

[COMMITTEE PRINT]

[SHOWING TEXT OF COMMITTEE PRINT AS APPROVED BY SUBCOMMITTEE ON HEALTH ON JUNE 19, 2007]

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. SHORT TITLE.**

4 This Act may be cited as the “Best Pharmaceuticals
5 for Children Act of 2007”.

6 **SEC. 2. REAUTHORIZATION OF BEST PHARMACEUTICALS**
7 **FOR CHILDREN ACT.**

8 (a) PEDIATRIC STUDIES OF DRUGS.—

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

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

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

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

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

1 section (d)(3), and if the Secretary determines that
2 labeling changes are appropriate, such changes are
3 made within the timeframe requested by the Sec-
4 retary—

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

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

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

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

2 “(I) a listed patent for which a certifi-
3 cation has been submitted under sub-
4 section (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of
5 section 505 and for which pediatric studies
6 were submitted prior to the expiration of
7 the patent (including any patent exten-
8 sions); or

9 “(II) a listed patent for which a cer-
10 tification has been submitted under sub-
11 sections (b)(2)(A)(iii) or (j)(2)(A)(vii)(III)
12 of section 505,

13 the period during which an application may not
14 be approved under section 505(c)(3) or section
15 505(j)(5)(B) shall be extended by a period of
16 six months after the date the patent expires (in-
17 cluding any patent extensions); or

18 “(ii) if the drug is the subject of a listed
19 patent for which a certification has been sub-
20 mitted under subsection (b)(2)(A)(iv) or
21 (j)(2)(A)(vii)(IV) of section 505, and in the pat-
22 ent infringement litigation resulting from the
23 certification the court determines that the pat-
24 ent is valid and would be infringed, the period
25 during which an application may not be ap-

1 proved under section 505(c)(3) or section
2 505(j)(5)(B) shall be extended by a period of
3 six months after the date the patent expires (in-
4 cluding any patent extensions).

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

9 “(c) MARKET EXCLUSIVITY FOR ALREADY-MAR-
10 KETED DRUGS.—

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

1 appropriate and such changes are approved within
2 the timeframe requested by the Secretary—

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

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

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

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

1 “(I) a listed patent for which a certifi-
2 cation has been submitted under sub-
3 section (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of
4 section 505 and for which pediatric studies
5 were submitted prior to the expiration of
6 the patent (including any patent exten-
7 sions); or

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

12 the period during which an application may not
13 be approved under section 505(c)(3) or section
14 505(j)(5)(B)(ii) shall be extended by a period of
15 six months after the date the patent expires (in-
16 cluding any patent extensions); or

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

1 505(j)(5)(B) shall be extended by a period of
2 six months after the date the patent expires (in-
3 cluding any patent extensions)

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

8 “(d) CONDUCT OF PEDIATRIC STUDIES.—

9 “(1) REQUEST FOR STUDIES.—

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

1 “(B) SINGLE WRITTEN REQUEST.—A sin-
2 gle written request—

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

5 “(ii) may include uses that are both
6 approved and unapproved.

7 “(2) WRITTEN REQUEST FOR PEDIATRIC STUD-
8 IES.—

9 “(A) REQUEST AND RESPONSE.—

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

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

23 “(II) indicating that the appli-
24 cant or holder does not agree to the

1 request and stating the reasons for
2 declining the request.

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

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

23 “(3) MEETING THE STUDIES REQUIREMENT.—
24 Not later than 180 days after the submission of the
25 reports of the studies, the Secretary shall accept or

1 reject such reports and so notify the sponsor or
2 holder. The Secretary's only responsibility in accept-
3 ing or rejecting the reports shall be to determine,
4 within the 180-day period, whether the studies fairly
5 respond to the written request, have been conducted
6 in accordance with commonly accepted scientific
7 principles and protocols, and have been reported in
8 accordance with the requirements of the Secretary
9 for filing.

10 “(4) EFFECT OF SUBSECTION.—Nothing in this
11 subsection alters or amends section 301(j) of this
12 Act or section 552 of title 5 or section 1905 of title
13 18, United States Code.

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 the enactment of the Best Pharmaceuticals
19 for Children Act of 2007, that the requirements of
20 subsection (d) have been met and that submissions
21 and approvals under subsection (b)(2) or (j) of sec-
22 tion 505 for a drug will be subject to the provisions
23 of this section. Such notice shall be published not
24 later than 30 days after the date of the Secretary's
25 determination regarding market exclusivity and shall

1 include a copy of the written request made under
2 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 the enact-
6 ment of the Best Pharmaceuticals for Children Act
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 one year after the date that
12 the 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 one 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 establish an internal review committee to review
21 all written requests issued on or after the date
22 of the enactment of the Best Pharmaceuticals
23 for Children Act of 2007, in accordance with
24 paragraph (2).

1 “(B) MEMBERS.—The committee estab-
2 lished under subparagraph (A) shall include in-
3 dividuals with expertise in pediatrics, biophar-
4 macology, statistics, drugs and drug formula-
5 tions, legal issues, pediatric ethics, the appro-
6 priate expertise, such as expertise in child and
7 adolescent psychiatry, pertaining to the pedi-
8 atric product under review, one or more experts
9 from the Office of Pediatric Therapeutics, and
10 other individuals designated by the Secretary.

11 “(2) REVIEW OF WRITTEN REQUESTS.—The
12 committee established under paragraph (1) shall re-
13 view all written requests issued pursuant to this sec-
14 tion prior to being issued.

15 “(3) TRACKING PEDIATRIC STUDIES AND LA-
16 BELING CHANGES.—The Secretary shall track and
17 make available to the public, in an easily accessible
18 manner, including through posting on the website of
19 the Food and Drug Administration—

20 “(A) the number of studies conducted
21 under this section and under section 409I of
22 the Public Health Service Act (42 U.S.C.
23 284m);

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

4 “(C) the types of studies conducted under
5 such sections, including trial design, the num-
6 ber of pediatric patients studied, and the num-
7 ber of centers and countries involved;

8 “(D) the number of pediatric formulations
9 developed and the number of pediatric formula-
10 tions not developed and the reasons such for-
11 mulations were not developed;

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

14 “(F) an annual summary of labeling
15 changes made as a result of studies conducted
16 under such sections for distribution pursuant to
17 subsection (k)(2); and

18 “(G) information regarding reports sub-
19 mitted on or after the date of the enactment of
20 the Best Pharmaceuticals for Children Act of
21 2007.

22 “(4) COMMITTEE.—The Committee established
23 under paragraph (1) is the committee established in
24 section 505B(f)(1).”

1 “(g) LIMITATIONS.—Notwithstanding subsection
2 (c)(2), a drug to which the six-month period under sub-
3 section (b) or (c) has already been applied—

4 “(1) may receive an additional six-month period
5 under subsection (c)(1)(A)(i)(II) for a supplemental
6 application if all other requirements under this sec-
7 tion are satisfied; and

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

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 Best Pharma-
8 ceuticals for Children Act of 2007, the Commis-
9 sioner 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
21 to make a labeling change requested by the
22 Commissioner, 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 Best Pharmaceuticals for
12 Children Act of 2007, the Secretary determines that a pe-
13 diatric 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 Best Pharmaceuticals
6 for Children Act of 2007, the Secretary shall include
7 as a requirement of a written request that the spon-
8 sors of the studies that result in labeling changes
9 that are reflected in the annual summary developed
10 pursuant to subsection (f)(3)(F) distribute, at least
11 annually (or more frequently if the Secretary deter-
12 mines that it would be beneficial to the public
13 health), such information to physicians and other
14 health care providers.

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

19 “(1) ADVERSE EVENT REPORTING.—

20 “(1) REPORTING IN YEAR ONE.—Beginning on
21 the date of the enactment of the Best Pharma-
22 ceuticals for Children Act of 2007, during the one-
23 year period beginning on the date a labeling change
24 is approved pursuant to subsection (i), the Secretary
25 shall ensure that all adverse event reports that have

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

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

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

4 “(m) CLARIFICATION OF INTERACTION OF MARKET
5 EXCLUSIVITY UNDER THIS SECTION AND MARKET EX-
6 CLUSIVITY AWARDED TO AN APPLICANT FOR APPROVAL
7 OF A DRUG UNDER SECTION 505(j).—If a 180-day period
8 under section 505(j)(5)(B)(iv) overlaps with a 6-month ex-
9 clusivity period under this section, so that the applicant
10 for approval of a drug under section 505(j) entitled to the
11 180-day period under that section loses a portion of the
12 180-day period to which the applicant is entitled for the
13 drug, the 180-day period shall be extended from—

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

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

24 “(n) REFERRAL IF PEDIATRIC STUDIES NOT COM-
25 PLETED.—

1 “(1) IN GENERAL.—Beginning on the date of
2 the enactment of the Best Pharmaceuticals for Chil-
3 dren Act of 2007, if pediatric studies have not been
4 completed under subsection (d) and if the Secretary,
5 through the committee established under subsection
6 (f), determines that there is a continuing need for
7 information relating to the use of the drug in the pe-
8 diatric population (including neonates, as appro-
9 priate), the Secretary shall—

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

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

20 “(2) FUNDING OF STUDIES.—If, pursuant to
21 paragraph (1), the Secretary determines that there
22 are funds available under section 736 to award a
23 grant to conduct the requested pediatric studies,
24 then the Secretary shall issue a proposal to award
25 a grant to conduct the requested studies. If the Sec-

1 retary determines that funds are not available under
2 section 736, the Secretary shall refer the drug for
3 inclusion on the list established under section 409I
4 of the Public Health Service Act or the conduct of
5 studies.

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

8 “(A) a decision under paragraph (1)(A)
9 not to require an assessment under section
10 505B and the basis for such decision;

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

14 “(C) any decision under paragraph (2) to
15 include a drug on the list established under sec-
16 tion 409I of the Public Health Service Act.

17 “(4) EFFECT OF SUBSECTION.—Nothing in this
18 subsection alters or amends section 301(j) of this
19 Act or section 552 of title 5 or section 1905 of Title
20 18, United States Code

21 “(o) PROMPT APPROVAL OF DRUGS UNDER SECTION
22 505(j) WHEN PEDIATRIC INFORMATION IS ADDED TO LA-
23 BELING.—

24 “(1) GENERAL RULE.—A drug for which an ap-
25 plication has been submitted or approved under sec-

1 tion 505(j) shall not be considered ineligible for ap-
2 proval under that section or misbranded under sec-
3 tion 502 on the basis that the labeling of the drug
4 omits a pediatric indication or any other aspect of
5 labeling pertaining to pediatric use when the omitted
6 indication or other aspect is protected by patent or
7 by exclusivity under clause (iii) or (iv) of section
8 505(j)(5)(F).

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

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

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

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

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

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

7 “(A) the availability or scope of exclusivity
8 under this section;

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

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

16 “(D) except as expressly provided in para-
17 graphs (1) and (2), the operation of section
18 505.

19 “(p) INSTITUTE OF MEDICINE STUDY.—Not later
20 than 3 years after the date of the enactment of the Best
21 Pharmaceuticals for Children Act of 2007, the Secretary
22 shall enter into a contract with the Institute of Medicine
23 to conduct a study and report to Congress regarding the
24 written requests made and the studies conducted pursuant
25 to this section. The Institute of Medicine may devise an

1 appropriate mechanism to review a representative sample
2 of requests made and studies conducted pursuant to this
3 section in order to conduct such study. Such study shall—

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

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

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

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

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

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

23 “(2) on or before October 1, 2012, an applica-
24 tion for the drug is accepted for filing under section
25 505(b); and

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

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

7 (b) PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.—
8 Section 409I of the Public Health Service Act (42 U.S.C.
9 284m) is amended to read as follows:

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

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

13 “(1) IN GENERAL.—Not later than one year
14 after the date of the enactment of the Best Pharma-
15 ceuticals for Children Act of 2007, the Secretary,
16 acting through the Director of the National Insti-
17 tutes of Health and in consultation with the Com-
18 missioner of Food and Drugs and experts in pedi-
19 atric research, shall develop and publish a priority
20 list of needs in pediatric therapeutics, including
21 drugs or indications that require study. The list
22 shall be revised every three years.

23 “(2) CONSIDERATION OF AVAILABLE INFORMA-
24 TION.—In developing and prioritizing the list under
25 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 Food and Drugs for pediatric
10 studies of a specific pediatric indication identified
11 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 Food and Drugs, in
14 consultation with the Director of the National Insti-
15 tutes 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 Food and Drugs does not receive a re-
9 sponse to a written request issued under paragraph
10 (2) not later than 30 days after the date on which
11 a request was issued, the Secretary, acting through
12 the Director of the National Institutes of Health and
13 in consultation with the Commissioner of Food and
14 Drugs, shall publish a request for proposals to con-
15 duct the pediatric studies described in the written
16 request in accordance with subsection (b).

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

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

1 and information as the Secretary determines to be
2 necessary to carry out this section.

3 “(6) REPORTING OF STUDIES.—

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

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

24 “(C) ACTION BY COMMISSIONER.—The
25 Commissioner of Food and Drugs shall take ap-

1 appropriate action in response to the reports sub-
2 mitted under subparagraph (A) in accordance
3 with paragraph (7).

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

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

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

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

20 “(ii) publish in the Federal Register and
21 through a posting on the website of the Food
22 and Drug Administration a summary of the re-
23 port and a copy of any requested labeling
24 changes.

25 “(8) DISPUTE RESOLUTION.—

1 “(A) REFERRAL TO PEDIATRIC ADVISORY
2 COMMITTEE.—If, not later than the end of the
3 180-day period specified in paragraph (7), the
4 holder of an approved application for the drug
5 involved does not agree to any labeling change
6 requested by the Commissioner of Food and
7 Drugs under that paragraph, the Commissioner
8 of Food and Drugs shall refer the request to
9 the Pediatric Advisory Committee.

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

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

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

21 “(9) FDA DETERMINATION.—Not later than 30
22 days after receiving a recommendation from the Pe-
23 diatric Advisory Committee under paragraph
24 (8)(B)(ii) with respect to a drug, the Commissioner
25 of Food and Drugs shall consider the recommenda-

1 tion and, if appropriate, make a request to the hold-
2 ers of approved applications for the drug to make
3 any labeling change that the Commissioner of Food
4 and Drugs determines to be appropriate.

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

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

22 “(d) DISSEMINATION OF PEDIATRIC INFORMA-
23 TION.—Not later than one year after the date of the enact-
24 ment of the Best Pharmaceuticals for Children Act of
25 2007, the Secretary, acting through the Director of the

1 National Institutes of Health, shall study the feasibility
2 of establishing a compilation of information on pediatric
3 drug use and report the findings to Congress.

4 “(e) AUTHORIZATION OF APPROPRIATIONS.—

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

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

8 and

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

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

14 (c) FEES RELATING TO DRUGS.—Section 735(6) of
15 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
16 379(6)) is amended by adding at the end the following
17 new subparagraph:

18 “(G) Activities relating to the support of
19 studies of drugs on pediatric populations under
20 section 505A(n)(1).”.

21 (d) FOUNDATION FOR THE NATIONAL INSTITUTES
22 OF HEALTH.—Section 499(c)(1)(C) of the Public Health
23 Service Act (42 U.S.C. 290b(c)(1)(C)) is amended by
24 striking “and studies listed by the Secretary pursuant to
25 section 409I(a)(1)(A) of this Act and referred under sec-

1 tion 505A(d)(4)(C) of the Federal Food, Drug, and Cos-
2 metic Act (21 U.S.C. 355(a)(d)(4)(C))”.

3 (e) CONTINUATION OF OPERATION OF COM-
4 MITTEE.—Section 14 of the Best Pharmaceuticals for
5 Children Act (42 U.S.C. 284m note) is amended by adding
6 at the end the following new subsection:

7 “(d) CONTINUATION OF OPERATION OF COM-
8 MITTEE.—Notwithstanding section 14 of the Federal Ad-
9 visory Committee Act (5 U.S.C. App.), the advisory com-
10 mittee shall continue to operate during the five-year period
11 beginning on the date of the enactment of the Best Phar-
12 maceuticals for Children Act of 2007.”.

13 (f) PEDIATRIC SUBCOMMITTEE OF THE ONCOLOGIC
14 DRUGS ADVISORY COMMITTEE.—Section 15 of the Best
15 Pharmaceuticals for Children Act (42 U.S.C. 284m note)
16 is amended—

17 (1) in subsection (a)—

18 (A) in paragraph (1)—

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

21 (ii) in subparagraph (C), by striking
22 the period at the end and inserting “;
23 and”; and

24 (iii) by adding at the end the fol-
25 lowing new subparagraph:

1 “(D) provide recommendations to the in-
2 ternal review committee created under section
3 505A(f) of the Federal Food, Drug, and Cos-
4 metic Act (21 U.S.C. 355a(f)) regarding the
5 implementation of amendments to sections
6 505A and 505B of the Federal Food, Drug,
7 and Cosmetic Act (21 U.S.C. 355a and 355c)
8 with respect to the treatment of pediatric can-
9 cers.”; and

10 (B) by adding at the end the following new
11 paragraph:

12 “(3) CONTINUATION OF OPERATION OF SUB-
13 COMMITTEE.—Notwithstanding section 14 of the
14 Federal Advisory Committee Act (5 U.S.C. App.),
15 the Subcommittee shall continue to operate during
16 the five-year period beginning on the date of the en-
17 actment of the Best Pharmaceuticals for Children
18 Act of 2007.”; and

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

21 (g) EFFECTIVE DATE AND LIMITATION FOR RULE
22 RELATING TO TOLL-FREE NUMBER FOR ADVERSE
23 EVENTS ON LABELING FOR HUMAN DRUG PRODUCTS.—

24 (1) IN GENERAL.—Notwithstanding subchapter
25 II of chapter 5, and chapter 7, of title 5, United

1 States Code (commonly known as the “Administra-
2 tive Procedure Act”) and any other provision of law,
3 the proposed rule issued by the Commissioner of
4 Food and Drugs entitled “Toll-Free Number for Re-
5 porting Adverse Events on Labeling for Human
6 Drug Products,” 69 Fed. Reg. 21778, (April 22,
7 2004) shall take effect on January 1, 2008, unless
8 such Commissioner issues the final rule before such
9 date.

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

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

18 (B) that is not described under section
19 503(b)(1) of such Act (21 U.S.C. 353(b)(1));
20 and

21 (C) the packaging of which includes a toll-
22 free number through which consumers can re-
23 port complaints to the manufacturer or dis-
24 tributor of the drug.