

107TH CONGRESS  
1ST SESSION

# S. 1301

To amend the Federal Food, Drug, and Cosmetic Act to improve the safety and efficacy of pharmaceuticals for children.

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IN THE SENATE OF THE UNITED STATES

AUGUST 1, 2001

Mr. BOND 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 amend the Federal Food, Drug, and Cosmetic Act to improve the safety and efficacy of pharmaceuticals for children.

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 “Better Medicine for  
5 Children Act”.

6 **SEC. 2. SECOND PERIOD OF EXCLUSIVITY FOR ALREADY-**  
7 **MARKETED DRUGS.**

8 (a) IN GENERAL.—Section 505A of the Federal  
9 Food, Drug, and Cosmetic Act (21 U.S.C. 355a) (as  
10 amended by section 11) is amended—

1           (1) by inserting after subsection (c) the fol-  
2           lowing:

3           “(d) SECOND PERIOD OF MARKET EXCLUSIVITY FOR  
4           ALREADY-MARKETED DRUGS.—

5           “(1) IN GENERAL.—If—

6           “(A) the Secretary determines that infor-  
7           mation relating to the use of an approved drug  
8           in an additional pediatric population may  
9           produce health benefits in that population and  
10          makes a second written request to the holder of  
11          an approved application under section  
12          505(b)(1) for pediatric studies (which shall  
13          specify a timeframe for completing the studies);

14          “(B) the holder has received a patent ex-  
15          tension under paragraph (1) or (2) of sub-  
16          section (b) or paragraph (1) or (2) of sub-  
17          section (c);

18          “(C) the holder agrees to the request and  
19          the studies are completed within the specified  
20          timeframe; and

21          “(D) reports on the studies are submitted  
22          in accordance with subsection (e)(2) or accepted  
23          in accordance with subsection (e)(3);

1 the applicable extension period referred to in sub-  
2 section (b) or (c) shall be extended by an additional  
3 3 months.

4 “(2) ONE EXTENSION ONLY.—Not more than 1  
5 patent extension may be granted under paragraph  
6 (1) for any single approved drug.”; and

7 (2) in subsection (a), by striking “As used in  
8 this section, the term” and inserting the following:  
9 “In this section:

10 “(1) ADDITIONAL PEDIATRIC POPULATION.—  
11 The term ‘additional pediatric population’ means a  
12 pediatric subpopulation for which information was  
13 not requested by the Secretary in a written  
14 request—

15 “(A) under subsection (b) or (c), because  
16 the approved drug in question was not used in  
17 that pediatric subpopulation at the time when  
18 the request was made; or

19 “(B) under subsection (c), because obtain-  
20 ing such information would have been impos-  
21 sible or inadvisable because of a need to pursue  
22 pediatric studies in a sequential manner for sci-  
23 entific, medical, or ethical reasons.

24 “(2) PEDIATRIC STUDIES; STUDIES.—The  
25 term”.

1 **SEC. 3. INFRASTRUCTURE FOR PEDIATRIC PHARMA-**  
2 **COLOGICAL RESEARCH.**

3 (a) INVESTMENT IN TOMORROW'S PEDIATRIC RE-  
4 SEARCHERS.—Section 452G of the Public Health Service  
5 Act (42 U.S.C. 285g–10) is amended—

6 (1) by redesignating subsection (b) as sub-  
7 section (c); and

8 (2) by inserting after subsection (a), the fol-  
9 lowing:

10 “(b) PRIORITY.—In awarding grants under sub-  
11 section (a), the Secretary shall give priority to pediatric  
12 specialty areas in which there is significant need (includ-  
13 ing pediatric pharmacology, as appropriate).”.

14 (b) PEDIATRIC RESEARCH LOAN REPAYMENT PRO-  
15 GRAM.—The second section 487F of the Public Health  
16 Service Act, relating to the pediatric research loan repay-  
17 ment program, (42 U.S.C. 288–6) is amended—

18 (1) by redesignating that section as section  
19 487G;

20 (2) by redesignating subsection (c) as sub-  
21 section (d); and

22 (3) by inserting after subsection (b) the fol-  
23 lowing:

24 “(c) PRIORITY.—In entering into loan repayment  
25 contracts under subsection (a)(1), the Secretary shall give  
26 priority to pediatric specialty areas in which there is sig-

1 nificant need (including pediatric pharmacology, as appro-  
2 priate).”.

3 (c) SENSE OF THE SENATE.—It is the sense of the  
4 Senate that the National Institutes of Health should con-  
5 sider the formation of a Pediatric/Developmental Pharma-  
6 cology Scientific Review Group or Special Emphasis Panel  
7 to evaluate Federal grant programs relating to pediatric  
8 pharmacology.

9 **SEC. 4. PEDIATRIC STUDIES OF ALREADY-MARKETED**  
10 **DRUGS.**

11 Section 505A of the Federal Food, Drug, and Cos-  
12 metic Act (21 U.S.C. 355a) is amended—

13 (1) by striking subsection (b); and

14 (2) in subsection (c)—

15 (A) by inserting after “the Secretary” the  
16 following: “determines that information relating  
17 to the use of an approved drug in the pediatric  
18 population may produce health benefits in that  
19 population and”; and

20 (B) by striking “concerning a drug identi-  
21 fied in the list described in subsection (b)”.

22 **SEC. 5. RESEARCH FUND FOR THE STUDY OF OFF-PATENT**  
23 **DRUGS.**

24 Part B of title IV of the Public Health Service Act  
25 (42 U.S.C. 284 et seq.) is amended—

1           (1) by redesignating the second section 409C,  
2 relating to clinical research (42 U.S.C. 284k), as  
3 section 409G;

4           (2) by redesignating the second section 409D,  
5 relating to enhancement awards (42 U.S.C. 284l), as  
6 section 409H; and

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

8 **“SEC. 409I. PROGRAM FOR PEDIATRIC STUDIES OF OFF-**  
9 **PATENT DRUGS.**

10           “(a) LIST OF OFF-PATENT DRUGS FOR WHICH PE-  
11 DIATRIC STUDIES ARE NEEDED.—

12           “(1) IN GENERAL.—Not later than 1 year after  
13 the date of enactment of this section, the Secretary,  
14 acting through the Director of the National Insti-  
15 tutes of Health and in consultation with the Com-  
16 missioner of Food and Drugs and experts in pedi-  
17 atric research (including United States Pharma-  
18 copoeia), shall develop, and publish a list of priority  
19 approved drugs for which—

20           “(A) there is no patent or market exclu-  
21 sivity protection; and

22           “(B) additional studies are needed to as-  
23 sess the safety and effectiveness of the use of  
24 the drug in the pediatric population.

1           “(2) CONSIDERATION OF AVAILABLE INFORMA-  
2           TION.—In developing the list under paragraph (1),  
3           the Secretary shall consider, for each drug on the  
4           list—

5                   “(A) the availability of information con-  
6                   cerning the safe and effective use of the drug  
7                   in the pediatric population;

8                   “(B) whether additional information is  
9                   needed; and

10                   “(C) whether new pediatric studies con-  
11                   cerning the drug may produce health benefits in  
12                   the pediatric population.

13           “(b) CONTRACTS FOR PEDIATRIC STUDIES.—

14                   “(1) IN GENERAL.—The Secretary shall award  
15                   contracts to entities that have the expertise to con-  
16                   duct pediatric clinical trials (including qualified uni-  
17                   versities, hospitals, laboratories, contract research  
18                   organizations, federally funded programs such as pe-  
19                   diatric pharmacology research units, other public or  
20                   private institutions, or individuals) to enable the en-  
21                   tities to conduct pediatric studies concerning 1 or  
22                   more drugs identified in the list described in sub-  
23                   section (a).

24                   “(2) REQUIREMENTS.—In awarding contracts  
25                   under paragraph (1), the Secretary shall, to the ex-

1       tent practicable award grants for a significant num-  
2       ber of approved drugs on the list.

3       “(c) PROCESS FOR CONTRACTS AND LABELING  
4 CHANGES.—

5               “(1) WRITTEN REQUEST TO HOLDERS OF AP-  
6 PROVED APPLICATIONS FOR OFF-PATENT DRUGS.—

7                       “(A) IN GENERAL.—The Commissioner of  
8 Food and Drugs, in consultation with the Di-  
9 rector of National Institutes of Health, may  
10 issue a written request for pediatric studies  
11 concerning a drug identified in the list de-  
12 scribed in subsection (a) to all holders of an ap-  
13 proved application for the drug under section  
14 505 of the Federal Food, Drug, and Cosmetic  
15 Act. Such a request shall be made in accord-  
16 ance with section 505A of the Federal Food,  
17 Drug, and Cosmetic Act.

18                       “(B) PUBLICATION OF REQUEST.—If the  
19 Commissioner of Food and Drugs does not re-  
20 ceive a response to a written request issued  
21 under subparagraph (A) within 30 days of the  
22 date on which a request was issued, the Sec-  
23 retary, acting through the Director of National  
24 Institutes of Health, shall publish a request for

1 contract proposals to conduct the pediatric  
2 studies described in the written request.

3 “(2) CONTRACTS.—A contract under this sec-  
4 tion may be awarded only if a proposal for the con-  
5 tract is submitted to the Secretary in such form and  
6 manner, and containing such agreements, assur-  
7 ances, and information as the Secretary determines  
8 to be necessary to carry out this section.

9 “(3) REPORTING OF STUDIES.—

10 “(A) Upon completion of a pediatric study  
11 in accordance with a contract awarded under  
12 this section, a report concerning the study shall  
13 be submitted to the Director of National Insti-  
14 tutes of Health and the Commissioner of Food  
15 and Drugs. The report shall include all data  
16 generated in connection with the study.

17 “(B) AVAILABILITY OF REPORTS.—Each  
18 report submitted under subparagraph (A) shall  
19 be considered to be in the public domain, and  
20 shall be assigned a docket number by the Com-  
21 missioner of Food and Drugs. An interested  
22 person may submit written comments con-  
23 cerning such pediatric studies to the Commis-  
24 sioner of Food and Drugs, and the written com-

1           ments shall become part of the docket file with  
2           respect to each drug.

3           “(C) ACTION BY COMMISSIONER.—The  
4           Commissioner of Food and Drugs shall take ap-  
5           propriate action in response to the reports sub-  
6           mitted under subparagraph (A) in accordance  
7           with paragraph (4).

8           “(4) REQUEST FOR LABELING CHANGES.—Dur-  
9           ing the 180-day period after the date on which a re-  
10          port is submitted under paragraph (3)(A), the Com-  
11          missioner of Food and Drugs shall—

12           “(A) review the report and such other data  
13           as are available concerning the safe and effec-  
14           tive use in the pediatric population of the drug  
15           studied;

16           “(B) negotiate with the holders of ap-  
17           proved applications for the drug studied for any  
18           labeling changes that the Commissioner of Food  
19           and Drugs determines to be appropriate and re-  
20           quests the holders to make; and

21           “(C)(i) place in the public docket file a  
22           copy of the report and of any requested labeling  
23           changes; and

1           “(ii) publish in the Federal Register a  
2           summary of the report and a copy of any re-  
3           quested labeling changes.

4           “(5) DISPUTE RESOLUTION.—If, not later than  
5           the end of the 180-day period specified in paragraph  
6           (4), the holder of an approved application for the  
7           drug involved does not agree to any labeling change  
8           requested by the Commissioner of Food and Drugs  
9           under that paragraph—

10           “(A) the Commissioner of Food and Drugs  
11           shall immediately refer the request to the Pedi-  
12           atric Advisory Subcommittee of the Anti-Infec-  
13           tive Drugs Advisory Committee; and

14           “(B) not later than 60 days after receiving  
15           the referral, the Subcommittee shall—

16           “(i) review the available information  
17           on the safe and effective use of the drug  
18           in the pediatric population, including study  
19           reports submitted under this section; and

20           “(ii) make a recommendation to the  
21           Commissioner of Food and Drugs as to ap-  
22           propriate labeling changes, if any.

23           “(6) FDA DETERMINATION.—Not later than 30  
24           days after receiving a recommendation from the  
25           Subcommittee under paragraph (5)B(ii) with respect

1 to a drug, the Commissioner of Food and Drugs  
2 shall consider the recommendation and, if appro-  
3 priate, make a request to the holders of approved  
4 applications for the drug to make any labeling  
5 change that the Commissioner of Food and Drugs  
6 determines to be appropriate.

7 “(7) FAILURE TO AGREE.—If a holder of an  
8 approved application for a drug, within 30 days  
9 after receiving a request to make a labeling change  
10 under paragraph (6), does not agree to make a re-  
11 quested labeling change, the Commissioner may  
12 deem the drug to be misbranded under the Federal  
13 Food, Drug, and Cosmetic Act.

14 “(d) AUTHORIZATION OF APPROPRIATIONS.—

15 “(1) IN GENERAL.—There are authorized to be  
16 appropriated to carry out this section—

17 “(A) \$200,000,000 for fiscal year 2002;

18 and

19 “(B) such sums as are necessary for each  
20 of the 5 succeeding fiscal years.

21 “(2) AVAILABILITY.—Any amount appropriated  
22 under paragraph (1) shall remain available to carry  
23 out this section until expended.”.

1 **SEC. 6. TIMELY LABELING CHANGES FOR DRUGS GRANTED**  
2 **EXCLUSIVITY; DRUG FEES.**

3 (a) **ELIMINATION OF USER FEE WAIVER FOR PEDI-**  
4 **ATRIC SUPPLEMENTS.**—Section 736(a)(1) of the Federal  
5 Food, Drug, and Cosmetic Act (21 U.S.C. 379h(A)(1))  
6 is amended—

- 7 (1) by striking subparagraph (F); and  
8 (2) by redesignating subparagraph (G) as sub-  
9 paragraph (F).

10 (b) **LABELING CHANGES.**—Section 505A of the Fed-  
11 eral Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is  
12 amended by adding at the end the following:

13 “(1) **LABELING SUPPLEMENTS.**—

14 “(1) **PRIORITY STATUS FOR PEDIATRIC SUP-**  
15 **PLEMENTS.**—Any supplement to a human drug ap-  
16 plication submitted under this section—

17 “(A) shall be considered to be a priority  
18 supplement; and

19 “(B) shall be subject to the performance  
20 goals established by the Commissioner for pri-  
21 ority drugs.

22 “(2) **DISPUTE RESOLUTION.**—If the Commis-  
23 sioner determines that a supplemental application  
24 submitted under this section is approvable and that  
25 the only open issue for final action on the supple-  
26 ment is the reaching of an agreement between the

1 sponsor of the application and the Commissioner on  
2 appropriate changes to the labeling for the drug that  
3 is the subject of the application—

4 “(A) not later than 180 days after the date  
5 of submission of the supplemental application—

6 “(i) the Commissioner shall request  
7 that the sponsor of the application make  
8 any labeling change that the Commissioner  
9 determines to be appropriate; and

10 “(ii) if the sponsor of the application  
11 does not agree to make a labeling change  
12 requested by the Commissioner by that  
13 date, the Commissioner shall immediately  
14 refer the matter to the Pediatric Advisory  
15 Subcommittee of the Anti-Infective Drugs  
16 Advisory Committee;

17 “(B) not later than 60 days after receiving  
18 the referral, the Pediatric Advisory Sub-  
19 committee of the Anti-Infective Drugs Advisory  
20 Committee shall—

21 “(i) review the pediatric study reports;  
22 and

23 “(ii) make a recommendation to the  
24 Commissioner concerning appropriate la-  
25 beling changes, if any;

1           “(C) the Commissioner shall consider the  
2           recommendations of the Pediatric Advisory  
3           Subcommittee of the Anti-Infective Drugs Advi-  
4           sory Committee and, if appropriate, not later  
5           than 30 days after receiving the recommenda-  
6           tion, make a request to the sponsor of the ap-  
7           plication to make any labeling change that the  
8           Commissioner determines to be appropriate;  
9           and

10           “(D) if the sponsor of the application,  
11           within 30 days after receiving a request under  
12           subparagraph (D), does not agree to make a la-  
13           beling change requested by the Commissioner,  
14           the Commissioner may deem the drug that is  
15           the subject of the application to be mis-  
16           branded.”.

17 **SEC. 7. OFFICE OF PEDIATRIC THERAPEUTICS.**

18           (a) **ESTABLISHMENT.**—The Secretary of Health and  
19           Human Services shall establish an Office of Pediatric  
20           Therapeutics within the Office of the Commissioner of  
21           Food and Drugs.

22           (b) **DUTIES.**—The Office of Pediatric Therapeutics  
23           shall be responsible for oversight and coordination of all  
24           activities of the Food and Drug Administration that may  
25           have any effect on a pediatric population or the practice

1 of pediatrics or may in any other way involve pediatric  
2 issues.

3 (c) STAFF.—The staff of the Office of Pediatric  
4 Therapeutics shall include—

5 (1) 1 or more individuals with expertise con-  
6 cerning ethical issues presented by the conduct of  
7 clinical research in the pediatric population; and

8 (2) 1 or more individuals with expertise in pedi-  
9 atries who shall consult with all components of the  
10 Food and Drug Administration concerning activities  
11 described in subsection (b).

12 **SEC. 8. NEONATES.**

13 Section 505A(g) of the Federal Food, Drug, and Cos-  
14 metic Act (21 U.S.C. 355a(g)) is amended by inserting  
15 “(including neonates in appropriate cases)” after “pedi-  
16 atric age groups”.

17 **SEC. 9. SUNSET.**

18 Section 505A of the Federal Food, Drug, and Cos-  
19 metic Act (21 U.S.C. 355a) is amended by striking sub-  
20 section (j) and inserting the following:

21 “(j) SUNSET.—A drug may not receive any 6-month  
22 period under subsection (a) or (c) unless—

23 “(1) on or before October 1, 2007, the Sec-  
24 retary makes a written request for pediatric studies  
25 of the drug;

1           “(2) on or before October 1, 2007, an applica-  
2           tion for the drug is submitted under section  
3           505(b)(1); and

4           “(3) all requirements of this section are met.”.

5 **SEC. 10. DISSEMINATION OF PEDIATRIC INFORMATION.**

6           Section 505A of the Federal Food, Drug, and Cos-  
7           metic Act (21 U.S.C 355a) (as amended by section 4(b))  
8           is amended by adding at the end the following:

9           “(m) DISSEMINATION OF PEDIATRIC INFORMA-  
10          TION.—

11           “(1) IN GENERAL.—Not later than 180 days  
12           after the date of submission of a supplemental appli-  
13           cation under this section, the Commissioner shall  
14           make available to the public a summary of the med-  
15           ical and clinical pharmacology reviews of pediatric  
16           studies conducted for the supplement, including by  
17           publication in the Federal Register.

18           “(2) EFFECT OF SUBSECTION.—Nothing in this  
19           subsection alters or amends in any way section 552  
20           of title 5 or section 1905 of title 18, United States  
21           Code.”.

22 **SEC. 11. TECHNICAL AND CONFORMING AMENDMENTS.**

23           Section 505A of the Federal Food, Drug, and Cos-  
24           metic Act (21 U.S.C. 355a) (as amended by sections 2(1),  
25           4(b), 7, and 8) is amended—

1           (1) by redesignating subsections (a), (d), (e),  
2           (f), (g), (j), (l), and (m) as subsections (b), (e), (f),  
3           (g), (a), (m), (k), and (l), respectively;

4           (2) by moving the subsections so as to appear  
5           in alphabetical order;

6           (3) in subsections (b) and (c)—

7                 (A) by striking “subsection (d)(2)” and in-  
8                 serting “subsection (e)(2)”; and

9                 (B) by striking “subsection (d)(3)” and in-  
10                serting “subsection (e)(3)”;

11           (4) in subsection (e)(2), by striking “subsection  
12           (d)” each place it appears and inserting “subsection  
13           (e)”;

14           (5) in paragraphs (1), (2), and (3) of sub-  
15           section (e) and subsections (f), (h) (as redesignated  
16           by paragraph (1)), and (m) (as redesignated by  
17           paragraph (1)), by striking “subsection (a) or (c)”  
18           and inserting “subsection (b) or (c)”; and

19           (6) in subsection (i), by striking “(a) or (b)”  
20           and inserting “(a), (e), or (d)”.

○