  
3 the proposed list and shall hold public meetings to  
4 elicit input from patient advocacy and other organi-  
5 zations prior to publishing the final list.

6           “(3) SUBSEQUENT UPDATE.—The Secretary  
7 may revise, and publish in accordance with para-  
8 graph (1)(A), the Priority List of Critical Needs for  
9 Neonates every 3 years, or as frequently as the Sec-  
10 retary determines necessary.

11           “(4) RESTRICTION ON REMOVAL FROM LIST.—  
12 No disease or condition on the Priority List of Crit-  
13 ical Needs for Neonates may be removed until after  
14 completion of the study and report under subsection  
15 (d).

16           “(d) GAO STUDY AND REPORT.—

17           “(1) STUDY.—

18           “(A) IN GENERAL.—Beginning 8 years  
19 after the date of enactment of the Promoting  
20 Life-Saving New Therapies for Neonates Act of  
21 2015 or on the date that the Secretary awards  
22 the third neonatal exclusivity voucher under  
23 this section, whichever is earlier, the Comp-  
24 troller General of the United States shall con-  
25 duct a study of the effectiveness of the program



1 under this section for the development of  
2 human drugs to treat and prevent diseases or  
3 conditions in the neonatal population.

4 “(B) CONTENTS OF THE STUDY.—In con-  
5 ducting the study under subparagraph (A), the  
6 Comptroller General shall examine the fol-  
7 lowing:

8 “(i) The number of neonatal drug  
9 vouchers awarded under this section.

10 “(ii) The indications for each drug for  
11 which a neonatal exclusivity voucher was  
12 approved under section 505 or section 351  
13 of the Public Health Service Act, and  
14 whether any other drugs with indications  
15 for populations other than neonates were  
16 approved with an indication for neonates  
17 under those sections.

18 “(iii) Whether, and to what extent, an  
19 unmet need related to the treatment or  
20 prevention of a disease or condition that  
21 affects the neonatal population was met  
22 through the approval of a neonatal drug.

23 “(iv) The value of the neonatal exclu-  
24 sivity voucher if transferred.

1                   “(v) Identification of each drug for  
2                   which a neonatal exclusivity voucher was  
3                   used.

4                   “(vi) The length of the period of time  
5                   between the date on which a neonatal ex-  
6                   clusivity voucher was awarded and the date  
7                   on which it was used.

8                   “(2) REPORT.—Not later than 1 year after the  
9                   date under paragraph (1)(A), the Comptroller Gen-  
10                  eral shall submit to the Committee on Health, Edu-  
11                  cation, Labor, and Pensions of the Senate and the  
12                  Committee on Energy and Commerce of the House  
13                  of Representatives a report containing the results of  
14                  the study under paragraph (1).”.

○