

107TH CONGRESS
1ST SESSION

H. R. 2887

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

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 13, 2001

Mr. GREENWOOD (for himself, Ms. ESHOO, Mr. UPTON, Mr. WYNN, Mr. BUYER, Mr. RUSH, Mr. BRADY of Pennsylvania, Ms. ROYBAL-ALLARD, and Ms. LOFGREN) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

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

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

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

6 **SEC. 2. PEDIATRIC STUDIES OF ALREADY-MARKETED**
7 **DRUGS.**

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

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

2 (2) in subsection (c)—

3 (A) by inserting after “the Secretary” the
4 following: “determines that information relating
5 to the use of an approved drug in the pediatric
6 population may produce health benefits in that
7 population and”; and

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

10 **SEC. 3. RESEARCH FUND FOR THE STUDY OF DRUGS LACK-**
11 **ING EXCLUSIVITY.**

12 Part B of title IV of the Public Health Service Act
13 (42 U.S.C. 284 et seq.) is amended—

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

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

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

21 **“SEC. 409I. PROGRAM FOR PEDIATRIC STUDIES OF DRUGS**
22 **LACKING EXCLUSIVITY.**

23 “(a) LIST OF DRUGS LACKING EXCLUSIVITY FOR
24 WHICH PEDIATRIC STUDIES ARE NEEDED.—

1 “(1) IN GENERAL.—Not later than 1 year after
2 the date of enactment of this section, the Secretary,
3 acting through the Director of the National Insti-
4 tutes of Health and in consultation with the Com-
5 missioner of Food and Drugs and experts in pedi-
6 atric research, shall develop, prioritize, and publish
7 an annual list of approved drugs for which—

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

11 “(ii) there is a submitted application that
12 could be approved under the criteria of section
13 505(j) of the Federal Food, Drug, and Cos-
14 metic Act (21 U.S.C. 355(j)); or

15 “(iii) there is no patent protection or mar-
16 ket exclusivity protection under the Federal
17 Food, Drug, and Cosmetic Act (21 U.S.C. 301
18 et seq.); and

19 “(B) additional studies are needed to as-
20 sess the safety and effectiveness of the use of
21 the drug in the pediatric population.

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

1 “(A) the availability of information con-
2 cerning the safe and effective use of the drug
3 in the pediatric population;

4 “(B) whether additional information is
5 needed;

6 “(C) whether new pediatric studies con-
7 cerning the drug may produce health benefits in
8 the pediatric population; and

9 “(D) whether reformulation of the drug is
10 necessary;

11 “(b) CONTRACTS FOR PEDIATRIC STUDIES.—The
12 Secretary shall award contracts to entities that have the
13 expertise to conduct pediatric clinical trials (including
14 qualified universities, hospitals, laboratories, contract re-
15 search organizations, federally funded programs such as
16 pediatric pharmacology research units, other public or pri-
17 vate institutions, or individuals) to enable the entities to
18 conduct pediatric studies concerning one or more drugs
19 identified in the list described in subsection (a).

20 “(c) PROCESS FOR CONTRACTS AND LABELING
21 CHANGES.—

22 “(1) WRITTEN REQUEST TO HOLDERS OF AP-
23 PROVED APPLICATIONS FOR DRUGS LACKING EXCLU-
24 SIVITY.—

1 “(A) IN GENERAL.—The Commissioner of
2 Food and Drugs, in consultation with the Di-
3 rector of National Institutes of Health, may
4 issue a written request (which shall include a
5 timeframe for negotiations for an agreement)
6 for pediatric studies concerning a drug identi-
7 fied in the list described in subsection (a) to all
8 holders of an approved application for the drug
9 under section 505 of the Federal Food, Drug,
10 and Cosmetic Act. Such a request shall be
11 made in accordance with section 505A of the
12 Federal Food, Drug, and Cosmetic Act.

13 “(B) PUBLICATION OF REQUEST.—If the
14 Commissioner of Food and Drugs does not re-
15 ceive a response to a written request issued
16 under subparagraph (A) within 30 days of the
17 date on which a request was issued, the Sec-
18 retary, acting through the Director of National
19 Institutes of Health and in consultation with
20 the Commissioner of Food and Drugs, shall
21 publish a request for contract proposals to con-
22 duct the pediatric studies described in the writ-
23 ten request.

24 “(C) DISQUALIFICATION.—A holder that
25 receives a first right of refusal shall not be enti-

1 tled to respond to a request for contract pro-
2 posals under subparagraph (B).

3 “(D) GUIDANCE.—Not later than 270 days
4 after the date of enactment of this section, the
5 Commissioner of Food and Drugs shall promul-
6 gate guidance to establish the process for the
7 submission of responses to written requests
8 under subparagraph (A).

9 “(2) CONTRACTS.—A contract under this sec-
10 tion may be awarded only if a proposal for the con-
11 tract is submitted to the Secretary in such form and
12 manner, and containing such agreements, assur-
13 ances, and information as the Secretary determines
14 to be necessary to carry out this section.

15 “(3) REPORTING OF STUDIES.—

16 “(A) Upon completion of a pediatric study
17 in accordance with a contract awarded under
18 this section, a report concerning the study shall
19 be submitted to the Director of National Insti-
20 tutes of Health and the Commissioner of Food
21 and Drugs. The report shall include all data
22 generated in connection with the study.

23 “(B) AVAILABILITY OF REPORTS.—Each
24 report submitted under subparagraph (A) shall
25 be considered to be in the public domain, and

1 shall be assigned a docket number by the Com-
2 missioner of Food and Drugs. An interested
3 person may submit written comments con-
4 cerning such pediatric studies to the Commis-
5 sioner of Food and Drugs, and the written com-
6 ments shall become part of the docket file with
7 respect to each of the drugs.

8 “(C) ACTION BY COMMISSIONER.—The
9 Commissioner of Food and Drugs shall take ap-
10 propriate action in response to the reports sub-
11 mitted under subparagraph (A) in accordance
12 with paragraph (4).

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

17 “(A) review the report and such other data
18 as are available concerning the safe and effec-
19 tive use in the pediatric population of the drug
20 studied; and

21 “(B) negotiate with the holders of ap-
22 proved applications for the drug studied for any
23 labeling changes that the Commissioner of Food
24 and Drugs determines to be appropriate and re-
25 quests the holders to make; and

1 “(C)(i) place in the public docket file a
2 copy of the report and of any requested labeling
3 changes; and

4 “(ii) publish in the Federal Register a
5 summary of the report and a copy of any re-
6 quested labeling changes.

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

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

17 “(B) not later than 90 days after receiving
18 the referral, the Subcommittee shall—

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

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

1 “(6) FDA DETERMINATION.—Not later than 30
2 days after receiving a recommendation from the
3 Subcommittee under paragraph (5)B(ii) with respect
4 to a drug, the Commissioner of Food and Drugs
5 shall consider the recommendation and, if appro-
6 priate, make a request to the holders of approved
7 applications for the drug to make any labeling
8 change that the Commissioner of Food and Drugs
9 determines to be appropriate.

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

17 “(8) RECOMMENDATION FOR FORMULATION
18 CHANGES.—If a pediatric study completed under
19 public contract indicates that a formulation change
20 is necessary and the Secretary agrees, the Secretary
21 shall send a nonbinding letter of recommendation re-
22 garding that change to each holder of an approved
23 application.

24 “(d) AUTHORIZATION OF APPROPRIATIONS.—

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

3 “(A) \$200,000,000 for fiscal year 2002;
4 and

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

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

10 **SEC. 4. TIMELY LABELING CHANGES FOR DRUGS GRANTED**
11 **EXCLUSIVITY; DRUG FEES.**

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

16 (1) by striking subparagraph (F); and

17 (2) by redesignating subparagraph (G) as sub-
18 paragraph (F).

19 (b) LABELING CHANGES.—

20 (1) DEFINITION OF PRIORITY SUPPLEMENT.—
21 Section 201 of the Federal Food Drug, and Cos-
22 metic Act (21 U.S.C. 321) is amended by adding at
23 the end the following:

24 “(kk) PRIORITY SUPPLEMENT.—The term ‘pri-
25 ority supplement’ means a drug application referred

1 to in section 101(4) of the Food and Drug Adminis-
2 tration Modernization Act of 1997 (111 Stat.
3 2298).”.

4 (2) TREATMENT AS PRIORITY SUPPLEMENTS.—
5 Section 505A of the Federal Food, Drug, and Cos-
6 metic Act (21 U.S.C. 355a) is amended by adding
7 at the end the following:

8 “(1) LABELING SUPPLEMENTS.—

9 “(1) PRIORITY STATUS FOR PEDIATRIC SUP-
10 PLEMENTS.—Any supplement to an application
11 under section 505 proposing a labeling change pur-
12 suant to a report on a pediatric study under this
13 section—

14 “(A) shall be considered to be a priority
15 supplement; and

16 “(B) shall be subject to the performance
17 goals established by the Commissioner for pri-
18 ority drugs.

19 “(2) DISPUTE RESOLUTION.—If the Commis-
20 sioner determines that an application with respect to
21 which a pediatric study is conducted under this sec-
22 tion is approvable and that the only open issue for
23 final action on the application is the reaching of an
24 agreement between the sponsor of the application
25 and the Commissioner on appropriate changes to the

1 labeling for the drug that is the subject of the
2 application—

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

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

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

16 “(B) not later than 90 days after receiving
17 the referral, the Pediatric Advisory Sub-
18 committee of the Anti-Infective Drugs Advisory
19 Committee shall—

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

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

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

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

17 **SEC. 5. OFFICE OF PEDIATRIC THERAPEUTICS.**

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

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

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

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

5 (1) employees of the Department of Health and
6 Human Services who, as of the date of enactment of
7 this Act, exercise responsibilities relating to pediatric
8 therapeutics;

9 (2) 1 or more additional individuals with exper-
10 tise concerning ethical issues presented by the con-
11 duct of clinical research in the pediatric population;
12 and

13 (3) 1 or more additional individuals with exper-
14 tise in pediatrics who shall consult and collaborate
15 with all components of the Food and Drug Adminis-
16 tration concerning activities described in subsection
17 (b).

18 **SEC. 6. NEONATES.**

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

1 **SEC. 7. SUNSET.**

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

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

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

10 “(2) on or before October 1, 2007, an approv-
11 able application for the drug is submitted under sec-
12 tion 505(b)(1); and

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

14 **SEC. 8. DISSEMINATION OF PEDIATRIC INFORMATION.**

15 Section 505A of the Federal Food, Drug, and Cos-
16 metic Act (21 U.S.C. 355a) (as amended by section
17 4(b)(2)) is amended by adding at the end the following:

18 “(m) DISSEMINATION OF PEDIATRIC INFORMA-
19 TION.—

20 “(1) IN GENERAL.—Not later than 180 days
21 after the date of submission of a report on a pedi-
22 atric study under this section, the Commissioner
23 shall make available to the public a summary of the
24 medical and clinical pharmacology reviews of pedi-
25 atric studies conducted for the supplement, including
26 by publication in the Federal Register.

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

5 **SEC. 9. CLARIFICATION OF INTERACTION OF MARKET EX-**
6 **CLUSIVITY UNDER SECTION 505A OF THE**
7 **FEDERAL FOOD, DRUG, AND COSMETIC ACT**
8 **AND MARKET EXCLUSIVITY AWARDED TO AN**
9 **APPLICANT FOR APPROVAL OF A DRUG**
10 **UNDER SECTION 505(j) OF THAT ACT.**

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

14 “(n) CLARIFICATION OF INTERACTION OF MARKET
15 EXCLUSIVITY UNDER THIS SECTION AND MARKET EX-
16 CLUSIVITY AWARDED TO AN APPLICANT FOR APPROVAL
17 OF A DRUG UNDER SECTION 505(j).—

18 “(1) IN GENERAL.—If a 180-day period under
19 section 505(j)(5)(B)(iv) overlaps with a 6-month ex-
20 tension under this section, so that the applicant for
21 approval of a drug under section 505(j) entitled to
22 the 180-day period under that section loses a portion
23 of the 180-day period to which the applicant is enti-
24 tled for the drug, the 180-day period shall be
25 extended—

1 “(A) if the 180-day period would, but for
2 this subsection, expire after the 6-month exten-
3 sion, by the number of days of the overlap; or

4 “(B) if the 180-day period would, but for
5 this subsection, expire during the 6-month ex-
6 tension, by 6 months.

7 “(2) EFFECT OF SUBSECTION.—Under no cir-
8 cumstances shall application of this section result in
9 an applicant for approval of a drug under section
10 505(j) being enabled to commercially market the
11 drug to the exclusion of a subsequent applicant for
12 approval of a drug under section 505(j) for more
13 than 180 days.”.

14 **SEC. 10. FOUNDATION FOR PEDIATRIC RESEARCH.**

15 Title IV of the Public Health Service Act (42 U.S.C.
16 281 et seq.) is amended by adding at the end the following
17 part:

18 **“PART J—FOUNDATION FOR PEDIATRIC**

19 **RESEARCH**

20 **“SEC. 499A. ESTABLISHMENT AND DUTIES OF FOUNDATION.**

21 “(a) IN GENERAL.—The Secretary, acting through
22 the Director of NIH and in consultation with the Commis-
23 sioner of Food and Drugs, shall establish a nonprofit cor-
24 poration to be known as the Foundation for Pediatric Re-
25 search (hereafter in this section referred to as the ‘Foun-

1 dation'). The Foundation shall not be an agency or instru-
2 mentality of the United States Government.

3 “(b) PURPOSE OF FOUNDATION.—The purpose of
4 the Foundation shall be to support the conduct of research
5 on drugs listed by the Secretary pursuant to section
6 409I(a)(1)(A)(iii).

7 “(c) CERTAIN ACTIVITIES OF FOUNDATION.—

8 “(1) IN GENERAL.—In carrying out subsection
9 (b), the Foundation may solicit and accept gifts,
10 grants, and other donations, establish accounts, and
11 invest and expend funds in support of a program to
12 encourage donations for the conduct of studies of
13 drugs referred to in subsection (b).

14 “(2) FEES.—The Foundation may assess fees
15 for the provision of professional, administrative and
16 management services by the Foundation in amounts
17 determined reasonable and appropriate by the Exec-
18 utive Director.

19 “(3) AUTHORITY OF FOUNDATION.—The Foun-
20 dation shall be the sole entity responsible for car-
21 rying out the activities described in this subsection.

22 “(d) BOARD OF DIRECTORS.—

23 “(1) COMPOSITION.—

24 “(A) The Foundation shall have a Board
25 of Directors (hereafter referred to in this sec-

1 tion as the “Board”), which shall be composed
2 of ex officio and appointed members in accord-
3 ance with this subsection. All appointed mem-
4 bers of the Board shall be voting members.

5 “(B) The ex officio members of the Board
6 shall be—

7 “(i) the Chairman and ranking minor-
8 ity member of the Subcommittee on Health
9 (Committee on Energy and Commerce) or
10 their designees, in the case of the House of
11 Representatives;

12 “(ii) the Chairman and ranking mi-
13 nority member of the Committee on
14 Health, Education, Labor and Pensions or
15 their designees, in the case of the Senate;

16 “(iii) the Director of NIH; and

17 “(iv) the Commissioner of Food and
18 Drugs.

19 “(C) The ex officio members of the Board
20 under subparagraph (B) shall appoint to the
21 Board 11 individuals from among a list of can-
22 didates to be provided by the National Academy
23 of Science. Of such appointed members—

1 “(i) 5 shall be representative of the
2 experts in pediatric medicine and research
3 field;

4 “(ii) 1 shall be a biomedical ethicist;
5 and

6 “(iii) 5 shall be representatives of the
7 general public, which may include rep-
8 resentatives of affected industries.

9 “(D)(i) Not later than 30 days after the
10 date of the enactment of the Best Pharma-
11 ceuticals for Children Act, the Director of NIH
12 shall convene a meeting of the ex officio mem-
13 bers of the Board to—

14 “(I) incorporate the Foundation and
15 establish the general policies of the Foun-
16 dation for carrying out the purposes of
17 subsection (b), including the establishment
18 of the bylaws of the Foundation; and

19 “(II) appoint the members of the
20 Board in accordance with subparagraph
21 (C).

22 “(ii) Upon the appointment of the mem-
23 bers of the Board under clause (i)(II), the
24 terms of service of the ex officio members of the

1 Board as members of the Board shall termi-
2 nate.

3 “(E) The agreement of not less than three-
4 fifths of the members of the ex officio members
5 of the Board shall be required for the appoint-
6 ment of each member to the initial Board.

7 “(F) No employee of the National Insti-
8 tutes of Health shall be appointed as a member
9 of the Board.

10 “(G) The Board may, through amend-
11 ments to the bylaws of the Foundation, provide
12 that the number of members of the Board shall
13 be greater than the number specified in sub-
14 paragraph (C).

15 “(2) CHAIR.—

16 “(A) The ex officio members of the Board
17 under paragraph (1)(B) shall designate an indi-
18 vidual to serve as the initial Chair of the Board.

19 “(B) Upon the termination of the term of
20 service of the initial Chair of the Board, the ap-
21 pointed members of the Board shall elect a
22 member of the Board to serve as the Chair of
23 the Board.

24 “(3) TERMS AND VACANCIES.—

1 “(A) The term of office of each member of
2 the Board appointed under paragraph (1)(C)
3 shall be 5 years, except that the terms of offices
4 for the initial appointed members of the Board
5 shall expire as determined by the ex officio
6 members and the Chair.

7 “(B) Any vacancy in the membership of
8 the Board shall be filled in the manner in which
9 the original position was made and shall not af-
10 fect the power of the remaining members to
11 execute the duties of the Board.

12 “(C) If a member of the Board does not
13 serve the full term applicable under subpara-
14 graph (A), the individual appointed to fill the
15 resulting vacancy shall be appointed for the re-
16 mainder of the term of the predecessor of the
17 individual.

18 “(D) A member of the Board may continue
19 to serve after the expiration of the term of the
20 member until a successor is appointed.

21 “(4) COMPENSATION.—Members of the Board
22 may not receive compensation for service on the
23 Board. Such members may be reimbursed for travel,
24 subsistence, and other necessary expenses incurred

1 in carrying out the duties of the Board, as set forth
2 in the bylaws issued by the Board.

3 “(5) MEETINGS AND QUORUM.—A majority of
4 the members of the Board shall constitute a quorum
5 for purposes of conducting the business of the
6 Board.

7 “(6) CERTAIN BYLAWS.—

8 “(A) In establishing bylaws under this sub-
9 section, the Board shall ensure that the fol-
10 lowing are provided for:

11 “(i) Policies for the selection of the
12 officers, employees, agents, and contractors
13 of the Foundation.

14 “(ii) Policies, including ethical stand-
15 ards, for the acceptance, solicitation, and
16 disposition of donations and grants to the
17 Foundation and for the disposition of the
18 assets of the Foundation. Policies with re-
19 spect to ethical standards shall ensure that
20 officers, employees and agents of the
21 Foundation (including members of the
22 Board) avoid encumbrances that would re-
23 sult in a conflict of interest, including a fi-
24 nancial conflict of interest or a divided al-
25 legiance. Such policies shall include re-

1 requirements for the provision of information
2 concerning any ownership or controlling in-
3 terest in entities related to the activities of
4 the Foundation by such officers, employees
5 and agents and their spouses and relatives.

6 “(iii) Policies for the conduct of the
7 general operations of the Foundation.

8 “(iv) Policies for writing, editing,
9 printing, publishing, and vending of books
10 and other materials.

11 “(B) In establishing bylaws under this sub-
12 section, the Board shall ensure that such by-
13 laws (and activities carried out under the by-
14 laws) do not—

15 “(i) reflect unfavorably upon the abil-
16 ity of the Foundation to carry out its re-
17 sponsibilities or official duties in a fair and
18 objective manner; or

19 “(ii) compromise, or appear to com-
20 promise, the integrity of any governmental
21 agency or program, or any officer or em-
22 ployee involved in such program.

23 “(e) INCORPORATION.—The initial members of the
24 Board shall serve as incorporators and shall take whatever
25 actions necessary to incorporate the Foundation.

1 “(f) NONPROFIT STATUS.—The Foundation shall be
2 considered to be a corporation under section 501(c) of the
3 Internal Revenue Code of 1986, and shall be subject to
4 the provisions of such section.

5 “(g) EXECUTIVE DIRECTOR.—

6 “(1) IN GENERAL.—The Foundation shall have
7 an Executive Director who shall be appointed by the
8 Board and shall serve at the pleasure of the Board.
9 The Executive Director shall be responsible for the
10 day-to-day operations of the Foundation and shall
11 have such specific duties and responsibilities as the
12 Board shall prescribe.

13 “(2) COMPENSATION.—The rate of compensa-
14 tion of the Executive Director shall be fixed by the
15 Board.

16 “(h) POWERS.—In carrying out subsection (b), the
17 Foundation may—

18 “(1) operate under the direction of its Board;

19 “(2) adopt, alter, and use a corporate seal,
20 which shall be judicially noticed;

21 “(3) provide for 1 or more officers, employees,
22 and agents, as may be necessary, define their duties,
23 and require surety bonds or make other provisions
24 against losses occasioned by acts of such persons;

1 “(4) hire, promote, compensate, and discharge
2 officers and employees of the Foundation, and define
3 the duties of the officers and employees;

4 “(5) with the consent of any executive depart-
5 ment or independent agency, use the information,
6 services, staff, and facilities of such in carrying out
7 this section;

8 “(6) sue and be sued in its corporate name, and
9 complain and defend in courts of competent jurisdic-
10 tion;

11 “(7) modify or consent to the modification of
12 any contract or agreement to which it is a party or
13 in which it has an interest under this part;

14 “(8) establish a process for the selection of can-
15 didates for positions under subsection (c);

16 “(9) enter into contracts with public and pri-
17 vate organizations for the writing, editing, printing,
18 and publishing of books and other material;

19 “(10) take such action as may be necessary to
20 obtain patents and licenses for devices and proce-
21 dures developed by the Foundation and its employ-
22 ees;

23 “(11) solicit, accept, hold, administer, invest,
24 and spend any gift, devise, or bequest of real or per-
25 sonal property made to the Foundation;

1 “(12) enter into such other contracts, leases,
2 cooperative agreements, and other transactions as
3 the Executive Director considers appropriate to con-
4 duct the activities of the Foundation;

5 “(13) appoint other groups of advisors as may
6 be determined necessary from time to time to carry
7 out the functions of the Foundation;

8 “(14) enter into such other contracts, leases,
9 cooperative agreements, and other transactions as
10 the Executive Director considers appropriate to con-
11 duct the activities of the Foundation; and

12 “(15) exercise other powers as set forth in this
13 section, and such other incidental powers as are nec-
14 essary to carry out its powers, duties, and functions
15 in accordance with this part.

16 “(i) ADMINISTRATIVE CONTROL.—No participant in
17 the program established under this part shall exercise any
18 administrative control over any Federal employee.

19 “(j) GENERAL PROVISIONS.—

20 “(1) FOUNDATION INTEGRITY.—The members
21 of the Board shall be accountable for the integrity
22 of the operations of the Foundation and shall ensure
23 such integrity through the development and enforce-
24 ment of criteria and procedures relating to stand-
25 ards of conduct (including those developed under

1 subsection (d)(6)(A)(ii), financial disclosure state-
2 ments, conflict of interest rules, recusal and waiver
3 rules, audits and other matter determined appro-
4 priate by the Board.

5 “(2) FINANCIAL CONFLICTS OF INTEREST.—

6 Any individual who is an officer, employee, or mem-
7 ber of the Board of the Foundation may not (in ac-
8 cordance with policies and requirements developed
9 under subsection (d)(6)(A)(ii) personally or substan-
10 tially participate in the consideration or determina-
11 tion by the Foundation of any matter that would di-
12 rectly or predictably affect any financial interest of
13 the individual or a relative (as such term is defined
14 in section 109(16) of the Ethics in Government Act
15 of 1978) of the individual, of any business organiza-
16 tion or other entity, or of which the individual is an
17 officer or employee, or is negotiating for employ-
18 ment, or in which the individual has any other finan-
19 cial interest.

20 “(3) AUDITS; AVAILABILITY OF RECORDS.—The

21 Foundation shall—

22 “(A) provide for annual audits of the fi-
23 nancial condition of the Foundation; and

24 “(B) make such audits, and all other
25 records, documents, and other papers of the

1 Foundation, available to the Secretary and the
2 Comptroller General of the United States for
3 examination or audit.

4 “(4) REPORTS.—

5 “(A) Not later than 5 months following the
6 end of each fiscal year, the Foundation shall
7 publish a report describing the activities of the
8 Foundation during the preceding fiscal year.
9 Each such report shall include for the fiscal
10 year involved a comprehensive statement of the
11 operations, activities, financial condition, and
12 accomplishments of the Foundation.

13 “(B) With respect to the financial condi-
14 tion of the Foundation, each report under sub-
15 paragraph (A) shall include the source, and a
16 description of, all gifts or grants to the Founda-
17 tion of real or personal property, and the source
18 and amount of all gifts or grants to the Foun-
19 dation of money. Each such report shall include
20 a specification of any restrictions on the pur-
21 poses for which gifts or grants to the Founda-
22 tion may be used.

23 “(C) The Foundation shall make copies of
24 each report submitted under subparagraph (A)
25 available for public inspection, and shall upon

1 request provide a copy of the report to any indi-
2 vidual for a charge not exceeding the cost of
3 providing the copy.

4 “(D) The Board shall annually hold a pub-
5 lic meeting to summarize the activities of the
6 Foundation and distribute written reports con-
7 cerning such activities and the scientific results
8 derived from such activities.

9 “(5) SERVICE OF FEDERAL EMPLOYEES.—Fed-
10 eral employees may serve on committees advisory to
11 the Foundation and otherwise cooperate with and
12 assist the Foundation in carrying out its function, so
13 long as the employees do not direct or control Foun-
14 dation activities.

15 “(6) RELATIONSHIP WITH EXISTING ENTI-
16 TIES.—The Foundation may, pursuant to appro-
17 priate agreements, merge with, acquire, or use the
18 resources of existing nonprofit private corporations
19 with missions similar to the purposes of the Founda-
20 tion.

21 “(7) INTELLECTUAL PROPERTY RIGHTS.—The
22 Board shall adopt written standards with respect to
23 the ownership of any intellectual property rights de-
24 rived from the collaborative efforts of the Founda-
25 tion prior to the commencement of such efforts.

1 “(8) NATIONAL INSTITUTES OF HEALTH
2 AMENDMENTS OF 1990.—The activities conducted in
3 support of the National Institutes of Health Amend-
4 ments of 1990 (Public Law 101–613), and the
5 amendments made by such Act, shall not be nullified
6 by the enactment of this section.

7 “(9) LIMITATION OF ACTIVITIES.—The Foun-
8 dation shall exist solely as an entity to work in col-
9 laboration with the research programs of the Na-
10 tional Institutes of Health. The Foundation may not
11 undertake activities (such as the operation of inde-
12 pendent laboratories or competing for Federal re-
13 search funds) that are independent of those of the
14 National Institutes of Health research programs.

15 “(10) TRANSFER OF FUNDS.—The Foundation
16 may transfer funds to the National Institutes of
17 Health. Any funds transferred under this paragraph
18 shall be subject to all Federal limitations relating to
19 federally-funded research.

20 “(k) DUTIES OF THE DIRECTOR.—

21 “(1) APPLICABILITY OF CERTAIN STANDARDS
22 TO NON-FEDERAL EMPLOYEES.—In the case of any
23 individual who is not an employee of the Federal
24 Government and who serves in association with the
25 National Institutes of Health, with respect to finan-

1 cial assistance received from the Foundation, the
2 Foundation may not provide the assistance of, or
3 otherwise permit the work at the National Institutes
4 of Health to begin until a memorandum of under-
5 standing between the individual and the Director of
6 NIH, or the designee of such Director, has been exe-
7 cuted specifying that the individual shall be subject
8 to such ethical and procedural standards of conduct
9 relating to duties performed at the National Insti-
10 tutes of Health, as the Director of NIH determines
11 is appropriate.

12 “(2) SUPPORT SERVICES.—The Director of
13 NIH may provide facilities, utilities and support
14 services to the Foundation if it is determined by the
15 Director to be advantageous to the research pro-
16 grams of the National Institutes of Health.

17 “(1) FUNDING.—

18 “(1) AUTHORIZATION OF APPROPRIATIONS.—
19 For the purpose of carrying out this part, there are
20 authorized to be appropriated such sums as may be
21 necessary for fiscal year 2002 and each subsequent
22 fiscal year.

23 “(2) LIMITATION REGARDING OTHER FUNDS.—
24 Amounts appropriated under any provision of law

1 other than paragraph (1) may not be expended to
2 establish or operate the Foundation.”.

3 **SEC. 11. STUDY CONCERNING RESEARCH INVOLVING CHIL-**
4 **DREN.**

5 (a) CONTRACT WITH INSTITUTE OF MEDICINE.—

6 The Secretary of Health and Human Services shall enter
7 into a contract with the Institute of Medicine for—

8 (1) the conduct, in accordance with subsection
9 (b), of a review of—

10 (A) Federal regulations in effect on the
11 date of the enactment of this Act relating to re-
12 search involving children;

13 (B) federally-prepared or supported reports
14 relating to research involving children; and

15 (C) federally-supported evidence-based re-
16 search involving children; and

17 (2) the submission to the appropriate commit-
18 tees of Congress, by not later than 2 years after the
19 date of enactment of this Act, of a report concerning
20 the review conducted under paragraph (1) that in-
21 cludes recommendations on best practices relating to
22 research involving children.

23 (b) AREAS OF REVIEW.—In conducting the review
24 under subsection (a)(1), the Institute of Medicine shall
25 consider the following:

1 (1) The written and oral process of obtaining
2 and defining “assent”, “permission” and “informed
3 consent” with respect to child clinical research par-
4 ticipants and the parents, guardians, and the indi-
5 viduals who may serve as the legally authorized rep-
6 resentatives of such children (as defined in subpart
7 A of part 46 of title 45, Code of Regulations).

8 (2) The expectations and comprehension of
9 child research participants and the parents, guard-
10 ians, or legally authorized representatives of such
11 children, for the direct benefits and risks of the
12 child’s research involvement, particularly in terms of
13 research versus therapeutic treatment.

14 (3) The definition of “minimal risk” with re-
15 spect to a healthy child or a child with an illness.

16 (4) The appropriateness of the regulations ap-
17 plicable to children of differing ages and maturity
18 levels, including regulations relating to legal status.

19 (5) Whether payment (financial or otherwise)
20 may be provided to a child or his or her parent,
21 guardian, or legally authorized representative for the
22 participation of the child in research, and if so, the
23 amount and type of payment that may be made.

24 (6) Compliance with the regulations referred to
25 in subsection (a)(1)(A), the monitoring of such com-

1 pliance (including the role of institutional review
2 boards), and the enforcement actions taken for viola-
3 tions of such regulations.

4 (7) The unique roles and responsibilities of in-
5 stitutional review boards in reviewing research in-
6 volving children, including composition of member-
7 ship on institutional review boards.

8 (c) REQUIREMENTS OF EXPERTISE.—The Institute
9 of Medicine shall conduct the review under subsection
10 (a)(1) and make recommendations under subsection (a)(2)
11 in conjunction with experts in pediatric medicine, pediatric
12 research, and the ethical conduct of research involving
13 children.

14 **SEC. 12. TECHNICAL AND CONFORMING AMENDMENTS.**

15 Section 505A of the Federal Food, Drug, and Cos-
16 metic Act (21 U.S.C. 355a) (as amended by sections 2(1),
17 4(b)(2), 8, and 9) is amended—

18 (1)(A) by striking “(j)(4)(D)(ii)” each place it
19 appears and inserting “(j)(5)(D)(ii)”;

20 (B) by striking “(j)(4)(D)” each place it ap-
21 pears and inserting “(j)(5)(D)”;

22 (C) by striking “505(j)(4)(D)” each place it ap-
23 pears and inserting “505(j)(5)(D)”;

1 (2) by redesignating subsections (a), (g), (h),
2 (i), (j), (k), (l), (m), and (n) as subsections (b), (a),
3 (g), (h), (m), (l), (i), (j), and (k), respectively;

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

6 (4) in paragraphs (1), (2), and (3) of sub-
7 section (d), subsection (e), and subsection (m) (as
8 redesignated by paragraph (1)), by striking “sub-
9 section (a) or (c)” and inserting “subsection (b) or
10 (c)”;

11 (5) in subsection (g) (as redesignated by para-
12 graph (1)), by striking “subsection (a) or (b)” and
13 inserting “subsection (b) or (c)”.

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