

107TH CONGRESS
1ST SESSION

H. R. 3047

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

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 4, 2001

Mr. WAXMAN (for himself, Mr. BROWN of Ohio, Mr. DINGELL, Mr. DEUTSCH, Mr. PALLONE, Mr. GREEN of Texas, Mr. STUPAK, and Mr. BARRETT of Wisconsin) 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 and the Public Health Service 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”.

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

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

1 **“SEC. 505A. PEDIATRIC STUDIES OF DRUGS; COST-PLUS**
2 **PAYMENTS.**

3 “(a) REQUIRED STUDIES.—

4 “(1) IN GENERAL.—In the case of a drug for
5 which a market application is pending or for which
6 such an application has been approved, or for which
7 a research exemption has been granted, if (pursuant
8 to regulations promulgated by the Secretary) the
9 Secretary requires the sponsor or holder for the drug
10 (as the case may be) to conduct a pediatric study of
11 the drug, the Secretary may enter into a contract
12 for payments in accordance with subsection (d) re-
13 garding such study.

14 “(2) MARKET APPLICATION; RESEARCH EXEMP-
15 TION.—For purposes of this section, the term ‘mar-
16 ket application’ means an application under section
17 505 or under section 351 of the Public Health Serv-
18 ice Act, and the term ‘research exemption’ means an
19 exemption under section 505(i).

20 “(3) DISPUTE RESOLUTION.—The Secretary
21 shall develop and publish in the Federal Register cri-
22 teria describing the manner in which the process of
23 dispute resolution under section 562 will be applied
24 with respect to paragraph (1). Such criteria shall be
25 so published not later than 180 days after the date
26 of the enactment of the Best Pharmaceuticals for

1 Children Act. Any process of dispute resolution re-
2 garding a requirement described in subsection (a)
3 that was commenced before the publication of the
4 criteria, including a process commenced before the
5 date of the enactment of such Act, may continue in
6 accordance with the applicable terms in effect before
7 the publication of the criteria.

8 “(b) REQUESTED STUDIES.—

9 “(1) IN GENERAL.—In the case of a drug that
10 is included on the list under paragraph (2), the Sec-
11 retary may award contracts for payments in accord-
12 ance with subsection (d) for the conduct of pediatric
13 studies of the drug.

14 “(2) LIST OF DRUGS.—The Secretary shall es-
15 tablish and maintain a list of drugs—

16 “(A) for which an approved market appli-
17 cation is in effect;

18 “(B) for which there is no patent protec-
19 tion, and for which no period of market exclu-
20 sivity is in effect under section 505 or section
21 527; and

22 “(C) for which the Secretary has deter-
23 mined that pediatric studies are needed to as-
24 sess the safety and effectiveness of the use of
25 the drug in a pediatric population.

1 The initial list under this paragraph shall be estab-
2 lished not later than one year after the date of the
3 enactment of the Best Pharmaceuticals for Children
4 Act. The reference in subparagraph (B) to a period
5 of market exclusivity in effect under section 505 in-
6 cludes such a period in effect pursuant to this sec-
7 tion as this section was in effect on the day before
8 such date of enactment.

9 “(3) PREFERENCE IN AWARDING CON-
10 TRACTS.—In awarding a contract under paragraph
11 (1) regarding a drug, the Secretary shall give pref-
12 erence to one or more of the holders for the drug (in
13 the event that Secretary has elected not to use the
14 authority under subsection (a) regarding the drug),
15 to the extent that one or more holders submit appli-
16 cations for the contract.

17 “(4) APPLICATION FOR CONTRACT.—A contract
18 may be made under subsection (a) only if an appli-
19 cation for the contract is submitted to the Secretary
20 and the application is in such form, is made in such
21 manner, and contains such agreements, assurances,
22 and information as the Secretary determines to be
23 necessary to carry out this subsection.

24 “(5) COMPETITIVE PROCESS.—Awards of con-
25 tracts under paragraph (1) shall be made through a

1 competitive process, and applications for such
2 awards shall undergo technical and scientific peer
3 review. The Secretary may provide for the assistance
4 of the Director of the National Institutes of Health
5 in the administration of the requirements of the pre-
6 ceding sentence.

7 “(c) CERTAIN STUDY PROCEDURES.—In providing
8 for pediatric studies under subsection (a) or (b), the Sec-
9 retary shall in writing (through publication in the Federal
10 Register or otherwise) specify the criteria of the Secretary
11 for the conduct of the studies, including with respect to
12 protocols and including timeframes for completion of the
13 studies and the submission to the Secretary of reports on
14 the studies.

15 “(d) PAYMENTS.—A contract under subsection (a) or
16 (b)—

17 “(1) shall provide for reimbursement by the
18 Secretary of the costs of conducting the pediatric
19 studies involved, upon the Secretary determining
20 that the applicable conditions under subsection (c)
21 are being or have been met; and

22 “(2) shall provide for an amount additional to
23 such reimbursement (payable once the reimburse-
24 ment in full has been made), which additional

1 amount shall be equal to 100 percent of the costs of
2 conducting such pediatric studies.

3 “(e) LABELING CHANGES FOR ALREADY-MARKETED
4 DRUGS.—

5 “(1) SUPPLEMENTAL APPLICATION; PRI-
6 ORITY.—Not later than 180 days after receiving a
7 report on pediatric studies under this section, the
8 Secretary shall determine whether a holder for the
9 drug involved should alter the labeling for the drug.
10 If the Secretary determines that a labeling change
11 should be made, the Secretary shall—

12 “(A) promptly request the holder in writ-
13 ing to submit to the Secretary a supplemental
14 application for purposes of making the labeling
15 change;

16 “(B) consider such application to be a pri-
17 ority application, except that the Secretary may
18 give greater priority to such applications re-
19 garding fast track products under section 506
20 (relating to the treatment of serious or life-
21 threatening conditions) as the Secretary deter-
22 mines to be appropriate;

23 “(C) apply to the application the perform-
24 ance goals established by the Secretary for pri-
25 ority drugs; and

1 “(D) upon submission of the application,
2 promptly offer to enter into negotiations with
3 the holder regarding the labeling change, and
4 promptly arrange for the negotiations to take
5 place.

6 “(2) DISPUTE RESOLUTION.—

7 “(A) IN GENERAL.—With respect to nego-
8 tiations under paragraph (1), if the Secretary
9 and the holder involved have not reached agree-
10 ment on a labeling change as of the expiration
11 of the 45-day period beginning on the date on
12 which the negotiations commenced, the Sec-
13 retary, upon the request of the holder, shall
14 commence the process of dispute resolution
15 under section 562 regarding the labeling
16 change. In providing for the review under such
17 section of the matter by an advisory panel, the
18 Secretary shall ensure that the matter is re-
19 viewed by the Pediatric Advisory Subcommittee
20 of the Anti-Infective Drugs Advisory Com-
21 mittee.

22 “(B) REPORT FROM ADVISORY PANEL.—

23 Not later than 90 days after receiving a referral
24 under subparagraph (A), the subcommittee re-
25 ferred to in such subparagraph shall—

1 “(i) review the available information
2 on the safety and effectiveness of the use
3 of the drug in the pediatric population, in-
4 cluding reports submitted under this sec-
5 tion; and

6 “(ii) make a recommendation to the
7 Secretary regarding a labeling change.

8 “(3) DETERMINATION BY SECRETARY.—Not
9 later than 30 days after receiving a recommendation
10 under paragraph (2)(B)(ii) with respect to a drug,
11 the Secretary shall make a determination regarding
12 a labeling change for the drug and inform the holder
13 involved in writing of the determination. Upon the
14 expiration of the 30-day period beginning on the
15 date on which the Secretary so informs the holder,
16 the Secretary may with respect to the labeling of the
17 drug take such actions in accordance with this Act
18 as the Secretary determines to be appropriate.

19 “(f) DEFINITIONS.—For purposes of this section:

20 “(1) The term ‘holder for a drug’ means the
21 holder of an approved market application.

22 “(2) The term ‘market application’ has the
23 meaning given such term in subsection (a)(2).

24 “(3) The term ‘pediatric studies’ means at least
25 one clinical investigation (that, at the Secretary’s

1 discretion, may include pharmacokinetic studies) in
2 pediatric age groups in which a drug is anticipated
3 to be used.

4 “(4) The term ‘priority application’ means a
5 drug application referred to in section 101(4) of the
6 Food and Drug Administration Modernization Act of
7 1997 (111 Stat. 2298).

8 “(5) The term ‘research exemption’ has the
9 meaning given such term in subsection (a)(2).

10 “(6) The term ‘sponsor for a drug’ means the
11 sponsor of an application for the drug under section
12 505(b)(1) or under section 351 of the Public Health
13 Service Act, or the sponsor of a clinical investigation
14 of the drug under an exemption under section
15 505(i), as the case may be.

16 “(g) FUNDING.—

17 “(1) AUTHORIZATION OF APPROPRIATIONS.—
18 For the purpose of contracts under subsection (a)
19 and (b), there are authorized to be appropriated
20 \$200,000,000 for fiscal year 2002, and such sums
21 as may be necessary for each of the fiscal years
22 2003 through 2007.

23 “(2) LIMITATION.—The authority of the Sec-
24 retary to enter into contracts under subsection (a)

1 or (b) is subject to the extent of amounts provided
2 in advance in an appropriations Act.”.

3 (b) FEES FOR SUPPLEMENTAL APPLICATIONS.—Sec-
4 tion 736(a)(1) of the Federal Food, Drug, and Cosmetic
5 Act (21 U.S.C. 379h(a)(1)) is amended—

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

7 (2) by redesignating subparagraph (G) as sub-
8 paragraph (F).

9 **SEC. 3. SAVINGS PROVISION; INTERACTION OF VARIOUS**
10 **MARKET-EXCLUSIVITY PROVISIONS.**

11 (a) SAVINGS PROVISION.—The amendment made by
12 section 2(a) does not apply with respect to pediatric stud-
13 ies of drugs that, before the date of the enactment of this
14 Act, were requested by the Secretary of Health and
15 Human Services under section 505A of the Federal Food,
16 Drug, and Cosmetic Act, as in effect on the day before
17 such date of enactment, or were required by the Secretary
18 within the meaning of subsection (i) of such section as
19 so in effect. Such section 505A as so in effect continues
20 to apply to the pediatric studies described in the preceding
21 sentence.

22 (b) MARKET-EXCLUSIVITY INTERACTIONS.—

23 (1) IN GENERAL.—Paragraph (2) applies in the
24 case of a period of market exclusivity that is in ef-
25 fect pursuant to subsection (a). References in para-

1 graph (2) to section 505A of the Federal Food,
2 Drug, and Cosmetic Act are references to such sec-
3 tion as in effect on the day before the date of the
4 enactment of this Act.

5 (2) OVERLAP OF PROVISIONS.—If a 180-day
6 period under section 505(j)(5)(B)(iv) of the Federal
7 Food, Drug, and Cosmetic Act overlaps with a 6-
8 month extension under section 505A of such Act, so
9 that the applicant for approval of a drug under sec-
10 tion 505(j) of such Act entitled to the 180-day pe-
11 riod under that section loses a portion of the 180-
12 day period to which the applicant is entitled for the
13 drug, the 180-day period shall be extended—

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

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

20 (3) EFFECT OF SUBSECTION.—Under no cir-
21 cumstances shall application of this subsection result
22 in an applicant for approval of a drug under section
23 505(j) of the Federal Food, Drug, and Cosmetic Act
24 being enabled to commercially market the drug to
25 the exclusion of a subsequent applicant for approval

1 of a drug under section 505(j) of such Act for more
2 than 180 days.

3 **SEC. 4. FOUNDATION FOR PEDIATRIC RESEARCH.**

4 Title IV of the Public Health Service Act (42 U.S.C.
5 281 et seq.) is amended by adding at the end the following
6 part:

7 **“PART J—FOUNDATION FOR PEDIATRIC**
8 **RESEARCH**

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

10 “(a) IN GENERAL.—The Secretary, acting through
11 the Director of NIH and in consultation with the Commis-
12 sioner of Food and Drugs, shall establish a nonprofit cor-
13 poration to be known as the Foundation for Pediatric Re-
14 search (hereafter in this section referred to as the ‘Foun-
15 dation’). The Foundation shall not be an agency or instru-
16 mentality of the United States Government.

17 “(b) PURPOSE OF FOUNDATION.—The purpose of
18 the Foundation shall be to support the conduct of research
19 on drugs listed by the Secretary pursuant to section
20 505A(b)(2) of the Federal Food, Drug, and Cosmetic Act.

21 “(c) CERTAIN ACTIVITIES OF FOUNDATION.—

22 “(1) IN GENERAL.—In carrying out subsection
23 (b), the Foundation may solicit and accept gifts,
24 grants, and other donations, establish accounts, and
25 invest and expend funds in support of a program to

1 encourage donations for the conduct of studies of
2 drugs referred to in subsection (b).

3 “(2) FEES.—The Foundation may assess fees
4 for the provision of professional, administrative and
5 management services by the Foundation in amounts
6 determined reasonable and appropriate by the Exec-
7 utive Director.

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

11 “(d) BOARD OF DIRECTORS.—

12 “(1) COMPOSITION.—

13 “(A) The Foundation shall have a Board
14 of Directors (hereafter referred to in this sec-
15 tion as the ‘Board’), which shall be composed of
16 ex officio and appointed members in accordance
17 with this subsection. All appointed members of
18 the Board shall be voting members.

19 “(B) The ex officio members of the Board
20 shall be—

21 “(i) the Chairman and ranking minor-
22 ity member of the Subcommittee on Health
23 (Committee on Energy and Commerce) or
24 their designees, in the case of the House of
25 Representatives;

1 “(ii) the Chairman and ranking mi-
2 nority member of the Committee on
3 Health, Education, Labor and Pensions or
4 their designees, in the case of the Senate;

5 “(iii) the Director of NIH; and

6 “(iv) the Commissioner of Food and
7 Drugs.

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

13 “(i) 5 shall be representative of the
14 experts in pediatric medicine and research
15 field;

16 “(ii) 1 shall be a biomedical ethicist;
17 and

18 “(iii) 5 shall be representatives of the
19 general public, which may include rep-
20 resentatives of affected industries.

21 “(D)(i) Not later than 30 days after the
22 date of the enactment of the Best Pharma-
23 ceuticals for Children Act, the Director of NIH
24 shall convene a meeting of the ex officio mem-
25 bers of the Board to—

1 “(I) incorporate the Foundation and
2 establish the general policies of the Foun-
3 dation for carrying out the purposes of
4 subsection (b), including the establishment
5 of the bylaws of the Foundation; and

6 “(II) appoint the members of the
7 Board in accordance with subparagraph
8 (C).

9 “(ii) Upon the appointment of the mem-
10 bers of the Board under clause (i)(II), the
11 terms of service of the ex officio members of the
12 Board as members of the Board shall termi-
13 nate.

14 “(E) The agreement of not less than three-
15 fifths of the members of the ex officio members
16 of the Board shall be required for the appoint-
17 ment of each member to the initial Board.

18 “(F) No employee of the National Insti-
19 tutes of Health shall be appointed as a member
20 of the Board.

21 “(G) The Board may, through amend-
22 ments to the bylaws of the Foundation, provide
23 that the number of members of the Board shall
24 be greater than the number specified in sub-
25 paragraph (C).

1 “(2) CHAIR.—

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

5 “(B) Upon the termination of the term of
6 service of the initial Chair of the Board, the ap-
7 pointed members of the Board shall elect a
8 member of the Board to serve as the Chair of
9 the Board.

10 “(3) TERMS AND VACANCIES.—

11 “(A) The term of office of each member of
12 the Board appointed under paragraph (1)(C)
13 shall be 5 years, except that the terms of offices
14 for the initial appointed members of the Board
15 shall expire as determined by the ex officio
16 members and the Chair.

17 “(B) Any vacancy in the membership of
18 the Board shall be filled in the manner in which
19 the original position was made and shall not af-
20 fect the power of the remaining members to
21 execute the duties of the Board.

22 “(C) If a member of the Board does not
23 serve the full term applicable under subpara-
24 graph (A), the individual appointed to fill the
25 resulting vacancy shall be appointed for the re-

1 mainder of the term of the predecessor of the
2 individual.

3 “(D) A member of the Board may continue
4 to serve after the expiration of the term of the
5 member until a successor is appointed.

6 “(4) COMPENSATION.—Members of the Board
7 may not receive compensation for service on the
8 Board. Such members may be reimbursed for travel,
9 subsistence, and other necessary expenses incurred
10 in carrying out the duties of the Board, as set forth
11 in the bylaws issued by the Board.

12 “(5) MEETINGS AND QUORUM.—A majority of
13 the members of the Board shall constitute a quorum
14 for purposes of conducting the business of the
15 Board.

16 “(6) CERTAIN BYLAWS.—

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

20 “(i) Policies for the selection of the
21 officers, employees, agents, and contractors
22 of the Foundation.

23 “(ii) Policies, including ethical stand-
24 ards, for the acceptance, solicitation, and
25 disposition of donations and grants to the

1 Foundation and for the disposition of the
2 assets of the Foundation. Policies with re-
3 spect to ethical standards shall ensure that
4 officers, employees and agents of the
5 Foundation (including members of the
6 Board) avoid encumbrances that would re-
7 sult in a conflict of interest, including a fi-
8 nancial conflict of interest or a divided al-
9 legiance. Such policies shall include re-
10 quirements for the provision of information
11 concerning any ownership or controlling in-
12 terest in entities related to the activities of
13 the Foundation by such officers, employees
14 and agents and their spouses and relatives.

15 “(iii) Policies for the conduct of the
16 general operations of the Foundation.

17 “(iv) Policies for writing, editing,
18 printing, publishing, and vending of books
19 and other materials.

20 “(B) In establishing bylaws under this sub-
21 section, the Board shall ensure that such by-
22 laws (and activities carried out under the by-
23 laws) do not—

24 “(i) reflect unfavorably upon the abil-
25 ity of the Foundation to carry out its re-

1 sponsibilities or official duties in a fair and
2 objective manner; or

3 “(ii) compromise, or appear to com-
4 promise, the integrity of any governmental
5 agency or program, or any officer or em-
6 ployee involved in such program.

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

10 “(f) NONPROFIT STATUS.—The Foundation shall be
11 considered to be a corporation under section 501(c) of the
12 Internal Revenue Code of 1986, and shall be subject to
13 the provisions of such section.

14 “(g) EXECUTIVE DIRECTOR.—

15 “(1) IN GENERAL.—The Foundation shall have
16 an Executive Director who shall be appointed by the
17 Board and shall serve at the pleasure of the Board.
18 The Executive Director shall be responsible for the
19 day-to-day operations of the Foundation and shall
20 have such specific duties and responsibilities as the
21 Board shall prescribe.

22 “(2) COMPENSATION.—The rate of compensa-
23 tion of the Executive Director shall be fixed by the
24 Board.

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

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

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

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

10 “(4) hire, promote, compensate, and discharge
11 officers and employees of the Foundation, and define
12 the duties of the officers and employees;

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

17 “(6) sue and be sued in its corporate name, and
18 complain and defend in courts of competent jurisdic-
19 tion;

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

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

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

4 “(10) take such action as may be necessary to
5 obtain patents and licenses for devices and proce-
6 dures developed by the Foundation and its employ-
7 ees;

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

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

15 “(13) appoint other groups of advisors as may
16 be determined necessary from time to time to carry
17 out the functions of the Foundation;

18 “(14) enter into such other contracts, leases,
19 cooperative agreements, and other transactions as
20 the Executive Director considers appropriate to con-
21 duct the activities of the Foundation; and

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

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

4 “(j) GENERAL PROVISIONS.—

5 “(1) FOUNDATION INTEGRITY.—The members
6 of the Board shall be accountable for the integrity
7 of the operations of the Foundation and shall ensure
8 such integrity through the development and enforce-
9 ment of criteria and procedures relating to stand-
10 ards of conduct (including those developed under
11 subsection (d)(6)(A)(ii)), financial disclosure state-
12 ments, conflict of interest rules, recusal and waiver
13 rules, audits and other matter determined appro-
14 priate by the Board.

15 “(2) FINANCIAL CONFLICTS OF INTEREST.—
16 Any individual who is an officer, employee, or mem-
17 ber of the Board of the Foundation may not (in ac-
18 cordance with policies and requirements developed
19 under subsection (d)(6)(A)(ii)) personally or sub-
20 stantially participate in the consideration or deter-
21 mination by the Foundation of any matter that
22 would directly or predictably affect any financial in-
23 terest of the individual or a relative (as such term
24 is defined in section 109(16) of the Ethics in Gov-
25 ernment Act of 1978) of the individual, of any busi-

1 ness organization or other entity, or of which the in-
2 dividual is an officer or employee, or is negotiating
3 for employment, or in which the individual has any
4 other financial interest.

5 “(3) AUDITS; AVAILABILITY OF RECORDS.—The
6 Foundation shall—

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

9 “(B) make such audits, and all other
10 records, documents, and other papers of the
11 Foundation, available to the Secretary and the
12 Comptroller General of the United States for
13 examination or audit.

14 “(4) REPORTS.—

15 “(A) Not later than 5 months following the
16 end of each fiscal year, the Foundation shall
17 publish a report describing the activities of the
18 Foundation during the preceding fiscal year.
19 Each such report shall include for the fiscal
20 year involved a comprehensive statement of the
21 operations, activities, financial condition, and
22 accomplishments of the Foundation.

23 “(B) With respect to the financial condi-
24 tion of the Foundation, each report under sub-
25 paragraph (A) shall include the source, and a

1 description of, all gifts or grants to the Founda-
2 tion of real or personal property, and the source
3 and amount of all gifts or grants to the Foun-
4 dation of money. Each such report shall include
5 a specification of any restrictions on the pur-
6 poses for which gifts or grants to the Founda-
7 tion may be used.

8 “(C) The Foundation shall make copies of
9 each report submitted under subparagraph (A)
10 available for public inspection, and shall upon
11 request provide a copy of the report to any indi-
12 vidual for a charge not exceeding the cost of
13 providing the copy.

14 “(D) The Board shall annually hold a pub-
15 lic meeting to summarize the activities of the
16 Foundation and distribute written reports con-
17 cerning such activities and the scientific results
18 derived from such activities.

19 “(5) SERVICE OF FEDERAL EMPLOYEES.—Fed-
20 eral employees may serve on committees advisory to
21 the Foundation and otherwise cooperate with and
22 assist the Foundation in carrying out its function, so
23 long as the employees do not direct or control Foun-
24 dation activities.

1 “(6) RELATIONSHIP WITH EXISTING ENTI-
2 TIES.—The Foundation may, pursuant to appro-
3 priate agreements, merge with, acquire, or use the
4 resources of existing nonprofit private corporations
5 with missions similar to the purposes of the Founda-
6 tion.

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

12 “(8) NATIONAL INSTITUTES OF HEALTH
13 AMENDMENTS OF 1990.—The activities conducted in
14 support of the National Institutes of Health Amend-
15 ments of 1990 (Public Law 101–613), and the
16 amendments made by such Act, shall not be nullified
17 by the enactment of this section.

18 “(9) LIMITATION OF ACTIVITIES.—The Foun-
19 dation shall exist solely as an entity to work in col-
20 laboration with the research programs of the Na-
21 tional Institutes of Health. The Foundation may not
22 undertake activities (such as the operation of inde-
23 pendent laboratories or competing for Federal re-
24 search funds) that are independent of those of the
25 National Institutes of Health research programs.

1 “(10) TRANSFER OF FUNDS.—The Foundation
2 may transfer funds to the National Institutes of
3 Health. Any funds transferred under this paragraph
4 shall be subject to all Federal limitations relating to
5 federally-funded research.

6 “(k) DUTIES OF THE DIRECTOR.—

7 “(1) APPLICABILITY OF CERTAIN STANDARDS
8 TO NON-FEDERAL EMPLOYEES.—In the case of any
9 individual who is not an employee of the Federal
10 Government and who serves in association with the
11 National Institutes of Health, with respect to finan-
12 cial assistance received from the Foundation, the
13 Foundation may not provide the assistance of, or
14 otherwise permit the work at the National Institutes
15 of Health to begin until a memorandum of under-
16 standing between the individual and the Director of
17 NIH, or the designee of such Director, has been exe-
18 cuted specifying that the individual shall be subject
19 to such ethical and procedural standards of conduct
20 relating to duties performed at the National Insti-
21 tutes of Health, as the Director of NIH determines
22 is appropriate.

23 “(2) SUPPORT SERVICES.—The Director of
24 NIH may provide facilities, utilities and support
25 services to the Foundation if it is determined by the

1 Director to be advantageous to the research pro-
2 grams of the National Institutes of Health.

3 “(1) FUNDING.—

4 “(1) AUTHORIZATION OF APPROPRIATIONS.—

5 For the purpose of carrying out this part, there are
6 authorized to be appropriated such sums as may be
7 necessary for fiscal year 2002 and each subsequent
8 fiscal year.

9 “(2) LIMITATION REGARDING OTHER FUNDS.—

10 Amounts appropriated under any provision of law
11 other than paragraph (1) may not be expended to
12 establish or operate the Foundation.”.

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

14 (a) ESTABLISHMENT.—The Secretary of Health and
15 Human Services shall establish an Office of Pediatric
16 Therapeutics within the Office of the Commissioner of
17 Food and Drugs.

18 (b) DUTIES.—The Office of Pediatric Therapeutics
19 shall be responsible for oversight and coordination of all
20 activities of the Food and Drug Administration that may
21 have any effect on a pediatric population or the practice
22 of pediatrics or may in any other way involve pediatric
23 issues.

24 (c) STAFF.—The staff of the Office of Pediatric
25 Therapeutics shall include—

1 (1) employees of the Department of Health and
2 Human Services who, as of the date of enactment of
3 this Act, exercise responsibilities relating to pediatric
4 therapeutics;

5 (2) 1 or more additional individuals with exper-
6 tise concerning ethical issues presented by the con-
7 duct of clinical research in the pediatric population;
8 and

9 (3) 1 or more additional individuals with exper-
10 tise in pediatrics who shall consult and collaborate
11 with all components of the Food and Drug Adminis-
12 tration concerning activities described in subsection
13 (b).

14 **SEC. 6. STUDY CONCERNING RESEARCH INVOLVING CHIL-**
15 **DREN.**

16 (a) **CONTRACT WITH INSTITUTE OF MEDICINE.—**
17 The Secretary of Health and Human Services shall enter
18 into a contract with the Institute of Medicine for—

19 (1) the conduct, in accordance with subsection
20 (b), of a review of—

21 (A) Federal regulations in effect on the
22 date of the enactment of this Act relating to re-
23 search involving children;

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

1 (C) federally-supported evidence-based re-
2 search involving children; and

3 (2) the submission to the appropriate commit-
4 tees of Congress, by not later than 2 years after the
5 date of enactment of this Act, of a report concerning
6 the review conducted under paragraph (1) that in-
7 cludes recommendations on best practices relating to
8 research involving children.

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

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

19 (2) The expectations and comprehension of
20 child research participants and the parents, guard-
21 ians, or legally authorized representatives of such
22 children, for the direct benefits and risks of the
23 child’s research involvement, particularly in terms of
24 research versus therapeutic treatment.

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

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

6 (5) Whether payment (financial or otherwise)
7 may be provided to a child or his or her parent,
8 guardian, or legally authorized representative for the
9 participation of the child in research, and if so, the
10 amount and type of payment that may be made.

11 (6) Compliance with the regulations referred to
12 in subsection (a)(1)(A), the monitoring of such com-
13 pliance (including the role of institutional review
14 boards), and the enforcement actions taken for viola-
15 tions of such regulations.

16 (7) The unique roles and responsibilities of in-
17 stitutional review boards in reviewing research in-
18 volving children, including composition of member-
19 ship on institutional review boards.

20 (c) REQUIREMENTS OF EXPERTISE.—The Institute
21 of Medicine shall conduct the review under subsection
22 (a)(1) and make recommendations under subsection (a)(2)
23 in conjunction with experts in pediatric medicine, pediatric

1 research, and the ethical conduct of research involving
2 children.

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