

110TH CONGRESS  
1ST SESSION

# S. 1156

To amend the Federal Food, Drug, and Cosmetic Act to reauthorize the Best Pharmaceuticals for Children program.

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## IN THE SENATE OF THE UNITED STATES

APRIL 18, 2007

Mr. DODD (for himself, Mr. KENNEDY, Mr. HARKIN, Mr. BINGAMAN, Mrs. MURRAY, Mrs. CLINTON, and Mr. BROWN) 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 reauthorize the Best Pharmaceuticals for Children program.

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 “Best Pharmaceuticals  
5 for Children Amendments of 2007”.

6 **SEC. 2. PEDIATRIC STUDIES OF DRUGS.**

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

1           (1) in subsection (a), by inserting before the pe-  
2           riod at the end the following: “, and, at the discre-  
3           tion of the Secretary, may include preclinical stud-  
4           ies”;

5           (2) in subsection (b)—

6                 (A) in paragraph (1)(A)(i), by striking  
7                 “(D)” both places it appears and inserting  
8                 “(E)”;

9                 (B) in paragraph (1)(A)(ii), by striking  
10                “(D)” and inserting “(E)”;

11               (C) by striking “(1)(A)(i)” and inserting  
12                “(A)(i)(I)”;

13               (D) by striking “(ii) the” and inserting  
14                “(II) the”;

15               (E) by striking “(B) if the drug is des-  
16                ignated” and inserting “(ii) if the drug is des-  
17                ignated”;

18               (F) by striking “(2)(A)” and inserting  
19                “(B)(i)”;

20               (G) by striking “(i) a listed patent” and  
21                inserting “(I) a listed patent”;

22               (H) by striking “(ii) a listed patent” and  
23                inserting “(II) a listed patent”;

1 (I) by striking “(B) if the drug is the sub-  
2 ject” and inserting “(ii) if the drug is the sub-  
3 ject”;

4 (J) by striking “If” and all that follows  
5 through “subsection (d)(3)” and inserting the  
6 following:

7 “(1) IN GENERAL.—Except as provided in para-  
8 graph (2), if, prior to approval of an application that  
9 is submitted under section 505(b)(1), the Secretary  
10 determines that information relating to the use of a  
11 new drug in the pediatric population may produce  
12 health benefits in that population, the Secretary  
13 makes a written request for pediatric studies (which  
14 shall include a timeframe for completing such stud-  
15 ies), the applicant agrees to the request, such stud-  
16 ies are completed using appropriate formulations for  
17 each age group for which the study is requested  
18 within any such timeframe and the reports thereof  
19 are submitted and accepted in accordance with sub-  
20 section (d)(3), and if the Secretary determines that  
21 labeling changes are appropriate, such changes are  
22 made within the timeframe requested by the Sec-  
23 retary—”;

24 (K) by adding at the end the following:

1           “(2) EXCEPTION.—The Secretary shall not ex-  
2           tend the period referred to in paragraph (1)(A) or  
3           in paragraph (1)(B) later than 9 months prior to  
4           the expiration of such period.”;

5           (3) in subsection (c)—

6           (A) in paragraph (1)(A)(i), by striking  
7           “(D)” both places it appears and inserting  
8           “(E)”;

9           (B) in paragraph (1)(A)(ii), by striking  
10          “(D)” and inserting “(E)”;

11          (C) by striking “(1)(A)(i)” and inserting  
12          “(A)(i)(I)”;

13          (D) by striking “(ii) the” and inserting  
14          “(II) the”;

15          (E) by striking “(B) if the drug is des-  
16          ignated” and inserting “(ii) if the drug is des-  
17          ignated”;

18          (F) by striking “(2)(A)” and inserting  
19          “(B)(i)”;

20          (G) by striking “(i) a listed patent” and  
21          inserting “(I) a listed patent”;

22          (H) by striking “(ii) a listed patent” and  
23          inserting “(II) a listed patent”;

1 (I) by striking “(B) if the drug is the sub-  
2 ject” and inserting “(ii) if the drug is the sub-  
3 ject”;

4 (J) by striking “If” and all that follows  
5 through “subsection (d)(3)” and inserting the  
6 following:

7 “(1) IN GENERAL.—Except as provided in para-  
8 graph (2), if the Secretary determines that informa-  
9 tion relating to the use of an approved drug in the  
10 pediatric population may produce health benefits in  
11 that population and makes a written request to the  
12 holder of an approved application under section  
13 505(b)(1) for pediatric studies (which shall include  
14 a timeframe for completing such studies), the holder  
15 agrees to the request, such studies are completed  
16 using appropriate formulations for each age group  
17 for which the study is requested within any such  
18 timeframe and the reports thereof are submitted and  
19 accepted in accordance with subsection (d)(3), and if  
20 the Secretary determines that labeling changes are  
21 appropriate, such changes are made within the time-  
22 frame requested by the Secretary—”; and

23 (K) by adding at the end the following:

24 “(2) EXCEPTION.—The Secretary shall not ex-  
25 tend the period referred to in paragraph (1)(A) or

1 in paragraph (1)(B) later than 9 months prior to  
2 the expiration of such period.”;

3 (4) by striking subsection (d) and inserting the  
4 following:

5 “(d) CONDUCT OF PEDIATRIC STUDIES.—

6 “(1) REQUEST FOR STUDIES.—

7 “(A) IN GENERAL.—The Secretary may,  
8 after consultation with the sponsor of an appli-  
9 cation for an investigational new drug under  
10 section 505(i), the sponsor of an application for  
11 a new drug under section 505(b)(1), or the  
12 holder of an approved application for a drug  
13 under section 505(b)(1), issue to the sponsor or  
14 holder a written request for the conduct of pedi-  
15 atric studies for such drug. In issuing such re-  
16 quest, the Secretary shall take into account  
17 adequate representation of children of ethnic  
18 and racial minorities. Such request to conduct  
19 pediatric studies shall be in writing and shall  
20 include a timeframe for such studies and a re-  
21 quest to the sponsor or holder to propose pedi-  
22 atric labeling resulting from such studies.

23 “(B) SINGLE WRITTEN REQUEST.—A sin-  
24 gle written request—

1                   “(i) may relate to more than 1 use of  
2                   a drug; and

3                   “(ii) may include uses that are both  
4                   approved and unapproved.

5                   “(2) WRITTEN REQUEST FOR PEDIATRIC STUD-  
6                   IES.—

7                   “(A) REQUEST AND RESPONSE.—

8                   “(i) IN GENERAL.—If the Secretary  
9                   makes a written request for pediatric stud-  
10                  ies (including neonates, as appropriate)  
11                  under subsection (b) or (c), the applicant  
12                  or holder, not later than 180 days after re-  
13                  ceiving the written request, shall respond  
14                  to the Secretary as to the intention of the  
15                  applicant or holder to act on the request  
16                  by—

17                               “(I) indicating when the pediatric  
18                               studies will be initiated, if the appli-  
19                               cant or holder agrees to the request;  
20                               or

21                               “(II) indicating that the appli-  
22                               cant or holder does not agree to the  
23                               request and the reasons for declining  
24                               the request.

1                   “(ii) DISAGREE WITH REQUEST.—If,  
2                   on or after the date of enactment of the  
3                   Best Pharmaceuticals for Children Amend-  
4                   ments of 2007, the applicant or holder  
5                   does not agree to the request on the  
6                   grounds that it is not possible to develop  
7                   the appropriate pediatric formulation, the  
8                   applicant or holder shall submit to the Sec-  
9                   retary the reasons such pediatric formula-  
10                  tion cannot be developed.

11                  “(B) ADVERSE EVENT REPORTS.—An ap-  
12                  plicant or holder that, on or after the date of  
13                  enactment of the Best Pharmaceuticals for  
14                  Children Amendments of 2007, agrees to the  
15                  request for such studies shall provide the Sec-  
16                  retary, at the same time as submission of the  
17                  reports of such studies, with all postmarket ad-  
18                  verse event reports regarding the drug that is  
19                  the subject of such studies and are available  
20                  prior to submission of such reports.

21                  “(3) MEETING THE STUDIES REQUIREMENT.—  
22                  Not later than 180 days after the submission of the  
23                  reports of the studies, the Secretary shall accept or  
24                  reject such reports and so notify the sponsor or  
25                  holder. The Secretary’s only responsibility in accept-

1 ing or rejecting the reports shall be to determine,  
2 within the 180 days, whether the studies fairly re-  
3 spond to the written request, have been conducted in  
4 accordance with commonly accepted scientific prin-  
5 ciples and protocols, and have been reported in ac-  
6 cordance with the requirements of the Secretary for  
7 filing.

8 “(4) EFFECT OF SUBSECTION.—Nothing in this  
9 subsection alters or amends section 301(j) of this  
10 Act or section 552 of title 5 or section 1905 of title  
11 18, United States Code.”;

12 (5) by striking subsections (e) and (f) and in-  
13 sserting the following:

14 “(e) NOTICE OF DETERMINATIONS ON STUDIES RE-  
15 QUIREMENT.—

16 “(1) IN GENERAL.—The Secretary shall publish  
17 a notice of any determination, made on or after the  
18 date of enactment of the Best Pharmaceuticals for  
19 Children Amendments of 2007, that the require-  
20 ments of subsection (d) have been met and that sub-  
21 missions and approvals under subsection (b)(2) or  
22 (j) of section 505 for a drug will be subject to the  
23 provisions of this section. Such notice shall be pub-  
24 lished not later than 30 days after the date of the  
25 Secretary’s determination regarding market exclu-

1 sivity and shall include a copy of the written request  
2 made under subsection (b) or (c).

3 “(2) IDENTIFICATION OF CERTAIN DRUGS.—

4 The Secretary shall publish a notice identifying any  
5 drug for which, on or after the date of enactment of  
6 the Best Pharmaceuticals for Children Amendments  
7 of 2007, a pediatric formulation was developed,  
8 studied, and found to be safe and effective in the pe-  
9 diatric population (or specified subpopulation) if the  
10 pediatric formulation for such drug is not introduced  
11 onto the market within 1 year of the date that the  
12 Secretary publishes the notice described in para-  
13 graph (1). Such notice identifying such drug shall be  
14 published not later than 30 days after the date of  
15 the expiration of such 1 year period.

16 “(f) INTERNAL REVIEW OF WRITTEN REQUESTS  
17 AND PEDIATRIC STUDIES.—

18 “(1) INTERNAL REVIEW.—

19 “(A) IN GENERAL.—The Secretary shall  
20 create an internal review committee to review  
21 all written requests issued and all reports sub-  
22 mitted on or after the date of enactment of the  
23 Best Pharmaceuticals for Children Amendments  
24 of 2007, in accordance with paragraphs (2) and  
25 (3).

1           “(B) MEMBERS.—The committee under  
2           subparagraph (A) shall include individuals, each  
3           of whom is an employee of the Food and Drug  
4           Administration, with the following expertise:

5                   “(i) Pediatrics.

6                   “(ii) Biopharmacology.

7                   “(iii) Statistics.

8                   “(iv) Drugs and drug formulations.

9                   “(v) Legal issues.

10                  “(vi) Appropriate expertise pertaining  
11                  to the pediatric product under review.

12                  “(vii) One or more experts from the  
13                  Office of Pediatric Therapeutics, including  
14                  an expert in pediatric ethics.

15                  “(viii) Other individuals as designated  
16                  by the Secretary.

17           “(2) REVIEW OF WRITTEN REQUESTS.—All  
18           written requests under this section shall be reviewed  
19           and approved by the committee established under  
20           paragraph (1) prior to being issued.

21           “(3) REVIEW OF PEDIATRIC STUDIES.—The  
22           committee established under paragraph (1) shall re-  
23           view all studies conducted pursuant to this section to  
24           determine whether to accept or reject such reports  
25           under subsection (d)(3).

1           “(4) TRACKING PEDIATRIC STUDIES AND LA-  
2           BELING CHANGES.—The committee established  
3           under paragraph (1) shall be responsible for track-  
4           ing and making available to the public, in an easily  
5           accessible manner, including through posting on the  
6           website of the Food and Drug Administration—

7                   “(A) the number of studies conducted  
8                   under this section;

9                   “(B) the specific drugs and drug uses, in-  
10                  cluding labeled and off-labeled indications, stud-  
11                  ied under this section;

12                  “(C) the types of studies conducted under  
13                  this section, including trial design, the number  
14                  of pediatric patients studied, and the number of  
15                  centers and countries involved;

16                  “(D) the number of pediatric formulations  
17                  developed and the number of pediatric formula-  
18                  tions not developed and the reasons such for-  
19                  mulations were not developed;

20                  “(E) the labeling changes made as a result  
21                  of studies conducted under this section;

22                  “(F) an annual summary of labeling  
23                  changes made as a result of studies conducted  
24                  under this section for distribution pursuant to  
25                  subsection (k)(2); and

1 “(G) information regarding reports sub-  
2 mitted on or after the date of enactment of the  
3 Best Pharmaceuticals for Children Amendments  
4 of 2007.”;

5 (6) in subsection (g)—

6 (A) in paragraph (1)—

7 (i) by striking “(c)(1)(A)(ii)” and in-  
8 serting “(c)(1)(A)(i)(II)”;

9 (ii) by striking “(c)(2)” and inserting  
10 “(c)(1)(B)”;

11 (B) in paragraph (2), by striking  
12 “(c)(1)(B)” and inserting “(c)(1)(A)(ii)”;

13 (C) by redesignating paragraphs (1) and  
14 (2) as subparagraphs (A) and (B), respectively;

15 (D) by striking “LIMITATIONS.—A drug”  
16 and inserting “LIMITATIONS.—

17 “(1) IN GENERAL.—Notwithstanding subsection  
18 (c)(2), a drug”;

19 (E) by adding at the end the following:

20 “(2) EXCLUSIVITY ADJUSTMENT.—

21 “(A) ADJUSTMENT.—

22 “(i) IN GENERAL.—With respect to  
23 any drug, if the organization designated  
24 under subparagraph (B) notifies the Sec-  
25 retary that the combined annual gross

1 sales for all drugs with the same active  
2 moiety exceeded \$1,000,000,000 in any  
3 calendar year prior to the time the sponsor  
4 or holder agrees to the initial written re-  
5 quest pursuant to subsection (d)(2), then  
6 each period of market exclusivity deemed  
7 or extended under subsection (b) or (c)  
8 shall be reduced by 3 months for such  
9 drug.

10 “(ii) DETERMINATION.—The deter-  
11 mination under clause (i) of the combined  
12 annual gross sales shall be determined—

13 “(I) taking into account only  
14 those sales within the United States;  
15 and

16 “(II) taking into account only the  
17 sales of all drugs with the same active  
18 moiety of the sponsor or holder and  
19 its affiliates.

20 “(B) DESIGNATION.—The Secretary shall  
21 designate an organization other than the Food  
22 and Drug Administration to evaluate whether  
23 the combined annual gross sales for all drugs  
24 with the same active moiety exceeded  
25 \$1,000,000,000 in a calendar year as described

1 in subparagraph (A). Prior to designating such  
2 organization, the Secretary shall determine that  
3 such organization is independent and is quali-  
4 fied to evaluate the sales of pharmaceutical  
5 products. The Secretary shall re-evaluate the  
6 designation of such organization once every 3  
7 years.

8 “(C) NOTIFICATION.—Once a year at a  
9 time designated by the Secretary, the organiza-  
10 tion designated under subparagraph (B) shall  
11 notify the Food and Drug Administration of all  
12 drugs with the same active moiety with com-  
13 bined annual gross sales that exceed  
14 \$1,000,000,000 during the previous calendar  
15 year.”.

16 (7) in subsection (i)—

17 (A) in the heading, by striking “SUPPLE-  
18 MENTS” and inserting “CHANGES”;

19 (B) in paragraph (1)—

20 (i) in the heading, by inserting “AP-  
21 PPLICATIONS AND” after “PEDIATRIC”;

22 (ii) by inserting “application or” after  
23 “Any”;

24 (iii) by striking “change pursuant to a  
25 report on a pediatric study under” and in-

1           serting “change as a result of any pedi-  
2           atric study conducted pursuant to”; and

3                   (iv) by inserting “application or” after  
4           “to be a priority”; and

5           (C) in paragraph (2)(A), by—

6                   (i) striking “If the Commissioner”  
7           and inserting “If, on or after the date of  
8           enactment of the Best Pharmaceuticals for  
9           Children Amendments of 2007, the Com-  
10          missioner”; and

11                   (ii) striking “an application with” and  
12          all that follows through “on appropriate”  
13          and inserting “the sponsor and the Com-  
14          missioner have been unable to reach agree-  
15          ment on appropriate”;

16          (8) by striking subsection (m);

17          (9) by redesignating subsections (j), (k), (l),  
18          and (n), as subsections (k), (m), (o), and (p), respec-  
19          tively;

20          (10) by inserting after subsection (i) the fol-  
21          lowing:

22          “(j) OTHER LABELING CHANGES.—If, on or after the  
23          date of enactment of the Best Pharmaceuticals for Chil-  
24          dren Amendments of 2007, the Secretary determines that  
25          a pediatric study conducted under this section does or does

1 not demonstrate that the drug that is the subject of the  
2 study is safe and effective, including whether such study  
3 results are inconclusive, in pediatric populations or sub-  
4 populations, the Secretary shall order the labeling of such  
5 product to include information about the results of the  
6 study and a statement of the Secretary’s determination.”;

7 (11) in subsection (k), as redesignated by para-  
8 graph (9)—

9 (A) in paragraph (1)—

10 (i) by striking “a summary of the  
11 medical and” and inserting “the medical,  
12 statistical, and”; and

13 (ii) by striking “for the supplement”  
14 and all that follows through the period and  
15 inserting “under subsection (b) or (c).”;

16 (B) by redesignating paragraph (2) as  
17 paragraph (3); and

18 (C) by inserting after paragraph (1) the  
19 following:

20 “(2) DISSEMINATION OF INFORMATION RE-  
21 GARDING LABELING CHANGES.—Beginning on the  
22 date of enactment of the Best Pharmaceuticals for  
23 Children Amendments of 2007, the Secretary shall  
24 require that the sponsors of the studies that result  
25 in labeling changes that are reflected in the annual

1 summary developed pursuant to subsection (f)(4)(F)  
2 distribute, at least annually (or more frequently if  
3 the Secretary determines that it would be beneficial  
4 to the public health), such information to physicians  
5 and other health care providers.”;

6 (12) by inserting after subsection (k), as reded-  
7 igned by paragraph (9), the following:

8 “(1) ADVERSE EVENT REPORTING.—

9 “(1) REPORTING IN YEAR ONE.—Beginning on  
10 the date of enactment of the Best Pharmaceuticals  
11 for Children Amendments of 2007, during the 1-year  
12 period beginning on the date a labeling change is  
13 made pursuant to subsection (i), the Secretary shall  
14 ensure that all adverse event reports that have been  
15 received for such drug (regardless of when such re-  
16 port was received) are referred to the Office of Pedi-  
17 atric Therapeutics established under section 6 of the  
18 Best Pharmaceuticals for Children Act (Public Law  
19 107–109). In considering such reports, the Director  
20 of such Office shall provide for the review of the re-  
21 port by the Pediatric Advisory Committee, including  
22 obtaining any recommendations of such Committee  
23 regarding whether the Secretary should take action  
24 under this section in response to such reports.

1           “(2) REPORTING IN SUBSEQUENT YEARS.—Fol-  
2           lowing the 1-year period described in paragraph (1),  
3           the Secretary shall, as appropriate, refer to the Of-  
4           fice of Pediatric Therapeutics all pediatric adverse  
5           event reports for a drug for which a pediatric study  
6           was conducted under this section. In considering  
7           such reports, the Director of such Office may pro-  
8           vide for the review of such reports by the Pediatric  
9           Advisory Committee, including obtaining any rec-  
10          ommendation of such Committee regarding whether  
11          the Secretary should take action in response to such  
12          reports.

13           “(3) EFFECT.—The requirements of this sub-  
14          section shall supplement, not supplant, other review  
15          of such adverse event reports by the Secretary.”;

16           (13) by inserting after subsection (m), as reded-  
17          esignated by paragraph (9), the following:

18          “(n) REFERRAL IF PEDIATRIC STUDIES NOT COM-  
19          PLETED.—

20           “(1) IN GENERAL.—Beginning on the date of  
21          enactment of the Best Pharmaceuticals for Children  
22          Amendments of 2007, if pediatric studies of a drug  
23          have not been completed under subsection (d) and if  
24          the Secretary, through the committee established  
25          under subsection (f), determines that there is a con-

1       tinuing need for information relating to the use of  
2       the drug in the pediatric population (including neo-  
3       nates, as appropriate), the Secretary shall carry out  
4       the following:

5               “(A) For a drug for which a listed patent  
6               has not expired, make a determination regard-  
7               ing whether an assessment shall be required to  
8               be submitted under section 505B. Prior to mak-  
9               ing such determination, the Secretary may take  
10              not more than 60 days to certify whether the  
11              Foundation for the National Institutes of  
12              Health has sufficient funding at the time of  
13              such certification to initiate 1 or more of the  
14              pediatric studies of such drug referred to in the  
15              sentence preceding this paragraph and fund 1  
16              or more of such studies in their entirety. Only  
17              if the Secretary makes such certification in the  
18              affirmative, the Secretary shall refer such pedi-  
19              atric study or studies to the Foundation for the  
20              National Institutes of Health for the conduct of  
21              such study or studies.

22              “(B) For a drug that has no listed patents  
23              or has 1 or more listed patents that have ex-  
24              pired, determine whether there are funds avail-  
25              able under section 736 to award a grant to con-

1           duct the requested studies pursuant to para-  
2           graph (2).

3           “(2) FUNDING OF STUDIES.—If, pursuant to  
4           paragraph (1), the Secretary determines that there  
5           are funds available under section 736 to award a  
6           grant to conduct the requested pediatric studies,  
7           then the Secretary shall issue a proposal to award  
8           a grant to conduct the requested studies. If the Sec-  
9           retary determines that funds are not available under  
10          section 736, the Secretary shall refer the drug for  
11          inclusion on the list established under section 409I  
12          of the Public Health Service Act for the conduct of  
13          studies.

14          “(3) PUBLIC NOTICE.—The Secretary shall give  
15          the public notice of—

16                 “(A) a decision under paragraph (1)(A)  
17                 not to require an assessment under section  
18                 505B and the basis for such decision;

19                 “(B) the name of any drug, its manufac-  
20                 turer, and the indications to be studied pursu-  
21                 ant to a grant made under paragraph (2); and

22                 “(C) any decision under paragraph (2) to  
23                 refer a drug for inclusion on the list established  
24                 under section 409I of the Public Health Service  
25                 Act.

1           “(4) EFFECT OF SUBSECTION.—Nothing in this  
2 subsection alters or amends section 301(j) of this  
3 Act or section 552 of title 5 or section 1905 of Title  
4 18, United States Code.”; and

5           (14) in subsection (p), as redesignated by para-  
6 graph (9)—

7           (A) striking “6-month period” and insert-  
8 ing “3-month or 6-month period”;

9           (B) by striking “subsection (a)” and in-  
10 sserting “subsection (b)”; and

11           (C) by striking “2007” both places it ap-  
12 pears and inserting “2012”.

13           (b) EFFECTIVE DATE.—Except as otherwise provided  
14 in the amendments made by subsection (a), such amend-  
15 ments shall apply to written requests under section 505A  
16 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
17 355a) made after the date of enactment of this Act.

18 **SEC. 3. PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.**

19           Section 409I of the Public Health Service Act (42  
20 U.S.C. 284m) is amended—

21           (1) by striking subsections (a) and (b) and in-  
22 sserting the following:

23           “(a) LIST OF PRIORITY ISSUES IN PEDIATRIC  
24 THERAPEUTICS.—

1           “(1) IN GENERAL.—Not later than 1 year after  
2           the date of enactment of the Best Pharmaceuticals  
3           for Children Amendments of 2007, the Secretary,  
4           acting through the Director of the National Insti-  
5           tutes of Health and in consultation with the Com-  
6           missioner of Food and Drugs and experts in pedi-  
7           atric research, shall develop and publish a priority  
8           list of needs in pediatric therapeutics, including  
9           drugs or indications that require study. The list  
10          shall be revised every 3 years.

11           “(2) CONSIDERATION OF AVAILABLE INFORMA-  
12          TION.—In developing and prioritizing the list under  
13          paragraph (1), the Secretary shall consider—

14                   “(A) therapeutic gaps in pediatrics that  
15                   may include developmental pharmacology,  
16                   pharmacogenetic determinants of drug re-  
17                   sponse, metabolism of drugs and biologics in  
18                   children, and pediatric clinical trials;

19                   “(B) particular pediatric diseases, dis-  
20                   orders or conditions where more complete  
21                   knowledge and testing of therapeutics, including  
22                   drugs and biologics, may be beneficial in pedi-  
23                   atric populations; and

24                   “(C) the adequacy of necessary infrastruc-  
25                   ture to conduct pediatric pharmacological re-

1 search, including research networks and trained  
2 pediatric investigators.

3 “(b) PEDIATRIC STUDIES AND RESEARCH.—The  
4 Secretary, acting through the National Institutes of  
5 Health, shall award funds to entities that have the exper-  
6 tise to conduct pediatric clinical trials or other research  
7 (including qualified universities, hospitals, laboratories,  
8 contract research organizations, practice groups, federally  
9 funded programs such as pediatric pharmacology research  
10 units, other public or private institutions, or individuals)  
11 to enable the entities to conduct the drug studies or other  
12 research on the issues described in subsection (a). The  
13 Secretary may use contracts, grants, or other appropriate  
14 funding mechanisms to award funds under this sub-  
15 section.”;

16 (2) in subsection (c)—

17 (A) in the heading, by striking “CON-  
18 TRACTS” and inserting “PROPOSED PEDIATRIC  
19 STUDY REQUESTS”;

20 (B) by striking paragraphs (4) and (12);

21 (C) by redesignating paragraphs (1), (2),  
22 and (3), as paragraphs (2), (3), and (4);

23 (D) by inserting before paragraph (2), as  
24 redesignated by subparagraph (C), the fol-  
25 lowing:

1           “(1) SUBMISSION OF PROPOSED PEDIATRIC  
2           STUDY REQUEST.—The Director of the National In-  
3           stitutes of Health shall, as appropriate, submit pro-  
4           posed pediatric study requests for consideration by  
5           the Commissioner of Food and Drugs for pediatric  
6           studies of a specific pediatric indication identified  
7           under subsection (a). Such a proposed pediatric  
8           study request shall be made in a manner equivalent  
9           to a written request made under subsection (b) or  
10          (c) of section 505A of the Federal Food, Drug, and  
11          Cosmetic Act, including with respect to the informa-  
12          tion provided on the pediatric studies to be con-  
13          ducted pursuant to the request. The Director of the  
14          National Institutes of Health may submit a pro-  
15          posed pediatric study request for a drug for which—

16                   “(A)(i) there is an approved application  
17                   under section 505(j) of the Federal Food,  
18                   Drug, and Cosmetic Act; or

19                   “(ii) there is a submitted application that  
20                   could be approved under the criteria of section  
21                   505(j) of the Federal Food, Drug, and Cos-  
22                   metic Act;

23                   “(B) there is no patent protection or mar-  
24                   ket exclusivity protection for at least 1 form of

1 the drug under the Federal Food, Drug, and  
2 Cosmetic Act; and

3 “(C) additional studies are needed to as-  
4 sess the safety and effectiveness of the use of  
5 the drug in the pediatric population.”;

6 (E) in paragraph (2), as redesignated by  
7 subparagraph (C)—

8 (i) by inserting “based on the pro-  
9 posed pediatric study request for the indi-  
10 cation or indications submitted pursuant to  
11 paragraph (1)” after “issue a written re-  
12 quest”;

13 (ii) by striking “in the list described  
14 in subsection (a)(1)(A) (except clause  
15 (iv))” and inserting “under subsection  
16 (a)”;

17 (iii) by inserting “and using appro-  
18 priate formulations for each age group for  
19 which the study is requested” before the  
20 period at the end;

21 (F) in paragraph (3), as redesignated by  
22 subparagraph (C)—

23 (i) in the heading, by striking “CON-  
24 TRACTS”;

1 (ii) by striking “paragraph (1)” and  
2 inserting “paragraph (2)”;

3 (iii) by striking “or if a referral de-  
4 scribed in subsection (a)(1)(A)(iv) is  
5 made,”;

6 (iv) by striking “for contract pro-  
7 posals” and inserting “for proposals”; and

8 (v) by inserting “in accordance with  
9 subsection (b)” before the period at the  
10 end;

11 (G) in paragraph (4), as redesignated by  
12 subparagraph (C)—

13 (i) by striking “contract”; and

14 (ii) by striking “paragraph (2)” and  
15 inserting “paragraph (3)”;

16 (H) in paragraph (5)—

17 (i) by striking the heading and insert-  
18 ing “CONTRACTS, GRANTS, OR OTHER  
19 FUNDING MECHANISMS”; and

20 (ii) by striking “A contract” and all  
21 that follows through “is submitted” and  
22 inserting “A contract, grant, or other  
23 funding may be awarded under this section  
24 only if a proposal is submitted”;

25 (I) in paragraph (6)(A)—

1 (i) by striking “a contract awarded”  
2 and inserting “an award”; and

3 (ii) by inserting “, including a written  
4 request if issued” after “with the study”;  
5 and

6 (3) by inserting after subsection (c) the fol-  
7 lowing:

8 “(d) DISSEMINATION OF PEDIATRIC INFORMA-  
9 TION.—Not later than 1 year after the date of enactment  
10 of the Best Pharmaceuticals for Children Amendments of  
11 2007, the Secretary, acting through the Director of the  
12 National Institutes of Health, shall study the feasibility  
13 of establishing a compilation of information on pediatric  
14 drug use and report the findings to Congress.”

15 “(e) AUTHORIZATION OF APPROPRIATIONS.—

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

18 “(A) \$200,000,000 for fiscal year 2008;

19 and

20 “(B) such sums as are necessary for each  
21 of the 4 succeeding fiscal years.

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

1 **SEC. 4. REPORTS AND STUDIES.**

2 (a) GAO REPORT.—Not later than January 31,  
3 2011, the Comptroller General of the United States, in  
4 consultation with the Secretary of Health and Human  
5 Services, shall submit to Congress a report that addresses  
6 the effectiveness of section 505A of the Federal Food,  
7 Drug, and Cosmetic Act (21 U.S.C. 355a) in ensuring  
8 that medicines used by children are tested and properly  
9 labeled, including—

10 (1) the number and importance of drugs for  
11 children that are being tested as a result of the  
12 amendments made by this Act and the importance  
13 for children, health care providers, parents, and oth-  
14 ers of labeling changes made as a result of such  
15 testing;

16 (2) the number and importance of drugs for  
17 children that are not being tested for their use not-  
18 withstanding the provisions of this Act and the  
19 amendments made by this Act, and possible reasons  
20 for the lack of testing, including whether the number  
21 of written requests declined by sponsors or holders  
22 of drugs subject to section 505A(g)(2) of the Fed-  
23 eral Food, Drug, and Cosmetic Act (21 U.S.C.  
24 355a(g)(2)), has increased or decreased as a result  
25 of the amendments made by this Act;

1           (3) the number of drugs for which testing is  
2           being done and labeling changes required, including  
3           the date labeling changes are made and which label-  
4           ing changes required the use of the dispute resolu-  
5           tion process established pursuant to the amendments  
6           made by this Act, together with a description of the  
7           outcomes of such process, including a description of  
8           the disputes and the recommendations of the Pedi-  
9           atric Advisory Committee;

10           (4) any recommendations for modifications to  
11           the programs established under section 505A of the  
12           Federal Food, Drug and Cosmetic Act (21 U.S.C.  
13           355a) and section 409I of the Public Health Service  
14           Act that the Secretary determines to be appropriate,  
15           including a detailed rationale for each recommenda-  
16           tion; and

17           (5)(A) the efforts made by the Secretary to in-  
18           crease the number of studies conducted in the  
19           neonate population; and

20           (B) the results of those efforts, including efforts  
21           made to encourage the conduct of appropriate stud-  
22           ies in neonates by companies with products that  
23           have sufficient safety and other information to make  
24           the conduct of the studies ethical and safe.

1 (b) IOM STUDY.—Not later than 3 years after the  
2 date of enactment of this Act, the Secretary of Health and  
3 Human Services shall enter into a contract with the Insti-  
4 tute of Medicine to conduct a study and report to Con-  
5 gress regarding the written requests made and the studies  
6 conducted pursuant to section 505A of the Federal Food,  
7 Drug, and Cosmetic Act. The Institute of Medicine may  
8 devise an appropriate mechanism to review a representa-  
9 tive sample of requests made and studies conducted pursu-  
10 ant to such section in order to conduct such study. Such  
11 study shall—

12 (1) review such representative written requests  
13 issued by the Secretary since 1997 under sub-  
14 sections (b) and (c) of such section 505A;

15 (2) review and assess such representative pedi-  
16 atric studies conducted under such subsections (b)  
17 and (c) since 1997 and labeling changes made as a  
18 result of such studies; and

19 (3) review the use of extrapolation for pediatric  
20 subpopulations, the use of alternative endpoints for  
21 pediatric populations, neonatal assessment tools, and  
22 ethical issues in pediatric clinical trials.

23 **SEC. 5. TRAINING OF PEDIATRIC PHARMACOLOGISTS.**

24 (a) INVESTMENT IN TOMORROW'S PEDIATRIC RE-  
25 SEARCHERS.—Section 452G(2) of the Public Health Serv-

1 ice Act (42 U.S.C. 285g–10(2)) is amended by adding be-  
 2 fore the period at the end the following: “, including pedi-  
 3 atric pharmacological research”.

4 (b) PEDIATRIC RESEARCH LOAN REPAYMENT PRO-  
 5 GRAM.—Section 487F(a)(1) of the Public Health Service  
 6 Act (42 U.S.C. 288–6(a)(1)) is amended by inserting “in-  
 7 cluding pediatric pharmacological research,” after “pedi-  
 8 atric research,”.

9 **SEC. 6. FOUNDATION FOR THE NATIONAL INSTITUTES OF**  
 10 **HEALTH.**

11 Section 499(c)(1)(C) of the Public Health Service Act  
 12 (42 U.S.C. 290b(e)(1)(C)) is amended by striking “and  
 13 studies listed by the Secretary pursuant to section  
 14 409I(a)(1)(A) of the is Act and referred under section  
 15 505A(d)(4)(C) of the Federal Food, Drug and Cosmetic  
 16 Act (21 U.S.C. 355(a)(d)(4)(C))” and inserting “and stud-  
 17 ies for which the Secretary issues a certification under sec-  
 18 tion 505A(n)(1)(A) of the Federal Food, Drug, and Cos-  
 19 metic Act (21 U.S.C. 355a(n)(1)(A))”.

20 **SEC. 7. CONTINUATION OF OPERATION OF COMMITTEE.**

21 Section 14 of the Best Pharmaceuticals for Children  
 22 Act (42 U.S.C. 284m note) is amended by adding at the  
 23 end the following:

24 “(d) CONTINUATION OF OPERATION OF COM-  
 25 MITTEE.—Notwithstanding section 14 of the Federal Ad-

1 visory Committee Act (5 U.S.C. App.), the advisory com-  
2 mittee shall continue to operate during the 5-year period  
3 beginning on the date of enactment of the Best Pharma-  
4 ceuticals for Children Amendments of 2007.”.

5 **SEC. 8. PEDIATRIC SUBCOMMITTEE OF THE ONCOLOGIC**  
6 **DRUGS ADVISORY COMMITTEE.**

7 Section 15 of the Best Pharmaceuticals for Children  
8 Act (42 U.S.C. 284m note) is amended—

9 (1) in subsection (a)—

10 (A) in paragraph (1)—

11 (i) in subparagraph (B), by striking  
12 “and” after the semicolon;

13 (ii) in subparagraph (C), by striking  
14 the period at the end and inserting “;  
15 and”; and

16 (iii) by adding at the end the fol-  
17 lowing:

18 “(D) provide recommendations to the in-  
19 ternal review committee created under section  
20 505A(f) of the Federal Food, Drug, and Cos-  
21 metic Act (21 U.S.C. 355a(f)) regarding the  
22 implementation of amendments to sections  
23 505A and 505B of the Federal Food, Drug,  
24 and Cosmetic Act (21 U.S.C. 355a and 355c)

1 with respect to the treatment of pediatric can-  
2 cers.”; and

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

4 “(3) CONTINUATION OF OPERATION OF SUB-  
5 COMMITTEE.—Notwithstanding section 14 of the  
6 Federal Advisory Committee Act (5 U.S.C. App.),  
7 the Subcommittee shall continue to operate during  
8 the 5-year period beginning on the date of enact-  
9 ment of the Best Pharmaceuticals for Children  
10 Amendments of 2007.”; and

11 (2) in subsection (d), by striking “2003” and  
12 inserting “2009”.

13 **SEC. 9. EFFECTIVE DATE AND LIMITATION FOR RULE RE-**  
14 **LATING TO TOLL-FREE NUMBER FOR AD-**  
15 **VERSE EVENTS ON LABELING FOR HUMAN**  
16 **DRUG PRODUCTS.**

17 (a) IN GENERAL.—Notwithstanding subchapter II of  
18 chapter 5, and chapter 7, of title 5, United States Code  
19 (commonly known as the “Administrative Procedure Act”)  
20 and any other provision of law, the proposed rule issued  
21 by the Commissioner of Food and Drugs entitled “Toll-  
22 Free Number for Reporting Adverse Events on Labeling  
23 for Human Drug Products”, 69 Fed. Reg. 21778, (April  
24 22, 2004) shall take effect on January 1, 2008, unless  
25 such Commissioner issues the final rule before such date.

1           (b) LIMITATION.—The proposed rule that takes ef-  
2   fect under subsection (a), or the final rule described under  
3   subsection (a), shall, notwithstanding section 17(a) of the  
4   Best Pharmaceuticals for Children Act (21 U.S.C.  
5   355b(a)), not apply to a drug—

6           (1) for which an application is approved under  
7   section 505 of the Federal Food, Drug, and Cos-  
8   metic Act (21 U.S.C. 355);

9           (2) that is not described under section  
10   503(b)(1) of such Act (21 U.S.C. 353(b)(1)); and

11          (3) the packaging of which includes a toll-free  
12   number through which consumers can report com-  
13   plaints to the manufacturer or distributor of the  
14   drug.

○