

**[Committee Print]**

110TH CONGRESS  
1ST SESSION

**H. R.** \_\_\_\_\_

To amend the Federal Food, Drug, and Cosmetic Act with respect to pediatric studies of drugs, and for other purposes.

\_\_\_\_\_  
IN THE HOUSE OF REPRESENTATIVES

M. \_\_\_\_\_ introduced the following bill; which was referred to the Committee on \_\_\_\_\_

\_\_\_\_\_  
**A BILL**

To amend the Federal Food, Drug, and Cosmetic Act with respect to pediatric studies of drugs, and for other purposes.

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. REAUTHORIZATION OF BEST PHARMA-**  
4 **CEUTICALS FOR CHILDREN ACT.**

5 (a) PEDIATRIC STUDIES OF DRUGS.—

6 (1) IN GENERAL.—Section 505A of the Federal  
7 Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is  
8 amended to read as follows:

1 **“SEC. 505A. PEDIATRIC STUDIES OF DRUGS.**

2 “(a) DEFINITIONS.—As used in this section, the term  
3 ‘pediatric studies’ or ‘studies’ means at least one clinical  
4 investigation (that, at the Secretary’s discretion, may in-  
5 clude pharmacokinetic studies) in pediatric age groups (in-  
6 cluding neonates in appropriate cases) in which a drug  
7 is anticipated to be used, and at the discretion of the Sec-  
8 retary, may include preclinical studies.

9 “(b) MARKET EXCLUSIVITY FOR NEW DRUGS.—

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

1           “(A)(i)(I) the period referred to in sub-  
2           section (c)(3)(E)(ii) of section 505, and in sub-  
3           section (j)(5)(F)(ii) of such section, is deemed  
4           to be five years and six months rather than five  
5           years, and the references in subsections  
6           (c)(3)(E)(ii) and (j)(5)(F)(ii) of such section to  
7           four years, to forty-eight months, and to seven  
8           and one-half years are deemed to be four and  
9           one-half years, fifty-four months, and eight  
10          years, respectively; or

11          “(II) the period referred to in clauses (iii)  
12          and (iv) of subsection (c)(3)(E) of such section,  
13          and in clauses (iii) and (iv) of subsection  
14          (j)(5)(F) of such section, is deemed to be three  
15          years and six months rather than three years;  
16          and

17          “(ii) if the drug is designated under sec-  
18          tion 526 for a rare disease or condition, the pe-  
19          riod referred to in section 527(a) is deemed to  
20          be seven years and six months rather than  
21          seven years; and

22          “(B)(i) if the drug is the subject of—

23                  “(I) a listed patent for which a certifi-  
24                  cation has been submitted under sub-  
25                  section (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of

1 section 505 and for which pediatric studies  
2 were submitted prior to the expiration of  
3 the patent (including any patent exten-  
4 sions); or

5 “(II) a listed patent for which a cer-  
6 tification has been submitted under sub-  
7 sections (b)(2)(A)(iii) or (j)(2)(A)(vii)(III)  
8 of section 505,

9 the period during which an application may not  
10 be approved under section 505(c)(3) or section  
11 505(j)(5)(B) shall be extended by a period of  
12 six months after the date the patent expires (in-  
13 cluding any patent extensions); or

14 “(ii) if the drug is the subject of a listed  
15 patent for which a certification has been sub-  
16 mitted under subsection (b)(2)(A)(iv) or  
17 (j)(2)(A)(vii)(IV) of section 505, and in the pat-  
18 ent infringement litigation resulting from the  
19 certification the court determines that the pat-  
20 ent is valid and would be infringed, the period  
21 during which an application may not be ap-  
22 proved under section 505(c)(3) or section  
23 505(j)(5)(B) shall be extended by a period of  
24 six months after the date the patent expires (in-  
25 cluding any patent extensions).

1           “(2) EXCEPTION.—The Secretary shall not ex-  
2           tend the period referred to in paragraph (1)(A) or  
3           (1)(B) if the determination is made later than one  
4           year prior to the expiration of such period.

5           “(c) MARKET EXCLUSIVITY FOR ALREADY-MAR-  
6           KETED DRUGS.—

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 and such changes are made within the  
22          timeframe requested by the Secretary—

23                       “(A)(i)(I) the period referred to in sub-  
24                       section (c)(3)(E)(ii) of section 505, and in sub-  
25                       section (j)(5)(F)(ii) of such section, is deemed

1 to be five years and six months rather than five  
2 years, and the references in subsections  
3 (c)(3)(E)(ii) and (j)(5)(F)(ii) of such section to  
4 four years, to forty-eight months, and to seven  
5 and one-half years are deemed to be four and  
6 one-half years, fifty-four months, and eight  
7 years, respectively; or

8 “(II) the period referred to in clauses (iii)  
9 and (iv) of subsection (c)(3)(D) of such section,  
10 and in clauses (iii) and (iv) of subsection  
11 (j)(5)(F) of such section, is deemed to be three  
12 years and six months rather than three years;  
13 and

14 “(ii) if the drug is designated under sec-  
15 tion 526 for a rare disease or condition, the pe-  
16 riod referred to in section 527(a) is deemed to  
17 be seven years and six months rather than  
18 seven years; and

19 “(B)(i) if the drug is the subject of—

20 “(I) a listed patent for which a certifi-  
21 cation has been submitted under sub-  
22 section (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of  
23 section 505 and for which pediatric studies  
24 were submitted prior to the expiration of

1 the patent (including any patent exten-  
2 sions); or

3 “(II) a listed patent for which a cer-  
4 tification has been submitted under sub-  
5 section (b)(2)(A)(iii) or (j)(2)(A)(vii)(III)  
6 of section 505,

7 the period during which an application may not  
8 be approved under section 505(c)(3) or section  
9 505(j)(5)(B)(ii) shall be extended by a period of  
10 six months after the date the patent expires (in-  
11 cluding any patent extensions); or

12 “(ii) if the drug is the subject of a listed  
13 patent for which a certification has been sub-  
14 mitted under subsection (b)(2)(A)(iv) or  
15 (j)(2)(A)(vii)(IV) of section 505, and in the pat-  
16 ent infringement litigation resulting from the  
17 certification the court determines that the pat-  
18 ent is valid and would be infringed, the period  
19 during which an application may not be ap-  
20 proved under section 505(c)(3) or section  
21 505(j)(5)(B) shall be extended by a period of  
22 six months after the date the patent expires (in-  
23 cluding any patent extensions)

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

1 (1)(B) if the determination is made later than one  
2 year prior to the expiration of such period.

3 “(d) CONDUCT OF PEDIATRIC STUDIES.—

4 “(1) REQUEST FOR STUDIES.—

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

21 “(B) SINGLE WRITTEN REQUEST.—A sin-  
22 gle written request—

23 “(i) may related to more than one use  
24 of a drug; and

1                   “(ii) may include uses that are both  
2                   approved and unapproved.

3                   “(2) WRITTEN REQUEST FOR PEDIATRIC STUD-  
4                   IES.—

5                   “(A) REQUEST AND RESPONSE.—

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

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

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

23                  “(ii) DISAGREE WITH REQUEST.—If,  
24                  on or after the date of the enactment of  
25                  the Improving Pharmaceuticals for Chil-

1           dren Act of 2007, the applicant or holder  
2           does not agree to the request on the  
3           grounds that it is not possible to develop  
4           the appropriate pediatric formulation, the  
5           applicant or holder shall submit to the Sec-  
6           retary the reasons such pediatric formula-  
7           tion cannot be developed.

8           “(B) ADVERSE EVENT REPORTS.—An ap-  
9           plicant or holder that, on or after the date of  
10          the enactment of the Improving Pharma-  
11          ceuticals for Children Act of 2007, agrees to  
12          the request for such studies shall provide the  
13          Secretary, at the same time as the submission  
14          of the reports of such studies, with all  
15          postmarket adverse event reports regarding the  
16          drug that is the subject of such studies and are  
17          available prior to submission of such reports.

18          “(3) MEETING THE STUDIES REQUIREMENT.—  
19          Not later than 180 days after the submission of the  
20          reports of the studies, the Secretary shall accept or  
21          reject such reports and so notify the sponsor or  
22          holder. The Secretary’s only responsibility in accept-  
23          ing or rejecting the reports shall be to determine,  
24          within the 180-day period, whether the studies fairly  
25          respond to the written request, have been conducted

1 in accordance with commonly accepted scientific  
2 principles and protocols, and have been reported in  
3 accordance with the requirements of the Secretary  
4 for filing.

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

9 “(e) NOTICE OF DETERMINATIONS ON STUDIES RE-  
10 QUIREMENT.—

11 “(1) IN GENERAL.—The Secretary shall publish  
12 a notice of any determination, made on or after the  
13 date of the enactment of the Improving Pharma-  
14 ceuticals for Children Act of 2007, that the require-  
15 ments of subsection (d) have been met and that sub-  
16 missions and approvals under subsection (b)(2) or  
17 (j) of section 505 for a drug will be subject to the  
18 provisions of this section. Such notice shall be pub-  
19 lished not later than 30 days after the date of the  
20 Secretary’s determination regarding market exclu-  
21 sivity and shall include a copy of the written request  
22 made under subsection (b) or (c).

23 “(2) IDENTIFICATION OF CERTAIN DRUGS.—  
24 The Secretary shall publish a notice identifying any  
25 drug for which, on or after the date of the enact-

1       ment of the Improving Pharmaceuticals for Children  
2       Act of 2007, a pediatric formulation was developed,  
3       studied, and found to be safe and effective in the pe-  
4       diatric population (or specified subpopulation) if the  
5       pediatric formulation for such drug is not introduced  
6       onto the market within one year after the date that  
7       the Secretary publishes the notice described in para-  
8       graph (1). Such notice identifying such drug shall be  
9       published not later than 30 days after the date of  
10      the expiration of such one year period.

11      “(f) INTERNAL REVIEW OF WRITTEN REQUESTS  
12      AND PEDIATRIC STUDIES.—

13              “(1) INTERNAL REVIEW.—

14                      “(A) IN GENERAL.—The Secretary shall  
15                      establish an internal review committee to review  
16                      all written requests issued on or after the date  
17                      of the enactment of the Improving Pharma-  
18                      ceuticals for Children Act of 2007, in accord-  
19                      ance with paragraph (2).

20                      “(B) MEMBERS.—The committee estab-  
21                      lished under subparagraph (A) shall include in-  
22                      dividuals with expertise in pediatrics, biophar-  
23                      macology, statistics, drugs and drug formula-  
24                      tions, legal issues, pediatric ethics, the appro-  
25                      priate expertise, such as expertise in child and

1           adolescent psychiatry, pertaining to the pedi-  
2           atric product under review, one or more experts  
3           from the Office of Pediatric Therapeutics, and  
4           other individuals designated by the Secretary.

5           “(2) REVIEW OF WRITTEN REQUESTS.—The  
6           committee established under paragraph (1) shall re-  
7           view all written requests issued pursuant to this sec-  
8           tion prior to being issued.

9           “(3) TRACKING PEDIATRIC STUDIES AND LA-  
10          BELING CHANGES.—The Secretary shall track and  
11          make available to the public, in an easily accessible  
12          manner, including through posting on the website of  
13          the Food and Drug Administration—

14                 “(A) the number of studies conducted  
15                 under this section and under section 409I of  
16                 the Public Health Service Act (42 U.S.C.  
17                 284m);

18                 “(B) the specific drugs and biological prod-  
19                 ucts and their uses, including labeled and off-  
20                 labeled indications, studied under such sections;

21                 “(C) the types of studies conducted under  
22                 such sections, including trial design, the num-  
23                 ber of pediatric patients studied, and the num-  
24                 ber of centers and countries involved;

1           “(D) the number of pediatric formulations  
2 developed and the number of pediatric formula-  
3 tions not developed and the reasons such for-  
4 mulations were not developed;

5           “(E) the labeling changes made as a result  
6 of studies conducted under such sections;

7           “(F) an annual summary of labeling  
8 changes made as a result of studies conducted  
9 under such sections for distribution pursuant to  
10 subsection (k)(2); and

11           “(G) information regarding reports sub-  
12 mitted on or after the date of the enactment of  
13 the Improving Pharmaceuticals for Children  
14 Act of 2007.

15           “(4) COMMITTEE.—The Committee established  
16 under paragraph (1) is the committee established in  
17 section 505B(f)(1).”

18           “(g) LIMITATIONS.—

19           “(1) IN GENERAL.—Notwithstanding subsection  
20 (c)(2), a drug to which the six-month period under  
21 subsection (b) or (c) has already been applied—

22           “(A) may receive an additional six-month  
23 period under subsection (c)(1)(A)(i)(II) for a  
24 supplemental application if all other require-  
25 ments under this section are satisfied; and

1           “(B) may not receive any additional such  
2 period under subsection (c)(1)(A)(ii).

3           “(2) EXCLUSIVITY ADJUSTMENT.—

4           “(A) IN GENERAL.—The Secretary may in  
5 accordance with this paragraph reduce by not  
6 more than 3 months the additional periods of  
7 market exclusivity that otherwise would apply  
8 under subsection (b) or (c) with respect to the  
9 drug involved.

10           “(B) REGULATIONS.—The Secretary shall  
11 by regulation establish criteria for determining  
12 whether a reduction under subparagraph (A)  
13 will be made with respect to a drug. Such cri-  
14 teria shall take into account—

15           “(i) the combined annual gross sales  
16 for all drugs with the same active moiety  
17 prior to the time the sponsor submits the  
18 results from an agreed upon written re-  
19 quest for a study under this section re-  
20 lative to the research and development ex-  
21 penses related to the requested study; and

22           “(ii) such other factors as the Sec-  
23 retary determines to be appropriate

24           “(C) DATE CERTAIN FOR ISSUANCE OF  
25 RULE; APPLICABILITY.—The final rule under

1           subparagraph (B) shall be promulgated and  
2           take effect not later than 180 days after the  
3           date of the enactment of the Best Pharma-  
4           ceuticals for Children Amendments of 2007.  
5           The authority under subparagraph (A) applies  
6           to each drug with respect to which an agree-  
7           ment to a request under subsection (b) or (c)  
8           is made on or after the effective date of such  
9           final rule.

10          “(h) RELATIONSHIP TO PEDIATRIC RESEARCH RE-  
11          QUIREMENTS.—Notwithstanding any other provision of  
12          law, if any pediatric study is required by a provision of  
13          law (including a regulation) other than this section and  
14          such study meets the completeness, timeliness, and other  
15          requirements of this section, such study shall be deemed  
16          to satisfy the requirement for market exclusivity pursuant  
17          to this section.

18          “(i) LABELING CHANGES.—

19                 “(1) PRIORITY STATUS FOR PEDIATRIC APPLI-  
20          CATIONS AND SUPPLEMENTS.—Any application or  
21          supplement to an application under section 505 pro-  
22          posing a labeling change as a result of any pediatric  
23          study conducted pursuant to this section—

24                         “(A) shall be considered to be a priority  
25                         application or supplement; and

1           “(B) shall be subject to the performance  
2 goals established by the Commissioner for pri-  
3 ority drugs.

4           “(2) DISPUTE RESOLUTION.—

5           “(A) REQUEST FOR LABELING CHANGE  
6 AND FAILURE TO AGREE.—If, on or after the  
7 date of the enactment of the Improving Phar-  
8 maceuticals for Children Act of 2007, the Com-  
9 missioner determines that the sponsor and the  
10 Commissioner have been unable to reach agree-  
11 ment on appropriate changes to the labeling for  
12 the drug that is the subject of the application,  
13 not later than 180 days after the date of sub-  
14 mission of the application—

15           “(i) the Commissioner shall request  
16 that the sponsor of the application make  
17 any labeling change that the Commissioner  
18 determines to be appropriate; and

19           “(ii) if the sponsor of the application  
20 does not agree within 30 days after the  
21 Commissioner’s request to make a labeling  
22 change requested by the Commissioner, the  
23 Commissioner shall refer the matter to the  
24 Pediatric Advisory Committee.

1           “(B) ACTION BY THE PEDIATRIC ADVISORY  
2           COMMITTEE.—Not later than 90 days after re-  
3           ceiving a referral under subparagraph (A)(ii),  
4           the Pediatric Advisory Committee shall—

5                     “(i) review the pediatric study reports;  
6                     and

7                     “(ii) make a recommendation to the  
8                     Commissioner concerning appropriate la-  
9                     beling changes, if any.

10           “(C) CONSIDERATION OF RECOMMENDA-  
11           TIONS.—The Commissioner shall consider the  
12           recommendations of the Pediatric Advisory  
13           Committee and, if appropriate, not later than  
14           30 days after receiving the recommendation,  
15           make a request to the sponsor of the applica-  
16           tion to make any labeling change that the Com-  
17           missioner determines to be appropriate.

18           “(D) MISBRANDING.—If the sponsor of the  
19           application, within 30 days after receiving a re-  
20           quest under subparagraph (c), does not agree to  
21           make a labeling change requested by the Com-  
22           missioner, the Commissioner may deem the  
23           drug that is the subject of the application to be  
24           misbranded.

1           “(E) NO EFFECT ON AUTHORITY.—Noth-  
2           ing in this subsection limits the authority of the  
3           United States to bring an enforcement action  
4           under this Act when a drug lacks appropriate  
5           pediatric labeling. Neither course of action (the  
6           Pediatric Advisory Committee process or an en-  
7           forcement action referred to in the preceding  
8           sentence) shall preclude, delay, or serve as the  
9           basis to stay the other course of action.

10          “(j) OTHER LABELING CHANGES.—If, on or after the  
11          date of the enactment of the Improving Pharmaceuticals  
12          for Children Act of 2007, the Secretary determines that  
13          a pediatric study conducted under this section does or does  
14          not demonstrate that the drug that is the subject of the  
15          study is safe and effective in pediatric populations or sub-  
16          populations, including whether such study results are in-  
17          conclusive, the Secretary shall order the labeling of such  
18          product to include information about the results of the  
19          study and a statement of the Secretary’s determination.

20          “(k) DISSEMINATION OF PEDIATRIC INFORMA-  
21          TION.—

22                 “(1) IN GENERAL.—Not later than 180 days  
23                 after the date of submission of a report on a pedi-  
24                 atric study under this section, the Secretary shall  
25                 make available to the public the medical, statistical,

1 and clinical pharmacology reviews of pediatric stud-  
2 ies conducted under subsection (b) or (c).

3 “(2) DISSEMINATION OF INFORMATION RE-  
4 GARDING LABELING CHANGES.—Beginning on the  
5 date of the enactment of the Improving Pharma-  
6 ceuticals for Children Act of 2007, the Secretary  
7 shall require that the sponsors of the studies that re-  
8 sult in labeling changes that are reflected in the an-  
9 nual summary developed pursuant to subsection  
10 (f)(3)(F) distribute, at least annually (or more fre-  
11 quently if the Secretary determines that it would be  
12 beneficial to the public health), such information to  
13 physicians and other health care providers.

14 “(3) EFFECT OF SUBSECTION.—Nothing in this  
15 subsection alters or amends section 301(j) of this  
16 Act or section 552 of title 5 or section 1905 of title  
17 18, United States Code.

18 “(1) ADVERSE EVENT REPORTING.—

19 “(1) REPORTING IN YEAR ONE.—Beginning on  
20 the date of the enactment of the Improving Pharma-  
21 ceuticals for Children Act of 2007, during the one-  
22 year period beginning on the date a labeling change  
23 is made pursuant to subsection (I), the Secretary  
24 shall ensure that all adverse event reports that have  
25 been received for such drug (regardless of when such

1 report was received) are referred to the Office of Pe-  
2 diatric Therapeutics established under section 6 of  
3 the Best Pharmaceuticals for Children Act (Public  
4 Law 107–109). In considering the reports, the Di-  
5 rector of such Office shall provide for the review of  
6 the reports by the Pediatric Advisory Committee, in-  
7 cluding obtaining any recommendations of such  
8 Committee regarding whether the Secretary should  
9 take action under this Act in response to such re-  
10 ports.

11 “(2) REPORTING IN SUBSEQUENT YEARS.—Fol-  
12 lowing the one-year period described in paragraph  
13 (1), the Secretary shall, as appropriate, refer to the  
14 Office of Pediatric Therapeutics all pediatric adverse  
15 event reports for a drug for which a pediatric study  
16 was conducted under this section. In considering  
17 such reports, the Director of such Office may pro-  
18 vide for the review of such reports by the Pediatric  
19 Advisory Committee, including obtaining any rec-  
20 ommendation of such Committee regarding whether  
21 the Secretary should take action in response to such  
22 reports.

23 “(3) EFFECT.—The requirements of this sub-  
24 section shall supplement, not supplant, other review  
25 of such adverse event reports by the Secretary.

1           “(m) CLARIFICATION OF INTERACTION OF MARKET  
2 EXCLUSIVITY UNDER THIS SECTION AND MARKET EX-  
3 CLUSIVITY AWARDED TO AN APPLICANT FOR APPROVAL  
4 OF A DRUG UNDER SECTION 505(j).—If a 180-day period  
5 under section 505(j)(5)(B)(iv) overlaps with a 6-month ex-  
6 clusivity period under this section, so that the applicant  
7 for approval of a drug under section 505(j) entitled to the  
8 180-day period under that section loses a portion of the  
9 180-day period to which the applicant is entitled for the  
10 drug, the 180-day period shall be extended from—

11           “(1) the date on which the 180-day period  
12 would have expired by the number of days of the  
13 overlap, if the 180-day period would, but for the ap-  
14 plication of this subsection, expire after the 6-month  
15 exclusivity period; or

16           “(2) the date on which the 6-month exclusivity  
17 period expires, by the number of days of the overlap  
18 if the 180-day period would, but for the application  
19 of this subsection, expire during the six-month exclu-  
20 sivity period.

21           “(n) REFERRAL IF PEDIATRIC STUDIES NOT COM-  
22 PLETED.—

23           “(1) IN GENERAL.—Beginning on the date of  
24 the enactment of the Improving Pharmaceuticals for  
25 Children Act of 2007, if pediatric studies have not

1       been completed under subsection (d) and if the Sec-  
2       retary, through the committee established under  
3       subsection (f), determines that there is a continuing  
4       need for information relating to the use of the drug  
5       in the pediatric population (including neonates, as  
6       appropriate), the Secretary shall—

7               “(A) for a drug for which listed patents  
8               have not expired, make a determination regard-  
9               ing whether an assessment shall be required to  
10              be submitted under section 505B; or

11              “(B) for a drug that has no listed patents  
12              or has 1 or more listed patents that have ex-  
13              pired, determine whether there are funds avail-  
14              able under section 736 to award a grant to con-  
15              duct the requested studies pursuant to para-  
16              graph (2).

17              “(2) FUNDING OF STUDIES.—If, pursuant to  
18              paragraph (1), the Secretary determines that there  
19              are funds available under section 736 to award a  
20              grant to conduct the requested pediatric studies,  
21              then the Secretary shall issue a proposal to award  
22              a grant to conduct the requested studies. If the Sec-  
23              retary determines that funds are not available under  
24              section 736, the Secretary shall refer the drug for  
25              inclusion on the list established under section 409I

1 of the Public Health Services Act or the conduct of  
2 studies.

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

5 “(A) a decision under paragraph (1)(A)  
6 not to require an assessment under section  
7 505B and the basis for such decision;

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

11 “(C) any decision under paragraph (2) to  
12 include a drug on the list established under sec-  
13 tion 409I of the Public Health Services Act.

14 “(4) EFFECT OF SUBSECTION.—Nothing in this  
15 subsection alters or amends section 301(j) of this  
16 Act or section 552 of title 5 or section 1905 of Title  
17 18, United States Code

18 “(o) PROMPT APPROVAL OF DRUGS UNDER SECTION  
19 505(j) WHEN PEDIATRIC INFORMATION IS ADDED TO LA-  
20 BELING.—

21 “(1) GENERAL RULE.—A drug for which an ap-  
22 plication has been submitted or approved under sec-  
23 tion 505(j) shall not be considered ineligible for ap-  
24 proval under that section or misbranded under sec-  
25 tion 502 on the basis that the labeling of the drug

1 omits a pediatric indication or any other aspect of  
2 labeling pertaining to pediatric use when the omitted  
3 indication or other aspect is protected by patent or  
4 by exclusivity under clause (iii) or (iv) of section  
5 505(j)(5)(F).

6 “(2) LABELING.—Notwithstanding clauses (iii)  
7 and (iv) of section 505(j)(5)(F), the Secretary may  
8 require that the labeling of a drug approved under  
9 section 505(j) that omits a pediatric indication or  
10 other aspect of labeling as described in paragraph  
11 (1) include—

12 “(A) a statement that, because of mar-  
13 keting exclusivity for a manufacturer—

14 “(i) the drug is not labeled for pedi-  
15 atric use; or

16 “(ii) in the case of a drug for which  
17 there is an additional pediatric use not re-  
18 ferred to in paragraph (1), the drug is not  
19 labeled for the pediatric use under para-  
20 graph (1); and

21 “(B) a statement of any appropriate pedi-  
22 atric contraindications, warnings, or pre-  
23 cautions that the Secretary considers necessary.

1           “(3) PRESERVATION OF PEDIATRIC EXCLU-  
2           SIVITY AND OTHER PROVISIONS.—This subsection  
3           does not affect—

4                   “(A) the availability or scope of exclusivity  
5           under this section;

6                   “(B) the availability or scope of exclusivity  
7           under section 505 for pediatric formulations;

8                   “(C) the question of the eligibility for ap-  
9           proval of any application under section 505(j)  
10          that omits any other conditions of approval en-  
11          titled to exclusivity under clause (iii) or (iv) of  
12          section 505(j)(5)(F); or

13                   “(D) except as expressly provided in para-  
14          graphs (1) and (2), the operation of section  
15          505.

16          “(p) INSTITUTE OF MEDICINE STUDY.—Not later  
17          than 3 years after the date of the enactment of the Im-  
18          proving Pharmaceuticals for Children Act of 2007, the  
19          Secretary shall enter into a contract with the Institute of  
20          Medicine to conduct a study and report to Congress re-  
21          garding the written requests made and the studies con-  
22          ducted pursuant to this section. The Institute of Medicine  
23          may devise an appropriate mechanism to review a rep-  
24          resentative sample of requests made and studies conducted

1 pursuant to this section in order to conduct such study.

2 Such study shall—

3 “(1) review such representative written requests  
4 issued by the Secretary since 1997 under sub-  
5 sections (b) and (c);

6 “(2) review and assess such representative pedi-  
7 atric studies conducted under subsections (b) and (c)  
8 since 1997 and labeling changes made as a result of  
9 such studies;

10 “(3) review the use of extrapolation for pedi-  
11 atric subpopulations, the use of alternative endpoints  
12 for pediatric populations, neonatal assessment tools,  
13 and ethical issues in pediatric clinical trials; and

14 “(4) make recommendations regarding appro-  
15 priate incentives for encouraging pediatric studies of  
16 biologics.

17 “(q) SUNSET.—A drug may not receive any 6-month  
18 period under subsection (b) or (c) unless—

19 “(1) on or before October 1, 2012, the Sec-  
20 retary makes a written request for pediatric studies  
21 of the drug;

22 “(2) on or before October 1, 2012, an applica-  
23 tion for the drug is accepted for filing under section  
24 505(b); and

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

1           (2) EFFECTIVE DATE.—The amendment made  
2           by this subsection shall apply to written requests  
3           under section 505A of the Federal Food, Drug, and  
4           Cosmetic Act (21 U.S.C. 355a) made after the date  
5           of the enactment of this Act.

6           (b) PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.—  
7           Section 409I of the Public Health Service Act (42 U.S.C.  
8           284m) is amended to read as follows:

9           **“SEC. 409I. PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.**

10          “(a) LIST OF PRIORITY ISSUES IN PEDIATRIC  
11          THERAPEUTICS.—

12                 “(1) IN GENERAL.—Not later than one year  
13                 after the date of the enactment of the Improving  
14                 Pharmaceuticals for Children Act of 2007, the Sec-  
15                 retary, acting through the Director of the National  
16                 Institutes of Health and in consultation with the  
17                 Commissioner of Food and Drugs and experts in pe-  
18                 diatric research, shall develop and publish a priority  
19                 list of needs in pediatric therapeutics, including  
20                 drugs or indications that require study. The list  
21                 shall be revised every three years.

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

1           “(A) therapeutic gaps in pediatrics that  
2           may include developmental pharmacology,  
3           pharmacogenetic determinants of drug re-  
4           sponse, metabolism of drugs and biologics in  
5           children, and pediatric clinical trials;

6           “(B) particular pediatric diseases, dis-  
7           orders or conditions where more complete  
8           knowledge and testing of therapeutics, including  
9           drugs and biologics, may be beneficial in pedi-  
10          atric populations; and

11          “(C) the adequacy of necessary infrastruc-  
12          ture to conduct pediatric pharmacological re-  
13          search, including research networks and trained  
14          pediatric investigators.

15          “(b) PEDIATRIC STUDIES AND RESEARCH.—The  
16          Secretary, acting through the National Institutes of  
17          Health, shall award funds to entities that have the exper-  
18          tise to conduct pediatric clinical trials or other research  
19          (including qualified universities, hospitals, laboratories,  
20          contract research organizations, practice groups, federally  
21          funded programs such as pediatric pharmacology research  
22          units, other public or private institutions, or individuals)  
23          to enable the entities to conduct the drug studies or other  
24          research on the issues described in subsection (a). The

1 Secretary may use contracts, grants or other appropriate  
2 funding mechanisms to award funds under this subsection.

3 “(c) PROCESS FOR PROPOSED PEDIATRIC STUDY  
4 REQUESTS AND LABELING CHANGES.—

5 “(1) SUBMISSION OF PROPOSED PEDIATRIC  
6 STUDY REQUEST.—The Director of the National In-  
7 stitutes of Health shall, as appropriate, submit pro-  
8 posed pediatric study requests for consideration by  
9 the Commissioner of the Food and Drugs for pedi-  
10 atric studies of a specific pediatric indication identi-  
11 fied under subsection (a). Such a proposed pediatric  
12 study request shall be made in a manner equivalent  
13 to a written request made under subsection (b) or  
14 (c) of Section 505A of the Federal Food, Drug, and  
15 Cosmetic Act (21 U.S.C. 355a), including with re-  
16 spect to the information provided on the pediatric  
17 studies to be conducted pursuant to the request. The  
18 Director of the National Institutes of Health may  
19 submit a proposed pediatric study request for a drug  
20 for which—

21 “(A)(i) there is an approved application  
22 under section 505(j) of the Federal Food,  
23 Drug, and Cosmetic Act (21 U.S.C. 355(j)); or

1           “(ii) there is a submitted application that  
2           could be approved under the criteria of such  
3           section; and

4           “(B) there is no patent protection or mar-  
5           ket exclusivity protection for at least one form  
6           of the drug under the Federal Food, Drug, and  
7           Cosmetic Act; and

8           “(C) additional studies are needed to as-  
9           sess the safety and effectiveness of the use of  
10          the drug in the pediatric population.

11          “(2) WRITTEN REQUEST TO HOLDERS OF AP-  
12          PROVED APPLICATIONS FOR DRUGS LACKING EXCLU-  
13          SIVITY.—The Commissioner of the Food and Drugs,  
14          in consultation with the Director of the National In-  
15          stitutes of Health, may issue a written request based  
16          on the proposed pediatric study request for the indi-  
17          cation or indications submitted pursuant to para-  
18          graph (1) (which shall include a timeframe for nego-  
19          tiations for an agreement) for pediatric studies con-  
20          cerning a drug identified under subsection (a) to all  
21          holders of an approved application for the drug  
22          under section 505 of the Federal Food, Drug, and  
23          Cosmetic Act (21 U.S.C. 355). Such a written re-  
24          quest shall be made in a manner equivalent to the  
25          manner in which a written request is made under

1 subsection (a) or (b) of section 505A of such Act  
2 (21 U.S.C. 355a), including with respect to informa-  
3 tion provided on the pediatric studies to be con-  
4 ducted pursuant to the request and using appro-  
5 priate formulations for each age group for which the  
6 study is requested.

7 “(3) REQUESTS FOR PROPOSALS.—If the Com-  
8 missioner of the Food and Drugs does not receive a  
9 response to a written request issued under para-  
10 graph (2) not later than 30 days after the date on  
11 which a request was issued, the Secretary, acting  
12 through the Director of the National Institutes of  
13 Health and in consultation with the Commissioner of  
14 the Food and Drugs, shall publish a request for pro-  
15 posals to conduct the pediatric studies described in  
16 the written request in accordance with subsection  
17 (b).

18 “(4) DISQUALIFICATION.—A holder that re-  
19 ceives a first right of refusal shall not be entitled to  
20 respond to a request for proposals under paragraph  
21 (3).

22 “(5) CONTRACTS, GRANTS, OR OTHER FUNDING  
23 MECHANISMS.—A contract, grant or other funding  
24 may be awarded under this section only if a proposal  
25 is submitted to the Secretary in such form and man-

1 ner, and containing such agreements, assurances,  
2 and information as the Secretary determines to be  
3 necessary to carry out this section.

4 “(6) REPORTING OF STUDIES.—

5 “(A) IN GENERAL.—On completion of a  
6 pediatric study in accordance with an award  
7 under this section, a report concerning the  
8 study shall be submitted to the Director of the  
9 National Institutes of Health and the Commis-  
10 sioner of Food and Drugs. The report shall in-  
11 clude all data generated in connection with the  
12 study, including a written request if issued.

13 “(B) AVAILABILITY OF REPORTS.—Each  
14 report submitted under subparagraph (A) shall  
15 be considered to be in the public domain (sub-  
16 ject to section 505A(d)(4)(D) of the Federal  
17 Food, Drug, and Cosmetic Act (21 U.S.C.  
18 355a(d)(4)(D)) and shall be assigned a docket  
19 number by the Commissioner of Food and  
20 Drugs. An interested person may submit writ-  
21 ten comments concerning such pediatric studies  
22 to the Commissioner of Food and Drugs, and  
23 the written comments shall become part of the  
24 docket file with respect to each of the drugs.

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

6           “(7) REQUESTS FOR LABELING CHANGE.—Dur-  
7           ing the 180-day period after the date on which a re-  
8           port is submitted under paragraph (6)(A), the Com-  
9           missioner of Food and Drugs shall—

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

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

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

22           “(ii) publish in the Federal Register and  
23           through a posting on the website of the Food  
24           and Drug Administration a summary of the re-

1 port and a copy of any requested labeling  
2 changes.

3 “(8) DISPUTE RESOLUTION.—

4 “(A) REFERRAL TO PEDIATRIC ADVISORY  
5 COMMITTEE.—If, not later than the end of the  
6 180-day period specified in paragraph (7), the  
7 holder of an approved application for the drug  
8 involved does not agree to any labeling change  
9 requested by the Commissioner of Food and  
10 Drugs under that paragraph, the Commissioner  
11 of Food and Drugs shall refer the request to  
12 the Pediatric Advisory Committee.

13 “(B) ACTION BY THE PEDIATRIC ADVISORY  
14 COMMITTEE.—Not later than 90 days after re-  
15 ceiving a referral under subparagraph (A), the  
16 Pediatric Advisory Committee shall—

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

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

24 “(9) FDA DETERMINATION.—Not later than 30  
25 days after receiving a recommendation from the Pe-

1       diatric Advisory Committee under paragraph  
2       (8)(B)(ii) with respect to a drug, the Commissioner  
3       of Food and Drugs shall consider the recommenda-  
4       tion and, if appropriate, make a request to the hold-  
5       ers of approved applications for the drug to make  
6       any labeling change that the Commissioner of Food  
7       and Drugs determines to be appropriate.

8               “(10) FAILURE TO AGREE.—If a holder of an  
9       approved application for a drug, within 30 days  
10      after receiving a request to make a labeling change  
11      under paragraph (9), does not agree to make a re-  
12      quested labeling change, the Commissioner of Food  
13      and Drugs may deem the drug to be misbranded  
14      under the Federal Food, Drug, and Cosmetic Act  
15      (21 U.S.C. 301 et seq.).

16              “(11) NO EFFECT ON AUTHORITY.—Nothing in  
17      this subsection limits the authority of the United  
18      States to bring an enforcement action under the  
19      Federal Food, Drug, and Cosmetic Act when a drug  
20      lacks appropriate pediatric labeling. Neither course  
21      of action (the Pediatric Advisory Committee process  
22      or an enforcement action referred to in the pre-  
23      ceding sentence) shall preclude, delay, or serve as  
24      the basis to stay the other course of action.

1           “(d) DISSEMINATION OF PEDIATRIC INFORMA-  
2 TION.—Not later than one year after the date of the enact-  
3 ment of the Improving Pharmaceuticals for Children Act  
4 of 2007, the Secretary, acting through the Director of the  
5 National Institutes of Health, shall study the feasibility  
6 of establishing a compilation of information on pediatric  
7 drug use and report the findings to Congress.

8           “(e) AUTHORIZATION OF APPROPRIATIONS.—

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

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

12                     and

13                     “(B) such sums as are necessary for each  
14 of the four succeeding fiscal years.

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

18           “(c) FEES RELATING TO DRUGS.—Section 735(6) of  
19 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
20 379(6)) is amended by adding at the end the following  
21 new subparagraph:

22                     “(G) Activities relating to the support of  
23 studies of drugs on pediatric populations under  
24 section 505A(n)(1).”.

25           “(d) TRAINING OF PEDIATRIC PHARMACOLOGISTS.—

1           (1) INVESTMENT IN TOMORROW'S PEDIATRIC  
2 RESEARCHERS.—Section 452G(2) of the Public  
3 Health Service Act (42 U.S.C. 285g–10(2)) is  
4 amended by inserting before the period at the end  
5 the following: “, including pediatric pharmacological  
6 research”.

7           (2) PEDIATRIC RESEARCH LOAN REPAYMENT  
8 PROGRAM.—Section 487F(a)(1) of the Public Health  
9 Service Act (42 U.S.C. 288–6(a)(1)) is amended by  
10 inserting “including pediatric pharmacological re-  
11 search,” after “pediatric research,”.

12          (e) FOUNDATION FOR THE NATIONAL INSTITUTES  
13 OF HEALTH.—Section 499(c)(1)(c) of the Public Health  
14 Service Act (42 U.S.C. 290b(c)(1)(c)) is amended by  
15 striking “and studies listed by the Secretary pursuant to  
16 section 409I(a)(1)(A) of this Act and referred under sec-  
17 tion 505A(d)(4)(c) of the Federal Food, Drug, and Cos-  
18 metic Act (21 U.S.C. 355(a)(d)(4)(c))”.

19          (f) CONTINUATION OF OPERATION OF COM-  
20 MITTEE.—Section 14 of the Best Pharmaceuticals for  
21 Children Act (42 U.S.C. 284m note) is amended by adding  
22 at the end the following new subsection:

23          “(d) CONTINUATION OF OPERATION OF COM-  
24 MITTEE.—Notwithstanding section 14 of the Federal Ad-  
25 visory Committee Act (5 U.S.C. App.), the advisory com-

1 mittee shall continue to operate during the five-year period  
2 beginning on the date of the enactment of the Improving  
3 Pharmaceuticals for Children Act of 2007.”.

4 (g) PEDIATRIC SUBCOMMITTEE OF THE ONCOLOGIC  
5 DRUGS ADVISORY COMMITTEE.—Section 15 of the Best  
6 Pharmaceuticals for Children Act (42 U.S.C. 284m note)  
7 is amended—

8 (1) in subsection (a)—

9 (A) in paragraph (1)—

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

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

15 (iii) by adding at the end the fol-  
16 lowing new subparagraph:

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

1 (B) by adding at the end the following new  
2 paragraph:

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

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

12 (h) EFFECTIVE DATE AND LIMITATION FOR RULE  
13 RELATING TO TOLL-FREE NUMBER FOR ADVERSE  
14 EVENTS ON LABELING FOR HUMAN DRUG PRODUCTS.—

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

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

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

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

12           (C) the packaging of which includes a toll-  
13 free number through which consumers can re-  
14 port complaints to the manufacturer or dis-  
15 tributor of the drug.