Calendar No. 228

107TH CONGRESS
1ST SESSION

H. R. 2887

IN THE SENATE OF THE UNITED STATES

NOVEMBER 16, 2001
Received; read twice and placed on the calendar

AN ACT

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

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 ALREADY-MARKETED DRUGS.

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

(1) by striking subsection (b); and

(2) by redesignating subsections (c) through through (k) as subsections (b) through (j), respectively.

(b) CONFORMING AMENDMENTS.—Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended in subsection (b) (as redesignated by subsection (a)(2) of this section)—

(1) by inserting after ''the Secretary'' the following: ''determines that information relating to the use of an approved drug in the pediatric population may produce health benefits in that population and''; and

(2) by striking ''concerning a drug identified in the list described in subsection (b)''.

SEC. 3. RESEARCH FUND FOR THE STUDY OF DRUGS LACKING EXCLUSIVITY.

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

(1) by redesignating the second section 409C (relating to clinical research) as section 409G;

(2) by redesignating the second section 409D (relating to enhancement awards) as section 409H; and

(3) by adding at the end the following:

"SEC. 409I. PROGRAM FOR PEDIATRIC STUDIES OF DRUGS LACKING EXCLUSIVITY.

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

''(1) IN GENERAL.—Not later than 1 year after the date of enactment of this section, the Secretary, acting through the Director of the National Institutes of Health and in consultation with the Commissioner of Food and Drugs and experts in pediatric research, shall develop, prioritize, and publish an annual list of approved drugs for which—

''(A)(i) there is an approved application under section 505(j) of the Federal Food, Drug, and Cosmetic Act;

''(ii) there is a submitted application that could be approved under the criteria of section

505(j) of the Federal Food, Drug, and Cosmetic Act;

"(iii) there is no patent protection or market exclusivity protection under the Federal Food, Drug, and Cosmetic Act; or

"(iv) there is, under section 505A(c)(4)(C) of the Federal Food, Drug, and Cosmetic Act, a referral for inclusion on such list; and

"(B) additional studies are needed to assess the safety and effectiveness of the use of the drug in the pediatric population.

"(2) CONSIDERATION OF AVAILABLE INFORMATION.—In developing the list under paragraph (1), the Secretary shall consider, for each drug on the list—

"(A) the availability of information concerning the safe and effective use of the drug in the pediatric population;

"(B) whether additional information is needed;

"(C) whether new pediatric studies concerning the drug may produce health benefits in the pediatric population; and

"(D) whether reformulation of the drug is necessary;

''(b) CONTRACTS FOR PEDIATRIC STUDIES.—The Secretary shall award contracts to entities that have the expertise to conduct pediatric clinical trials (including qualified universities, hospitals, laboratories, contract research organizations, federally funded programs such as pediatric pharmacology research units, other public or private institutions, or individuals) to enable the entities to conduct pediatric studies concerning one or more drugs identified in the list described in subsection (a).

''(c) PROCESS FOR CONTRACTS AND LABELING CHANGES.—

''(1) WRITTEN REQUEST TO HOLDERS OF APPROVED APPLICATIONS FOR DRUGS LACKING EXCLUSIVITY.—

''(A) IN GENERAL.—The Commissioner of Food and Drugs, in consultation with the Director of National Institutes of Health, may issue a written request (which shall include a timeframe for negotiations for an agreement) for pediatric studies concerning a drug identified in the list described in subsection (a) to all holders of an approved application for the drug under section 505 of the Federal Food, Drug, and Cosmetic Act. Such a written request shall be made in a manner equivalent to the manner

in which a written request is made under subsection (a) or (b) of section 505A of the Federal Food, Drug, and Cosmetic Act, including with respect to information provided on the pediatric studies to be conducted pursuant to the request.

''(B) PUBLICATION OF REQUEST.—If the Commissioner of Food and Drugs does not receive a response to a written request issued under subparagraph (A) within 30 days of the date on which a request was issued, the Secretary, acting through the Director of National Institutes of Health and in consultation with the Commissioner of Food and Drugs, shall publish a request for contract proposals to conduct the pediatric studies described in the written request.

''(C) DISQUALIFICATION.—A holder that receives a first right of refusal shall not be entitled to respond to a request for contract proposals under subparagraph (B).

''(D) GUIDANCE.—Not later than 270 days after the date of enactment of this section, the Commissioner of Food and Drugs shall promulgate guidance to establish the process for the

submission of responses to written requests under subparagraph (A).

''(2) CONTRACTS.—A contract under this section may be awarded only if a proposal for the contract is submitted to the Secretary in such form and manner, and containing such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

''(3) REPORTING OF STUDIES.—

''(A) Upon completion of a pediatric study in accordance with a contract awarded under this section, a report concerning the study shall be submitted to the Director of National Institutes of Health and the Commissioner of Food and Drugs. The report shall include all data generated in connection with the study.

''(B) AVAILABILITY OF REPORTS.—Each report submitted under subparagraph (A) shall be considered to be in the public domain, and shall be assigned a docket number by the Commissioner of Food and Drugs. An interested person may submit written comments concerning such pediatric studies to the Commissioner of Food and Drugs, and the written com-

ments shall become part of the docket file with respect to each of the drugs.

"(C) ACTION BY COMMISSIONER.—The Commissioner of Food and Drugs shall take appropriate action in response to the reports submitted under subparagraph (A) in accordance with paragraph (4).

"(4) REQUEST FOR LABELING CHANGES.—During the 180-day period after the date on which a report is submitted under paragraph (3)(A), the Commissioner of Food and Drugs shall—

"(A) review the report and such other data as are available concerning the safe and effective use in the pediatric population of the drug studied; and

"(B) negotiate with the holders of approved applications for the drug studied for any labeling changes that the Commissioner of Food and Drugs determines to be appropriate and requests the holders to make; and

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

''(ii) publish in the Federal Register a summary of the report and a copy of any requested labeling changes.

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

''(A) the Commissioner of Food and Drugs shall immediately refer the request to the Pediatric Advisory Subcommittee of the Anti-Infective Drugs Advisory Committee; and

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

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

''(ii) make a recommendation to the Commissioner of Food and Drugs as to appropriate labeling changes, if any.

''(6) FDA DETERMINATION.—Not later than 30 days after receiving a recommendation from the Subcommittee under paragraph (5)(B)(ii) with re-

spect to a drug, the Commissioner of Food and Drugs shall consider the recommendation and, if appropriate, make a request to the holders of approved applications for the drug to make any labeling change that the Commissioner of Food and Drugs determines to be appropriate.

''(7) FAILURE TO AGREE.—If a holder of an approved application for a drug, within 30 days after receiving a request to make a labeling change under paragraph (6), does not agree to make a requested labeling change, the Commissioner may deem the drug to be misbranded under the Federal Food, Drug, and Cosmetic Act.

''(8) RECOMMENDATION FOR FORMULATION CHANGES.—If a pediatric study completed under public contract indicates that a formulation change is necessary and the Secretary agrees, the Secretary shall send a nonbinding letter of recommendation regarding that change to each holder of an approved application.

''(d) CONFIDENTIAL COMMERCIAL INFORMATION; TRADE SECRETS.—Nothing in this section requires or authorizes the use or disclosure of confidential commercial information or trade secrets.

''(e) AUTHORIZATION OF APPROPRIATIONS.—

''(1) IN GENERAL.—For the purpose of carrying out this section, 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) AVAILABILITY.—Any amount appropriated under paragraph (1) shall remain available to carry out this section until expended.''.

SEC. 4. WRITTEN REQUEST TO HOLDERS OF APPROVED APPLICATIONS FOR DRUGS THAT HAVE MARKET EXCLUSIVITY.

Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended in subsection (c) (as redesignated by section 2(a)(2) of this Act) by adding at the end the following:

''(4) WRITTEN REQUEST TO HOLDERS OF APPROVED APPLICATIONS FOR DRUGS THAT HAVE MARKET EXCLUSIVITY.—

''(A) REQUEST AND RESPONSE.—If the Secretary makes a written request for pediatric studies under subsection (b) to the holder of an application approved under section 505(b)(1), the holder, not later than 180 days after receiving the written request, shall respond to the

Secretary as to the intention of the holder to act on the request by—

"(i) indicating when the pediatric studies will be initiated, if the holder agrees to the request; or

"(ii) indicating that the holder does not agree to the request.

"(B) NO AGREEMENT TO REQUEST.—

"(i) REFERRAL.—If the holder does not agree to a written request within the time period specified in subparagraph (A), and if the Secretary determines that there is a continuing need for information relating to the use of the drug in the pediatric population (including neonates as appropriate), the Secretary shall refer the drug to the Foundation for Pediatric Research established under section 499A of the Public Health Service Act (referred to in this paragraph as the 'Foundation') for consideration for the conduct of the pediatric studies described in the written request.

"(ii) PUBLIC NOTICE.—The Secretary shall give public notice of a referral under clause (i), including notice of the name of

the drug, the name of the manufacturer, and the indication to be studied.

''(C) LACK OF FUNDS.—If, on referral of a drug under subparagraph (B)(i), the Foundation certifies to the Secretary that the Foundation does not have funds available to conduct the requested studies, the Secretary shall refer the drug for inclusion on the list established under section 409I of the Public Health Service Act for the conduct of the studies.

''(D) CONFIDENTIAL COMMERCIAL INFORMATION; TRADE SECRETS.—Nothing in this paragraph requires or authorizes the use or disclosure of confidential commercial information or trade secrets.

''(E) NO REQUIREMENT TO REFER.—Nothing in this subsection shall be construed to require that every declined written request shall be referred to the Foundation.''.

SEC. 5. TIMELY LABELING CHANGES FOR DRUGS GRANTED EXCLUSIVITY; DRUG FEES.

(a) ELIMINATION OF USER FEE WAIVER FOR PEDIATRIC SUPPLEMENTS.—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).

(b) LABELING CHANGES.—

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

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

(2) TREATMENT AS PRIORITY SUPPLEMENTS.—Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a), as amended by section 2(a)(2) of this Act, is amended by adding at the end the following:

''(k) LABELING SUPPLEMENTS.—

''(1) PRIORITY STATUS FOR PEDIATRIC SUPPLEMENTS.—Any supplement to an application under section 505 proposing a labeling change pursuant to a report on a pediatric study under this section—

''(A) shall be considered to be a priority supplement; and

''(B) shall be subject to the performance goals established by the Commissioner for priority drugs.

''(2) DISPUTE RESOLUTION.—If the Commissioner determines that an application with respect to which a pediatric study is conducted under this section is approvable and that the only open issue for final action on the application is the reaching of an agreement between the sponsor of the application and the Commissioner on appropriate changes to the labeling for the drug that is the subject of the application—

''(A) not later than 180 days after the date of submission of the application—

''(i) the Commissioner shall request that the sponsor of the application make any labeling change that the Commissioner determines to be appropriate; and

''(ii) if the sponsor of the application does not agree to make a labeling change requested by the Commissioner by that date, the Commissioner shall immediately refer the matter to the Pediatric Advisory Subcommittee of the Anti-Infective Drugs Advisory Committee;

''(B) not later than 90 days after receiving the referral, the Pediatric Advisory Subcommittee of the Anti-Infective Drugs Advisory Committee shall—

''(i) review the pediatric study reports; and

''(ii) make a recommendation to the Commissioner concerning appropriate labeling changes, if any;

''(C) the Commissioner shall consider the recommendations of the Pediatric Advisory Subcommittee of the Anti-Infective Drugs Advisory Committee and, if appropriate, not later than 30 days after receiving the recommendation, make a request to the sponsor of the application to make any labeling change that the Commissioner determines to be appropriate; and

''(D) if the sponsor of the application, within 30 days after receiving a request under subparagraph (C), does not agree to make a labeling change requested by the Commissioner, the Commissioner may deem the drug that is the subject of the application to be misbranded.''.

SEC. 6. 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. 7. NEONATES.

Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended in subsection (f) (as redesignated by section 2(a)(2) of this Act) by inserting ''(including neonates in appropriate cases)'' after ''pediatric age groups''.

SEC. 8. SUNSET.

Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended by striking subsection (i) (as redesignated by section 2(a)(2) of this Act) and inserting the following:

''(i) SUNSET.—A drug may not receive any 6-month period under subsection (a) or (b) unless—

''(1) on or before October 1, 2007, the Secretary makes a written request for pediatric studies of the drug;

''(2) on or before October 1, 2007, an approvable application for the drug is submitted under section 505(b)(1); and

''(3) all requirements of this section are met.''.

SEC. 9. DISSEMINATION OF PEDIATRIC INFORMATION.

Section 505A of the Federal Food, Drug, and Cosmetic Act, as amended by section 5(b)(2) of this Act, is amended by adding at the end the following:

''(l) DISSEMINATION OF PEDIATRIC INFORMATION.—

''(1) IN GENERAL.—Not later than 180 days after the date of submission of a report on a pediatric study under this section, the Commissioner shall make available to the public a summary of the medical and clinical pharmacology reviews of pediatric studies conducted for the supplement, including by publication in the Federal Register.

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

SEC. 10. CLARIFICATION OF INTERACTION OF MARKET EXCLUSIVITY UNDER SECTION 505A OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT AND MARKET EXCLUSIVITY AWARDED TO AN APPLICANT FOR APPROVAL OF A DRUG UNDER SECTION 505(j) OF THAT ACT.

Section 505A of the Federal Food, Drug, and Cosmetic Act, as amended by section 9 of this Act, is amended by adding at the end the following:

''(m) CLARIFICATION OF INTERACTION OF MARKET EXCLUSIVITY UNDER THIS SECTION AND MARKET EXCLUSIVITY AWARDED TO AN APPLICANT FOR APPROVAL OF A DRUG UNDER SECTION 505(j).—

''(1) IN GENERAL.—If a 180-day period under section 505(j)(5)(B)(iv) overlaps with a 6-month extension under this section, so that the applicant for approval of a drug under section 505(j) 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.

''(2) EFFECT OF SUBSECTION.—Under no circumstances shall application of this section result in an applicant for approval of a drug under section 505(j) being enabled to commercially market the drug to the exclusion of a subsequent applicant for approval of a drug under section 505(j) for more than 180 days.''.

SEC. 11. PROMPT APPROVAL OF GENERIC DRUGS WHEN PEDIATRIC INFORMATION ADDED TO LABELING.

(a) IN GENERAL.—Section 505A of the Federal Food, Drug, and Cosmetic Act, as amended by section 10 of this Act, is amended by adding at the end the following subsection:

''(n) PROMPT APPROVAL OF GENERIC DRUGS WHEN PEDIATRIC INFORMATION ADDED TO LABELING.—

''(1) IN GENERAL.—A drug for which an application has been submitted or approved under section 505(j) and which otherwise meets all other applicable requirements under that section shall be considered eligible for approval and shall not be considered misbranded under section 502 even when its labeling omits a pediatric indication or other aspect of labeling pertaining to pediatric use that is protected by patent or by market exclusivity pursuant to clause (iii) or (iv) of section 505(j)(5)(D).

''(2) LABELING OF GENERIC DRUG.—Notwithstanding the provisions of clause (iii) or (iv) of section 505(j)(5)(D), the Secretary may require that the labeling of a drug approved under section 505(j) that omits pediatric labeling pursuant to paragraph (1) include—

"(A) a statement that the drug is not labeled for the protected pediatric use; and

"(B) any warnings against unsafe pediatric use that the Secretary considers necessary.

"(3) RULE OF CONSTRUCTION.—Paragraphs 1 and 2 of this subsection do not affect—

"(A) the availability or scope of exclusivity under this section;

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

"(C) except as expressly provided in paragraph (1) and (2), the operation of section 505.".

(b) EFFECTIVE DATE.—The amendments made by subsection (a) take effect on the date of the enactment of this Act, including with respect to applications under section 505(j) of the Federal Food, Drug, and Cosmetic Act that are approved or pending on that date.

SEC. 12. ADVERSE-EVENT REPORTING.

(a) TOLL-FREE NUMBER IN LABELING.—Not later than one year after the date of the enactment of this Act, the Secretary of Health and Human Services shall promulgate a final rule requiring that the labeling of each drug for which an application is approved under section 505 of the Federal Food, Drug, and Cosmetic Act (regardless

of the date on which approved) include the toll-free number maintained by the Secretary for the purpose of receiving reports of adverse events regarding drugs. With respect to the final rule:

(1) The rule shall provide for the implementation of such labeling requirement in a manner that the Secretary considers to be most likely to reach the broadest consumer audience.

(2) In promulgating the rule, the Secretary shall seek to minimize the cost of the rule on the pharmacy profession.

(3) The rule shall take effect not later than 60 days after the date on which the rule is promulgated.

(b) DRUGS WITH PEDIATRIC MARKET EXCLUSIVITY.—

(1) IN GENERAL.—During the one-year beginning on the date on which a drug receives a period of market exclusivity under 505A of the Federal Food, Drug, and Cosmetic Act, any report of an adverse event regarding the drug that the Secretary of Health and Human Services receives shall be referred to the Office of Pediatric Therapeutics established under section 6 of this Act. In considering the report, the Director of such Office shall provide for

the review of the report by the Pediatric Advisory Subcommittee of the Anti-Infective Drugs Advisory Committee, including obtaining any recommendations of such Subcommittee regarding whether the Secretary should take action under the Federal Food, Drug, and Cosmetic Act in response to the report.

(2) RULE OF CONSTRUCTION.—Paragraph (1) may not be construed as restricting the authority of the Secretary of Health and Human Services to continue carrying out the activities described in such paragraph regarding a drug after the one-year period described in such paragraph regarding the drug has expired.

SEC. 13. 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 Re-

search (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 collect funds and award grants for research on drugs listed by the Secretary pursuant to section 409I(a)(1)(A).

''(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. Appointed members of the Board shall be the 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.

''(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 remainder 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, and agents 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.

''(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 responsibilities 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 shall operate under the direction of its Board, and may—

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

''(2) 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;

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

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

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

''(6) 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;

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

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

''(9) 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

''(10) 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, nor shall the Foundation attempt to influence an executive branch agency or 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 business 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 pur-

poses 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, acquire the resources of existing nonprofit private corporations with missions similar to the purposes of the Foundation.

''(7) INTELLECTUAL PROPERTY RIGHTS.—The Board may 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 collect funds and award grants for research on drugs listed by the Secretary pursuant to section 409I(a)(1)(A).

''(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 shall provide facilities, utilities and support services to the Foundation.

''(l) REPORTS OF STUDIES; LABELING CHANGES.—

''(1) IN GENERAL.—Upon completion of a pediatric study conducted pursuant to this section, a report concerning the study shall be submitted to the Director of National Institutes of Health and the Commissioner of Food and Drugs. The report shall include all data generated in connection with the study.

''(2) AVAILABILITY OF REPORTS; ACTION BY FOOD AND DRUG ADMINISTRATION; LABELING

CHANGES.—With respect to a report submitted under paragraph (1), the provisions of paragraphs (3)(B) through (8) of section 409I(c) apply to such report to the same extent and in the same manner as such provision apply to a report submitted under section 409I(c)(3)(A).

''(m) 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. 14. 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 Federal 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.

SEC. 15. STUDY ON EFFECTS OF THIS ACT.

Not later than October 1, 2006, the Comptroller General of the United States shall submit to the Congress and the Secretary of Health and Human Services a report that describes the following:

(1) The effectiveness of the amendments made by this Act in ensuring that all drugs used by children are tested and properly labeled, including—

(A) the number and importance for children of drugs that are being tested as a result of such amendments, and the importance for children, health care providers, parents, and others of labeling changes made as a result of such testing;

(B) the number and importance for children of drugs that are not being tested for their use notwithstanding the amendments, and possible reason for this; and

(C) the number of drugs for which pediatric testing has been done, for which a period of market exclusivity has been granted, and for which labeling changes required the use of the dispute resolution process established pursuant to the amendments, together with a description of the outcomes of such process, including a description of the disputes and the recommendations of the advisory committee.

(2) The economic impact of the amendments made by this Act, including an estimate of—

(A) costs to taxpayers in the form of higher expenditures by Medicaid and other government programs;

(B) costs to consumers as a result of any delay in the availability of lower cost generic equivalents of drugs tested and granted exclusivity pursuant to such amendments, and loss of revenue by the generic drug industry and any other affected industry as a result of any such delay; and

(C) benefits to the government, to private insurers, and to consumers resulting from decreased health care costs, including—

(i) decreased hospitalizations, due to more appropriate and more effective use of medications in children as a result of testing and re-labeling because of such amendments;

(ii) direct and indirect benefits associated with fewer physician visits not related to hospitalization;

(iii) benefits to children from missing less time at school and being less affected by chronic illnesses, thereby allowing a better quality of life;

(iv) benefits to consumers from lower health insurance premiums due to lower treatment costs and hospitalization rates; and

(v) benefits to employers from reduced need for employees to care for family members.

(3) The nature and types of studies in children of drugs granted a period of market exclusivity pursuant to the amendments made by this Act, including a description of the complexity of such studies, the number of study sites necessary to obtain appropriate data, and the numbers of children involved in

any clinical studies, and the cost of such studies for each type of study identified.

(4) The increased pediatric research capability, both private and government-funded, associated with the amendments made by this Act.

SEC. 16. MINORITY CHILDREN AND PEDIATRIC-EXCLUSIVITY PROGRAM.

(a) PROTOCOLS FOR PEDIATRIC STUDIES.—Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended in subsection (c)(2) (as redesignated by section 2(a)(2) of this Act) by inserting after the first sentence the following: ''In reaching an agreement regarding written protocols, the Secretary shall take into account adequate representation of children of ethnic and racial minorities.''.

(b) STUDY BY GENERAL ACCOUNTING OFFICE.—

(1) IN GENERAL.—The Comptroller General of the United States shall conduct a study for the purpose of determining the following:

(A) The extent to which children of ethnic and racial minorities are adequately represented in studies under section 505A of the Federal Food, Drug, and Cosmetic Act; and to the extent ethnic and racial minorities are not adequately represented, the reasons for such under

representation and recommendations to increase such representation.

(B) Whether the Food and Drug Administration has appropriate management systems to monitor the representation of the children of ethnic and racial minorities in such studies.

(C) Whether drugs used to address diseases that disproportionately affect racial and ethnic minorities are being studied for their safety and effectiveness under section 505A of the Federal Food, Drug, and Cosmetic Act.

(2) DATE CERTAIN FOR COMPLETING STUDY.—Not later than January 10, 2003, the Comptroller General shall complete the study required in paragraph (1) and submit to the Congress a report describing the findings of the study.

SEC. 17. TECHNICAL AND CONFORMING AMENDMENTS.

Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended—

(1)(A) by striking ''(j)(4)(D)(ii)'' each place such term appears and inserting ''(j)(5)(D)(ii)''; and

(B) by striking ''(j)(4)(D)'' each place such term appears and inserting ''(j)(5)(D)''; and

(2)(A) in subsection (c) (as redesignated by section 2(a)(2) of this Act), in each of paragraphs (1)

through (3), by striking ''subsection (a) or (c)'' and inserting ''subsection (a) or (b)''; and

(B) in subsection (d) (as so redesignated), in the last sentence, by striking ''subsection (a) or (c)'' and inserting ''subsection (a) or (b)''.

Passed the House of Representatives November 15, 2001.

Attest: JEFF TRANDAHL,

Clerk.

Calendar No. 228

107TH CONGRESS
1ST SESSION

H. R. 2887

AN ACT

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

NOVEMBER 16, 2001

Received; read twice and placed on the calendar