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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

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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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Best Pharmaceuticals for Children Act''.

SEC. 2. PEDIATRIC STUDIES OF DRUGS.

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

"SEC. 505A. PEDIATRIC STUDIES OF DRUGS; COST-PLUS PAYMENTS.

''(a) REQUIRED STUDIES.—

''(1) IN GENERAL.—In the case of a drug for which a market application is pending or for which such an application has been approved, or for which a research exemption has been granted, if (pursuant to regulations promulgated by the Secretary) the Secretary requires the sponsor or holder for the drug (as the case may be) to conduct a pediatric study of the drug, the Secretary may enter into a contract for payments in accordance with subsection (d) regarding such study.

''(2) MARKET APPLICATION; RESEARCH EXEMPTION.—For purposes of this section, the term 'market application' means an application under section 505 or under section 351 of the Public Health Service Act, and the term 'research exemption' means an exemption under section 505(i).

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

Children Act. Any process of dispute resolution regarding a requirement described in subsection (a) that was commenced before the publication of the criteria, including a process commenced before the date of the enactment of such Act, may continue in accordance with the applicable terms in effect before the publication of the criteria.

''(b) REQUESTED STUDIES.—

''(1) IN GENERAL.—In the case of a drug that is included on the list under paragraph (2), the Secretary may award contracts for payments in accordance with subsection (d) for the conduct of pediatric studies of the drug.

''(2) LIST OF DRUGS.—The Secretary shall establish and maintain a list of drugs—

''(A) for which an approved market application is in effect;

''(B) for which there is no patent protection, and for which no period of market exclusivity is in effect under section 505 or section 527; and

''(C) for which the Secretary has determined that pediatric studies are needed to assess the safety and effectiveness of the use of the drug in a pediatric population.

The initial list under this paragraph shall be established not later than one year after the date of the enactment of the Best Pharmaceuticals for Children Act. The reference in subparagraph (B) to a period of market exclusivity in effect under section 505 includes such a period in effect pursuant to this section as this section was in effect on the day before such date of enactment.

''(3) PREFERENCE IN AWARDING CONTRACTS.—In awarding a contract under paragraph (1) regarding a drug, the Secretary shall give preference to one or more of the holders for the drug (in the event that Secretary has elected not to use the authority under subsection (a) regarding the drug), to the extent that one or more holders submit applications for the contract.

''(4) APPLICATION FOR CONTRACT.—A contract may be made under subsection (a) only if an application for the contract is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this subsection.

''(5) COMPETITIVE PROCESS.—Awards of contracts under paragraph (1) shall be made through a

competitive process, and applications for such awards shall undergo technical and scientific peer review. The Secretary may provide for the assistance of the Director of the National Institutes of Health in the administration of the requirements of the preceding sentence.

''(c) CERTAIN STUDY PROCEDURES.—In providing for pediatric studies under subsection (a) or (b), the Secretary shall in writing (through publication in the Federal Register or otherwise) specify the criteria of the Secretary for the conduct of the studies, including with respect to protocols and including timeframes for completion of the studies and the submission to the Secretary of reports on the studies.

''(d) PAYMENTS.—A contract under subsection (a) or (b)—

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

''(2) shall provide for an amount additional to such reimbursement (payable once the reimbursement in full has been made), which additional

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

''(e) LABELING CHANGES FOR ALREADY-MARKETED DRUGS.—

''(1) SUPPLEMENTAL APPLICATION; PRIORITY.—Not later than 180 days after receiving a report on pediatric studies under this section, the Secretary shall determine whether a holder for the drug involved should alter the labeling for the drug. If the Secretary determines that a labeling change should be made, the Secretary shall—

''(A) promptly request the holder in writing to submit to the Secretary a supplemental application for purposes of making the labeling change;

''(B) consider such application to be a priority application, except that the Secretary may give greater priority to such applications regarding fast track products under section 506 (relating to the treatment of serious or life-threatening conditions) as the Secretary determines to be appropriate;

''(C) apply to the application the performance goals established by the Secretary for priority drugs; and

"(D) upon submission of the application, promptly offer to enter into negotiations with the holder regarding the labeling change, and promptly arrange for the negotiations to take place.

"(2) DISPUTE RESOLUTION.—

"(A) IN GENERAL.—With respect to negotiations under paragraph (1), if the Secretary and the holder involved have not reached agreement on a labeling change as of the expiration of the 45-day period beginning on the date on which the negotiations commenced, the Secretary, upon the request of the holder, shall commence the process of dispute resolution under section 562 regarding the labeling change. In providing for the review under such section of the matter by an advisory panel, the Secretary shall ensure that the matter is reviewed by the Pediatric Advisory Subcommittee of the Anti-Infective Drugs Advisory Committee.

"(B) REPORT FROM ADVISORY PANEL.—Not later than 90 days after receiving a referral under subparagraph (A), the subcommittee referred to in such subparagraph shall—

''(i) review the available information on the safety and effectiveness of the use of the drug in the pediatric population, including reports submitted under this section; and

''(ii) make a recommendation to the Secretary regarding a labeling change.

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

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

''(1) The term 'holder for a drug' means the holder of an approved market application.

''(2) The term 'market application' has the meaning given such term in subsection (a)(2).

''(3) The term 'pediatric studies' means at least one clinical investigation (that, at the Secretary's

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

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

''(5) The term 'research exemption' has the meaning given such term in subsection (a)(2).

''(6) The term 'sponsor for a drug' means the sponsor of an application for the drug under section 505(b)(1) or under section 351 of the Public Health Service Act, or the sponsor of a clinical investigation of the drug under an exemption under section 505(i), as the case may be.

''(g) FUNDING.—

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

''(2) LIMITATION.—The authority of the Secretary to enter into contracts under subsection (a)

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

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

(1) by striking subparagraph (F); and

(2) by redesignating subparagraph (G) as subparagraph (F).

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

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

(b) MARKET-EXCLUSIVITY INTERACTIONS.—

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

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

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

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

(B) if the 180-day period would, but for this subsection, expire during the 6-month extension, by 6 months.

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

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

SEC. 4. FOUNDATION FOR PEDIATRIC RESEARCH.

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

"PART J—FOUNDATION FOR PEDIATRIC RESEARCH

"SEC. 499A. ESTABLISHMENT AND DUTIES OF FOUNDATION.

''(a) IN GENERAL.—The Secretary, acting through the Director of NIH and in consultation with the Commissioner of Food and Drugs, shall establish a nonprofit corporation to be known as the Foundation for Pediatric Research (hereafter in this section referred to as the 'Foundation'). The Foundation shall not be an agency or instrumentality of the United States Government.

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

''(c) CERTAIN ACTIVITIES OF FOUNDATION.—

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

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

''(2) FEES.—The Foundation may assess fees for the provision of professional, administrative and management services by the Foundation in amounts determined reasonable and appropriate by the Executive Director.

''(3) AUTHORITY OF FOUNDATION.—The Foundation shall be the sole entity responsible for carrying out the activities described in this subsection.

''(d) BOARD OF DIRECTORS.—

''(1) COMPOSITION.—

''(A) The Foundation shall have a Board of Directors (hereafter referred to in this section as the 'Board'), which shall be composed of ex officio and appointed members in accordance with this subsection. All appointed members of the Board shall be voting members.

''(B) The ex officio members of the Board shall be—

''(i) the Chairman and ranking minority member of the Subcommittee on Health (Committee on Energy and Commerce) or their designees, in the case of the House of Representatives;

"(ii) the Chairman and ranking minority member of the Committee on Health, Education, Labor and Pensions or their designees, in the case of the Senate;

"(iii) the Director of NIH; and

"(iv) the Commissioner of Food and Drugs.

"(C) The ex officio members of the Board under subparagraph (B) shall appoint to the Board 11 individuals from among a list of candidates to be provided by the National Academy of Science. Of such appointed members—

"(i) 5 shall be representative of the experts in pediatric medicine and research field;

"(ii) 1 shall be a biomedical ethicist; and

"(iii) 5 shall be representatives of the general public, which may include representatives of affected industries.

"(D)(i) Not later than 30 days after the date of the enactment of the Best Pharmaceuticals for Children Act, the Director of NIH shall convene a meeting of the ex officio members of the Board to—

"(I) incorporate the Foundation and establish the general policies of the Foundation for carrying out the purposes of subsection (b), including the establishment of the bylaws of the Foundation; and

"(II) appoint the members of the Board in accordance with subparagraph (C).

"(ii) Upon the appointment of the members of the Board under clause (i)(II), the terms of service of the ex officio members of the Board as members of the Board shall terminate.

"(E) The agreement of not less than three-fifths of the members of the ex officio members of the Board shall be required for the appointment of each member to the initial Board.

"(F) No employee of the National Institutes of Health shall be appointed as a member of the Board.

"(G) The Board may, through amendments to the bylaws of the Foundation, provide that the number of members of the Board shall be greater than the number specified in subparagraph (C).

''(2) CHAIR.—

''(A) The ex officio members of the Board under paragraph (1)(B) shall designate an individual to serve as the initial Chair of the Board.

''(B) Upon the termination of the term of service of the initial Chair of the Board, the appointed members of the Board shall elect a member of the Board to serve as the Chair of the Board.

''(3) TERMS AND VACANCIES.—

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

''(B) Any vacancy in the membership of the Board shall be filled in the manner in which the original position was made and shall not affect the power of the remaining members to execute the duties of the Board.

''(C) If a member of the Board does not serve the full term applicable under subparagraph (A), the individual appointed to fill the resulting vacancy shall be appointed for the re-

mainder of the term of the predecessor of the individual.

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

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

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

''(6) CERTAIN BYLAWS.—

''(A) In establishing bylaws under this subsection, the Board shall ensure that the following are provided for:

''(i) Policies for the selection of the officers, employees, agents, and contractors of the Foundation.

''(ii) Policies, including ethical standards, for the acceptance, solicitation, and disposition of donations and grants to the

Foundation and for the disposition of the assets of the Foundation. Policies with respect to ethical standards shall ensure that officers, employees and agents of the Foundation (including members of the Board) avoid encumbrances that would result in a conflict of interest, including a financial conflict of interest or a divided allegiance. Such policies shall include requirements for the provision of information concerning any ownership or controlling interest in entities related to the activities of the Foundation by such officers, employees and agents and their spouses and relatives.

''(iii) Policies for the conduct of the general operations of the Foundation.

''(iv) Policies for writing, editing, printing, publishing, and vending of books and other materials.

''(B) In establishing bylaws under this subsection, the Board shall ensure that such bylaws (and activities carried out under the bylaws) do not—

''(i) reflect unfavorably upon the ability of the Foundation to carry out its re-

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

''(ii) compromise, or appear to compromise, the integrity of any governmental agency or program, or any officer or employee involved in such program.

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

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

''(g) EXECUTIVE DIRECTOR.—

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

''(2) COMPENSATION.—The rate of compensation of the Executive Director shall be fixed by the Board.

''(h) POWERS.—In carrying out subsection (b), the Foundation may—

''(1) operate under the direction of its Board;

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

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

''(4) hire, promote, compensate, and discharge officers and employees of the Foundation, and define the duties of the officers and employees;

''(5) with the consent of any executive department or independent agency, use the information, services, staff, and facilities of such in carrying out this section;

''(6) sue and be sued in its corporate name, and complain and defend in courts of competent jurisdiction;

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

''(8) establish a process for the selection of candidates for positions under subsection (c);

''(9) enter into contracts with public and private organizations for the writing, editing, printing, and publishing of books and other material;

''(10) take such action as may be necessary to obtain patents and licenses for devices and procedures developed by the Foundation and its employees;

''(11) solicit, accept, hold, administer, invest, and spend any gift, devise, or bequest of real or personal property made to the Foundation;

''(12) enter into such other contracts, leases, cooperative agreements, and other transactions as the Executive Director considers appropriate to conduct the activities of the Foundation;

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

''(14) enter into such other contracts, leases, cooperative agreements, and other transactions as the Executive Director considers appropriate to conduct the activities of the Foundation; and

''(15) exercise other powers as set forth in this section, and such other incidental powers as are necessary to carry out its powers, duties, and functions in accordance with this part.

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

''(j) GENERAL PROVISIONS.—

''(1) FOUNDATION INTEGRITY.—The members of the Board shall be accountable for the integrity of the operations of the Foundation and shall ensure such integrity through the development and enforcement of criteria and procedures relating to standards of conduct (including those developed under subsection (d)(6)(A)(ii)), financial disclosure statements, conflict of interest rules, recusal and waiver rules, audits and other matter determined appropriate by the Board.

''(2) FINANCIAL CONFLICTS OF INTEREST.—Any individual who is an officer, employee, or member of the Board of the Foundation may not (in accordance with policies and requirements developed under subsection (d)(6)(A)(ii)) personally or substantially participate in the consideration or determination by the Foundation of any matter that would directly or predictably affect any financial interest of the individual or a relative (as such term is defined in section 109(16) of the Ethics in Government Act of 1978) of the individual, of any busi-

ness organization or other entity, or of which the individual is an officer or employee, or is negotiating for employment, or in which the individual has any other financial interest.

''(3) AUDITS; AVAILABILITY OF RECORDS.—The Foundation shall—

''(A) provide for annual audits of the financial condition of the Foundation; and

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

''(4) REPORTS.—

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

''(B) With respect to the financial condition of the Foundation, each report under subparagraph (A) shall include the source, and a

description of, all gifts or grants to the Foundation of real or personal property, and the source and amount of all gifts or grants to the Foundation of money. Each such report shall include a specification of any restrictions on the purposes for which gifts or grants to the Foundation may be used.

''(C) The Foundation shall make copies of each report submitted under subparagraph (A) available for public inspection, and shall upon request provide a copy of the report to any individual for a charge not exceeding the cost of providing the copy.

''(D) The Board shall annually hold a public meeting to summarize the activities of the Foundation and distribute written reports concerning such activities and the scientific results derived from such activities.

''(5) SERVICE OF FEDERAL EMPLOYEES.—Federal employees may serve on committees advisory to the Foundation and otherwise cooperate with and assist the Foundation in carrying out its function, so long as the employees do not direct or control Foundation activities.

''(6) RELATIONSHIP WITH EXISTING ENTITIES.—The Foundation may, pursuant to appropriate agreements, merge with, acquire, or use the resources of existing nonprofit private corporations with missions similar to the purposes of the Foundation.

''(7) INTELLECTUAL PROPERTY RIGHTS.—The Board shall adopt written standards with respect to the ownership of any intellectual property rights derived from the collaborative efforts of the Foundation prior to the commencement of such efforts.

''(8) NATIONAL INSTITUTES OF HEALTH AMENDMENTS OF 1990.—The activities conducted in support of the National Institutes of Health Amendments of 1990 (Public Law 101–613), and the amendments made by such Act, shall not be nullified by the enactment of this section.

''(9) LIMITATION OF ACTIVITIES.—The Foundation shall exist solely as an entity to work in collaboration with the research programs of the National Institutes of Health. The Foundation may not undertake activities (such as the operation of independent laboratories or competing for Federal research funds) that are independent of those of the National Institutes of Health research programs.

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

''(k) DUTIES OF THE DIRECTOR.—

''(1) APPLICABILITY OF CERTAIN STANDARDS TO NON-FEDERAL EMPLOYEES.—In the case of any individual who is not an employee of the Federal Government and who serves in association with the National Institutes of Health, with respect to financial assistance received from the Foundation, the Foundation may not provide the assistance of, or otherwise permit the work at the National Institutes of Health to begin until a memorandum of understanding between the individual and the Director of NIH, or the designee of such Director, has been executed specifying that the individual shall be subject to such ethical and procedural standards of conduct relating to duties performed at the National Institutes of Health, as the Director of NIH determines is appropriate.

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

Director to be advantageous to the research programs of the National Institutes of Health.

''(l) FUNDING.—

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

''(2) LIMITATION REGARDING OTHER FUNDS.—Amounts appropriated under any provision of law other than paragraph (1) may not be expended to establish or operate the Foundation.''.

SEC. 5. OFFICE OF PEDIATRIC THERAPEUTICS.

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

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

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

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

(2) 1 or more additional individuals with expertise concerning ethical issues presented by the conduct of clinical research in the pediatric population; and

(3) 1 or more additional individuals with expertise in pediatrics who shall consult and collaborate with all components of the Food and Drug Administration concerning activities described in subsection (b).

SEC. 6. STUDY CONCERNING RESEARCH INVOLVING CHILDREN.

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

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

(A) Federal regulations in effect on the date of the enactment of this Act relating to research involving children;

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

(C) federally-supported evidence-based research involving children; and

(2) the submission to the appropriate committees of Congress, by not later than 2 years after the date of enactment of this Act, of a report concerning the review conducted under paragraph (1) that includes recommendations on best practices relating to research involving children.

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

(1) The written and oral process of obtaining and defining ''assent'', ''permission'' and ''informed consent'' with respect to child clinical research participants and the parents, guardians, and the individuals who may serve as the legally authorized representatives of such children (as defined in subpart A of part 46 of title 45, Code of Regulations).

(2) The expectations and comprehension of child research participants and the parents, guardians, or legally authorized representatives of such children, for the direct benefits and risks of the child's research involvement, particularly in terms of research versus therapeutic treatment.

(3) The definition of ''minimal risk'' with respect to a healthy child or a child with an illness.

(4) The appropriateness of the regulations applicable to children of differing ages and maturity levels, including regulations relating to legal status.

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

(6) Compliance with the regulations referred to in subsection (a)(1)(A), the monitoring of such compliance (including the role of institutional review boards), and the enforcement actions taken for violations of such regulations.

(7) The unique roles and responsibilities of institutional review boards in reviewing research involving children, including composition of membership on institutional review boards.

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

research, and the ethical conduct of research involving children.

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