Calendar No. 184

107TH CONGRESS
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S. 838

[Report No. 107–79]

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

IN THE SENATE OF THE UNITED STATES

MAY 7, 2001

Mr. DODD (for himself, Mr. DEWINE, Ms. MIKULSKI, Mr. FRIST, Mr. JEFFORDS, Mr. BOND, Ms. COLLINS, Ms. LANDRIEU, Mrs. FEINSTEIN, Mr. CORZINE, Mr. CARPER, Mrs. MURRAY, Mr. REED, Mr. BINGAMAN, and Mr. ROBERTS) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

OCTOBER 4, 2001

Reported by Mr. KENNEDY, with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

A BILL

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.

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

(1) by striking subsection (b); and

(2) in subsection (c)—

(A) 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

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

SEC. 3. RESEARCH FUND FOR THE STUDY OF OFF-PATENT DRUGS.

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 (42 U.S.C. 284k), as section 409G;

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

(3) by adding at the end the following:

"SEC. 409I. PROGRAM FOR PEDIATRIC STUDIES OF OFF-PATENT DRUGS.

"(a) LIST OF OFF-PATENT DRUGS 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 (including United States Pharmacopoeia), shall develop, prioritize, and publish a list of approved drugs for which—

"(A) there is no patent or market exclusivity protection; 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; and

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

"(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 OFF-PATENT DRUGS.—

"(A) IN GENERAL.—The Commissioner of Food and Drugs, in consultation with the Director of National Institutes of Health, may issue a written request 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 request shall be made in accordance with section 505A of the Federal Food, Drug, and Cosmetic Act.

"(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, shall publish a request for contract proposals to conduct the pediatric studies described in the written request.

"(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 comments shall become part of the docket file with respect to each the drug.

"(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 60 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 respect 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.

"(d) AUTHORIZATION OF APPROPRIATIONS.—

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

''(A) $200,000,000 for fiscal year 2002; and

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

''(2) AVAILABILITY.—Any amount appropriated under paragraph (1) shall remain available to carry out this section until expended.''.

SEC. 4. 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.—Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended by adding at the end the following:

''(l) LABELING SUPPLEMENTS.—

''(1) PRIORITY STATUS FOR PEDIATRIC SUPPLEMENTS.—Any supplement to a human drug application submitted 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 a supplemental application submitted under this section is approvable and that the only open issue for final action on the supplement 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 supplemental 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 60 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 (D), 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. 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) 1 or more individuals with expertise concerning ethical issues presented by the conduct of clinical research in the pediatric population; and

(2) 1 or more individuals with expertise in pediatrics who shall consult with all components of the Food and Drug Administration concerning activities described in subsection (b).

SEC. 6. NEONATES.

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

SEC. 7. SUNSET.

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

''(j) SUNSET.—A drug may not receive any 6-month period under subsection (a) or (c) 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 application for the drug is submitted under section 505(b)(1); and

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

SEC. 8. DISSEMINATION OF PEDIATRIC INFORMATION.

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

''(m) DISSEMINATION OF PEDIATRIC INFORMATION.—

''(1) IN GENERAL.—Not later than 180 days after the date of submission of a supplemental application 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. 9. TECHNICAL AND CONFORMING AMENDMENTS.~~

~~Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) (as amended by sections 2(1), 4(b), 7, and 8) is amended—~~

~~(1) by redesignating subsections (a), (g), (h), (i), (j), (l), and (m) as subsections (b), (a), (g), (h), (l), (i), and (j), respectively;~~

~~(2) by moving the subsections so as to appear in alphabetical order; and~~

~~(3) in paragraphs (1), (2), and (3) of subsection (d) and subsections (e), (g) (as redesignated by paragraph (1)), and (l) (as redesignated by paragraph (1)), by striking "subsection (a) or (c)" and inserting "subsection (b) or (c)".~~

SECTION 1. SHORT TITLE.

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

SEC. 2. PEDIATRIC STUDIES OF ALREADY-MARKETED DRUGS.

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

(1) by striking subsection (b); and

(2) in subsection (c)—

(A) 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

(B) 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 (42 U.S.C. 284k), as section 409G;

(2) by redesignating the second section 409D, relating to enhancement awards (42 U.S.C. 284l), 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 (21 U.S.C. 355(j));

"(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 (21 U.S.C. 355(j)); or

"(iii) there is no patent protection or market exclusivity protection under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.); 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 request shall be made in accordance with section 505A of the Federal Food, Drug, and Cosmetic Act.

"(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 comments 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 respect 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) AUTHORIZATION OF APPROPRIATIONS.—

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

"(A) $200,000,000 for fiscal year 2002; and

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

"(2) AVAILABILITY.—Any amount appropriated under paragraph (1) shall remain available to carry out this section until expended.".

SEC. 4. 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) is amended by adding at the end the following:

"(l) 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. 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. NEONATES.

Section 505A(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(g)) is amended by inserting "(including neonates in appropriate cases)" after "pediatric age groups".

SEC. 7. SUNSET.

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

"(j) SUNSET.—A drug may not receive any 6-month period under subsection (a) or (c) 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. 8. DISSEMINATION OF PEDIATRIC INFORMATION.

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

"(m) 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. 9. 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 (21 U.S.C. 355a) (as amended by section 8) is amended by adding at the end the following:

"(n) 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. 10. 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. 11. TECHNICAL AND CONFORMING AMENDMENTS.

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

(1)(A) by striking "(j)(4)(D)(ii)" each place it appears and inserting "(j)(5)(D)(ii)";

(B) by striking "(j)(4)(D)" each place it appears and inserting "(j)(5)(D)"; and

(C) by striking "505(j)(4)(D)" each place it appears and inserting "505(j)(5)(D)";

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

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

(4) in paragraphs (1), (2), and (3) of subsection (d), subsection (e), and subsection (m) (as redesignated by paragraph (1)), by striking "subsection (a) or (c)" and inserting "subsection (b) or (c)"; and

(5) in subsection (g) (as redesignated by paragraph (1)), by striking "subsection (a) or (b)" and inserting "subsection (b) or (c)".

Calendar No. 184

107TH CONGRESS
1ST SESSION

S. 838

[Report No. 107–79]

A BILL

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

OCTOBER 4, 2001

Reported with an amendment