



Best Pharmaceuticals for Children Act Pediatric Research Equity Act

2007 REAUTHORIZATION Improvements to Existing Law

110th Congress: H.R. 3580, Public Law 110-85

Best Pharmaceuticals for Children Act: Improvements to Existing Law		
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<p>SEC. 505A. [21 U.S.C. 355a] PEDIATRIC STUDIES OF DRUGS.</p> <p>(a) DEFINITIONS.—As used in this section, the term “pediatric studies” or “studies” means at least one clinical investigation (that, at the Secretary’s discretion, may include pharmacokinetic studies) in pediatric age groups (including neonates in appropriate cases) in which a drug is anticipated to be used.</p> <p>(b) MARKET EXCLUSIVITY FOR NEW DRUGS.—If, prior to approval of an application that is submitted under section 505(b)(1), the Secretary determines that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, the Secretary makes a written request for pediatric studies (which shall include a timeframe for completing such studies), and such studies are completed within any such timeframe and the reports thereof submitted in accordance with subsection (d)(2) or</p>	<p>SEC. 501. SHORT TITLE.</p> <p>This title may be cited as the ‘Best Pharmaceuticals for Children Act of 2007’.</p> <p>SEC. 502. REAUTHORIZATION OF BEST PHARMACEUTICALS FOR CHILDREN ACT.</p> <p>(a) Pediatric Studies of Drugs—</p> <p>(1) IN GENERAL- Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended to read as follows:</p> <p>‘SEC. 505A. PEDIATRIC STUDIES OF DRUGS.</p> <p>‘(a) DEFINITIONS.—As used in this section, the term ‘pediatric studies’ or ‘studies’ means at least one clinical investigation (that, at the Secretary’s discretion, may include pharmacokinetic studies) in pediatric age groups (including neonates in appropriate cases) in which a drug is anticipated to be used, and, at the discretion of the Secretary, may include preclinical studies.</p> <p>‘(b) MARKET EXCLUSIVITY FOR NEW DRUGS.—</p> <p>‘(1) IN GENERAL—Except as provided in paragraph (2), if, prior to approval of an application that is submitted under section 505(b)(1), the Secretary determines that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, the Secretary makes a written request for pediatric studies (which shall include a timeframe for completing such studies), the</p>	<p>Preclinical Studies Allows FDA to ask for preclinical studies as part of a written request.</p>

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<p>accepted in accordance with subsection (d)(3)—</p> <p>(1)(A)(i) the period referred to in subsection (c)(3)(D)(ii) of section 505, and in subsection (j)(5)(F)(ii) of such section, is deemed to be five years and six months rather than five years, and the references in subsections (c)(3)(D)(ii) and (j)(5)(F)(ii) of such section to four years, to forty-eight months, and to seven and one-half years are deemed to be four and one-half years, fifty-four months, and eight years, respectively; or</p> <p>(ii) the period referred to in clauses (iii) and (iv) of subsection (c)(3)(D) of such section, and in clauses (iii) and (iv) of subsection (j)(5)(F) of such section, is deemed to be three years and six months rather than three years; and</p> <p>(B) if the drug is designated under section 526 for a rare disease or condition, the period referred to in section 527(a) is deemed to be seven years and six months rather than seven years; and</p> <p>(2)(A) if the drug is the subject of—</p> <p>(i) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of section 505 and for which pediatric studies were submitted prior to the expiration of the patent (including any patent extensions); or</p> <p>(ii) a listed patent for which a certification has been submitted under subsections (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section 505,</p> <p>the period during which an application may not be approved under section 505(c)(3) or section 505(j)(5)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions); or</p> <p>(B) if the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505, and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under section 505(c)(3) or section 505(j)(5)(B) shall be extended by a period of six months after the date the</p>	<p>applicant agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe, and the reports thereof are submitted and accepted in accordance with subsection (d)(3)—</p> <p>`(A)(i)(I) the period referred to in subsection (c)(3)(E)(ii) of section 505, and in subsection (j)(5)(F)(ii) of such section, is deemed to be five years and six months rather than five years, and the references in subsections (c)(3)(E)(ii) and (j)(5)(F)(ii) of such section to four years, to forty-eight months, and to seven and one-half years are deemed to be four and one-half years, fifty-four months, and eight years, respectively; or</p> <p>`(II) the period referred to in clauses (iii) and (iv) of subsection (c)(3)(E) of such section, and in clauses (iii) and (iv) of subsection (j)(5)(F) of such section, is deemed to be three years and six months rather than three years; and</p> <p>`(ii) if the drug is designated under section 526 for a rare disease or condition, the period referred to in section 527(a) is deemed to be seven years and six months rather than seven years; and</p> <p>`(B)(i) if the drug is the subject of—</p> <p>`(I) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of section 505 and for which pediatric studies were submitted prior to the expiration of the patent (including any patent extensions); or</p> <p>`(II) a listed patent for which a certification has been submitted under subsections (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section 505,</p> <p>the period during which an application may not be approved under section 505(c)(3) or section 505(j)(5)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions); or</p> <p>`(ii) if the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505, and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under section 505(c)(3) or section 505(j)(5)(B) shall be extended by a period of six months after the date the</p>	

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<p>patent expires (including any patent extensions).</p> <p>(c) MARKET EXCLUSIVITY FOR ALREADY-MARKETED DRUGS.—If the Secretary determines that information relating to the use of an approved drug in the pediatric population may produce health benefits in that population and makes a written request to the holder of an approved application under section 505(b)(1) for pediatric studies (which shall include a timeframe for completing such studies) , the holder agrees to the request, the studies are completed within any such timeframe, and the reports thereof are submitted in accordance with subsection (d)(2) or accepted in accordance with subsection (d)(3)—</p> <p>(1)(A)(i) the period referred to in subsection (c)(3)(D)(ii) of section 505, and in subsection (j)(5)(F)(ii) of such section, is deemed to be five years and six months rather than five years, and the references in subsections (c)(3)(D)(ii) and (j)(5)(F)(ii) of such section to four years, to forty-eight months, and to seven and one-half years are deemed to be four and one-half years, fifty-four months, and eight years, respectively; or</p> <p>(ii) the period referred to in clauses (iii) and (iv) of subsection (c)(3)(D) of such section, and in clauses (iii) and (iv) of subsection (j)(5)(F) of such section, is deemed to be three years and six months rather than three years; and</p> <p>(B) if the drug is designated under section 526 for a rare disease or condition, the period referred to in section 527(a) is deemed to be seven years and six months rather than seven years; and</p> <p>(2)(A) if the drug is the subject of—</p> <p>(i) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of section 505 and for which pediatric studies were submitted prior to the expiration of the patent (including any patent extensions); or</p> <p>(ii) a listed patent for which a certification</p>	<p>patent expires (including any patent extensions).</p> <p>“(2) EXCEPTION—The Secretary shall not extend the period referred to in paragraph (1)(A) or (1)(B) if the determination made under subsection (d)(3) is made later than 9 months prior to the expiration of such period.</p> <p>“(c) MARKET EXCLUSIVITY FOR ALREADY-MARKETED DRUGS.—</p> <p>“(1) IN GENERAL- Except as provided in paragraph (2), if the Secretary determines that information relating to the use of an approved drug in the pediatric population may produce health benefits in that population and makes a written request to the holder of an approved application under section 505(b)(1) for pediatric studies (which shall include a timeframe for completing such studies), the holder agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe, and the reports thereof are submitted and accepted in accordance with subsection (d)(3)—</p> <p>“(A)(i)(I) the period referred to in subsection (c)(3)(E)(ii) of section 505, and in subsection (j)(5)(F)(ii) of such section, is deemed to be five years and six months rather than five years, and the references in subsections (c)(3)(E)(ii) and (j)(5)(F)(ii) of such section to four years, to forty-eight months, and to seven and one-half years are deemed to be four and one-half years, fifty-four months, and eight years, respectively; or</p> <p>“(II) the period referred to in clauses (iii) and (iv) of subsection (c)(3)(D) of such section, and in clauses (iii) and (iv) of subsection (j)(5)(F) of such section, is deemed to be three years and six months rather than three years; and</p> <p>“(ii) if the drug is designated under section 526 for a rare disease or condition, the period referred to in section 527(a) is deemed to be seven years and six months rather than seven years; and</p> <p>“(B)(i) if the drug is the subject of—</p> <p>“(I) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of section 505 and for which pediatric studies were submitted prior to the expiration of the patent (including any patent extensions); or</p> <p>“(II) a listed patent for which a certification</p>	<p>Market Predictability Requires that pediatric studies under BPCA be submitted and exclusivity awarded nine months before expiration of patent.</p>

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<p>has been submitted under subsection (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section 505,</p> <p>the period during which an application may not be approved under section 505(c)(3) or section 505(j)(5)(B)(ii) shall be extended by a period of six months after the date the patent expires (including any patent extensions); or</p> <p>(B) if the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505, and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under section 505(c)(3) or section 505(j)(5)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions).</p> <p>(d) CONDUCT OF PEDIATRIC STUDIES.— (1) AGREEMENT FOR STUDIES.—The Secretary may, pursuant to a written request from the Secretary under subsection (b) or (c), after consultation with—</p> <p>(A) the sponsor of an application for an investigational new drug under section 505(i);</p> <p>(B) the sponsor of an application for a new drug under section 505(b)(1); or</p> <p>(C) the holder of an approved application for a drug under section 505(b)(1),</p> <p>agree with the sponsor or holder for the conduct of pediatric studies for such drug. Such agreement shall be in writing and shall include a timeframe for such studies.</p>	<p>has been submitted under subsection (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section 505,</p> <p>the period during which an application may not be approved under section 505(c)(3) or section 505(j)(5)(B)(ii) shall be extended by a period of six months after the date the patent expires (including any patent extensions); or</p> <p>“(ii) if the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505, and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under section 505(c)(3) or section 505(j)(5)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions).</p> <p>“(2) EXCEPTION- The Secretary shall not extend the period referred to in paragraph (1)(A) or (1)(B) if the determination made under subsection (d)(3) is made later than 9 months prior to the expiration of such period.</p> <p>“(d) CONDUCT OF PEDIATRIC STUDIES.—</p> <p>“(1) REQUEST FOR STUDIES—</p> <p>“(A) IN GENERAL—The Secretary may, after consultation with the sponsor of an application for an investigational new drug under section 505(i), the sponsor of an application for a new drug under section 505(b)(1), or the holder of an approved application for a drug under section 505(b)(1), issue to the sponsor or holder a written request for the conduct of pediatric studies for such drug. In issuing such request, the Secretary shall take into account adequate representation of children of ethnic and racial minorities. Such request to conduct pediatric studies shall be in writing and shall include a timeframe for such studies and a request to the sponsor or holder to propose pediatric labeling resulting from such studies.</p> <p>“(B) SINGLE WRITTEN REQUEST—A single written request—</p> <p>“(i) may relate to more than one use of a drug; and</p> <p>“(ii) may include uses that are both approved and unapproved.</p>	<p>Market Predictability Requires that pediatric studies under BPCA be submitted and exclusivity awarded nine months before expiration of patent.</p> <p>Multiple Drug Uses and On- and Off-Label Written Requests Allows FDA to issue one study request for more than one use of a drug, and allows FDA to issue one study request to capture both on- and off-label uses.</p>

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<p>(2) WRITTEN PROTOCOLS TO MEET THE STUDIES REQUIREMENT.—If the sponsor or holder and the Secretary agree upon written protocols for the studies, the studies requirement of subsection (b) or (c) is satisfied upon the completion of the studies and submission of the reports thereof in accordance with the original written request and the written agreement referred to in paragraph (1). In reaching an agreement regarding written protocols, the Secretary shall take into account adequate representation of children of ethnic and racial minorities. Not later than 60 days after the submission of the report of the studies, the Secretary shall determine if such studies were or were not conducted in accordance with the original written request and the written agreement and reported in accordance with the requirements of the Secretary for filing and so notify the sponsor or holder.</p> <p>(3) OTHER METHODS TO MEET THE STUDIES REQUIREMENT.—If the sponsor or holder and the Secretary have not agreed in writing on the protocols for the studies, the studies requirement of subsection (b) or (c) is satisfied when such studies have been completed and the reports accepted by the Secretary. Not later than 90 days after the submission of the reports of the studies, the Secretary shall accept or reject such reports and so notify the sponsor or holder. The Secretary's only responsibility in accepting or rejecting the reports shall be to determine, within the 90 days, whether the studies fairly respond to the written request, have been conducted in accordance with commonly accepted scientific principles and protocols, and have been reported in accordance with the requirements of the Secretary for filing.</p>	<p>(2) WRITTEN REQUEST FOR PEDIATRIC STUDIES—</p> <p>(A) REQUEST AND RESPONSE—</p> <p>(i) IN GENERAL—If the Secretary makes a written request for pediatric studies (including neonates, as appropriate) under subsection (b) or (c), the applicant or holder, not later than 180 days after receiving the written request, shall respond to the Secretary as to the intention of the applicant or holder to act on the request by—</p> <p>(I) indicating when the pediatric studies will be initiated, if the applicant or holder agrees to the request; or</p> <p>(II) indicating that the applicant or holder does not agree to the request and stating the reasons for declining the request.</p> <p>(ii) DISAGREE WITH REQUEST—If, on or after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, the applicant or holder does not agree to the request on the grounds that it is not possible to develop the appropriate pediatric formulation, the applicant or holder shall submit to the Secretary the reasons such pediatric formulation cannot be developed.</p> <p>(B) ADVERSE EVENT REPORTS—An applicant or holder that, on or after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, agrees to the request for such studies shall provide the Secretary, at the same time as the submission of the reports of such studies, with all postmarket adverse event reports regarding the drug that is the subject of such studies and are available prior to submission of such reports.</p> <p>(3) MEETING THE STUDIES REQUIREMENT—Not later than 180 days after the submission of the reports of the studies, the Secretary shall accept or reject such reports and so notify the sponsor or holder. The Secretary's only responsibility in accepting or rejecting the reports shall be to determine, within the 180-day period, whether the studies fairly respond to the written request, have been conducted in accordance with commonly accepted scientific principles and protocols, and have been reported in accordance with the requirements of the Secretary for filing.</p>	<p>Pediatric Formulations Requires a manufacturer who declines a written request on the basis that it was unable to produce a pediatric formulation to submit to FDA the reasons why the formulation cannot be developed.</p> <p>Adverse Events Requires manufacturers to submit all post-market adverse events as part of the exclusivity application or supplement.</p> <p>Time to Review Submitted Studies Lengthens the period of time FDA has to review submitted studies from 90 to 180 days.</p>

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<p>(4) WRITTEN REQUEST TO HOLDERS OF APPROVED APPLICATIONS FOR DRUGS THAT HAVE MARKET EXCLUSIVITY—</p> <p>(A) REQUEST AND RESPONSE—If the Secretary makes a written request for pediatric studies (including neonates, as appropriate) under subsection (c) 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—</p> <p>(i) indicating when the pediatric studies will be initiated, if the holder agrees to the request; or</p> <p>(ii) indicating that the holder does not agree to the request.</p> <p>(B) NO AGREEMENT TO REQUEST—</p> <p>(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 the National Institutes of Health established under section 499 of the Public Health Service Act (42 U.S.C. 290b) (referred to in this paragraph as the `Foundation') for the conduct of the pediatric studies described in the written request.</p> <p>(ii) PUBLIC NOTICE—The Secretary shall give public notice of the name of the drug, the name of the manufacturer, and the indications to be studied made in a referral under clause (i).</p> <p>(C) LACK OF FUNDS—On referral of a drug under subparagraph (B)(i), the Foundation shall issue a proposal to award a grant to conduct the requested studies unless the Foundation certifies to the Secretary, within a timeframe that the Secretary determines is appropriate through guidance, that the Foundation does not have funds available under section 499(j)(9)(B)(i) to conduct the requested studies. If the Foundation so certifies, 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.</p> <p>(D) EFFECT OF SUBSECTION—Nothing in this subsection (including with respect to referrals from the Secretary to the Foundation) alters or amends section 301(j)</p>	<p>(4) EFFECT OF SUBSECTION—Nothing in this subsection alters or amends section 301(j) of this Act or section 552 of title 5 or section 1905 of title 18, United States Code.</p>	<p>“Exhaustion” Process Eliminates “exhaustion” provision in favor of an expedited 30-day review of private funding before referral to PREA. See subsection (n) of BPCA.</p>

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<p>of this Act or section 552 of title 5 or section 1905 of title 18, United States Code.</p> <p>(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.</p> <p>(F) WRITTEN REQUESTS UNDER SUBSECTION (b)—For drugs under subsection (b) for which written requests have not been accepted, 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 issue a written request under subsection (c) after the date of approval of the drug.</p> <p>(e) DELAY OF EFFECTIVE DATE FOR CERTAIN APPLICATION.—If the Secretary determines that the acceptance or approval of an application under section 505(b)(2) or 505(j) for a new drug may occur after submission of reports of pediatric studies under this section, which were submitted prior to the expiration of the patent (including any patent extension) or the applicable period under clauses (ii) through (iv) of section 505(c)(3)(D) or clauses (ii) through (iv) of section 505(j)(5)(F), but before the Secretary has determined whether the requirements of subsection (d) have been satisfied, the Secretary shall delay the acceptance or approval under section 505(b)(2) or 505(j) until the determination under subsection (d) is made, but any such delay shall not exceed 90 days. In the event that requirements of this section are satisfied, the applicable six month period under subsection (b) or (c) shall be deemed to have been running during the period of delay.</p> <p>(f) NOTICE OF DETERMINATIONS ON STUDIES REQUIREMENT.—The Secretary shall publish a notice of any determination that the requirements of subsection (d) have been met and that submissions and approvals under subsection (b)(2) or (j) of section 505 for a drug will be subject to the provisions of this section.</p>	<p>“(e) NOTICE OF DETERMINATIONS ON STUDIES REQUIREMENT.—</p> <p>“(1) IN GENERAL—The Secretary shall publish a notice of any determination, made on or after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, that the requirements of subsection (d) have been met and that submissions and approvals under subsection (b)(2) or (j) of section 505 for a drug will be subject to the provisions of this section. Such notice shall be published not later than 30 days after the date of the Secretary's determination regarding market exclusivity and shall include a copy of the written request made under subsection (b) or (c).</p> <p>“(2) IDENTIFICATION OF CERTAIN</p>	<p>Written Requests Public Requires FDA to make study requests public after the drug has been granted exclusivity.</p> <p>Pediatric Formulations Not Marketed</p>

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	<p>DRUGS—The Secretary shall publish a notice identifying any drug for which, on or after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, a pediatric formulation was developed, studied, and found to be safe and effective in the pediatric population (or specified subpopulation) if the pediatric formulation for such drug is not introduced onto the market within one year after the date that the Secretary publishes the notice described in paragraph (1). Such notice identifying such drug shall be published not later than 30 days after the date of the expiration of such one year period.</p> <p>`(f) INTERNAL REVIEW OF WRITTEN REQUESTS AND PEDIATRIC STUDIES—</p> <p>`(1) INTERNAL REVIEW—The Secretary shall utilize the internal review committee established under section 505C to review all written requests issued on or after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, in accordance with paragraph (2).</p> <p>`(2) REVIEW OF WRITTEN REQUESTS—The committee referred to in paragraph (1) shall review all written requests issued pursuant to this section prior to being issued.</p> <p>`(3) REVIEW OF PEDIATRIC STUDIES—The committee referred to in paragraph (1) may review studies conducted pursuant to this section to make a recommendation to the Secretary whether to accept or reject such reports under subsection (d)(3).</p> <p>`(4) ACTIVITY BY COMMITTEE- The committee referred to in paragraph (1) may operate using appropriate members of such committee and need not convene all members of the committee.</p> <p>`(5) DOCUMENTATION OF COMMITTEE ACTION—For each drug, the committee referred to in paragraph (1) shall document, for each activity described in paragraph (2) or (3), which members of the committee participated in such activity.</p> <p>`(6) TRACKING PEDIATRIC STUDIES AND LABELING CHANGES—The Secretary, in consultation with the committee referred to in paragraph (1), shall track and make available to the public, in an easily accessible manner, including through posting on the Web site of the Food and Drug Administration—</p> <p>`(A) the number of studies conducted under this section and under section 409I of the Public Health Service Act;</p>	<p>Requires prominent public disclosure when a manufacturer creates a pediatric formulation and fails to market it.</p> <p>Internal Review of Written Requests Requires new internal committee to review written requests prior to issuance.</p> <p>Internal Review of Studies Provides committee authority to review studies submitted in response to a written request, as needed.</p> <p>Tracking Requires FDA to track the number and type of studies completed, as well as labeling changes and other data resulting from BPCA.</p>

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<p>(g) LIMITATIONS.—A drug to which the six-month period under subsection (b) or (c) has already been applied—</p> <p>(1) may receive an additional six-month period under subsection (c)(1)(A)(ii) for a supplemental application if all other requirements under this section are satisfied, except that such a drug may not receive any additional such period under subsection (c)(2); and</p> <p>(2) may not receive any additional such period under subsection (c)(1)(B).</p> <p>(h) RELATIONSHIP TO PEDIATRIC RESEARCH REQUIREMENTS.—Notwithstanding any other provision of law, if any pediatric study is required by a provision of law (including a regulation) other than this section and such study meets the completeness, timeliness, and other requirements of this section, such study shall be deemed to satisfy the requirement for market exclusivity pursuant to this section.</p> <p>(i) LABELING SUPPLEMENTS—</p> <p>(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—</p>	<p>`(B) the specific drugs and drug uses, including labeled and off-labeled indications, studied under such sections;</p> <p>`(C) the types of studies conducted under such sections, including trial design, the number of pediatric patients studied, and the number of centers and countries involved;</p> <p>`(D) the number of pediatric formulations developed and the number of pediatric formulations not developed and the reasons such formulations were not developed;</p> <p>`(E) the labeling changes made as a result of studies conducted under such sections;</p> <p>`(F) an annual summary of labeling changes made as a result of studies conducted under such sections for distribution pursuant to subsection (k)(2); and</p> <p>`(G) information regarding reports submitted on or after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007.</p> <p>`(g) LIMITATIONS.—Notwithstanding subsection (c)(2), a drug to which the six-month period under subsection (b) or (c) has already been applied—</p> <p>`(1) may receive an additional six-month period under subsection (c)(1)(A)(i)(II) for a supplemental application if all other requirements under this section are satisfied, except that such drug may not receive any additional such period under subsection (c)(1)(B); and</p> <p>`(2) may not receive any additional such period under subsection (c)(1)(A)(ii).</p> <p>`(h) RELATIONSHIP TO PEDIATRIC RESEARCH REQUIREMENTS.—Notwithstanding any other provision of law, if any pediatric study is required by a provision of law (including a regulation) other than this section and such study meets the completeness, timeliness, and other requirements of this section, such study shall be deemed to satisfy the requirement for market exclusivity pursuant to this section.</p> <p>`(i) LABELING CHANGES—</p> <p>`(1) PRIORITY STATUS FOR PEDIATRIC APPLICATIONS AND SUPPLEMENTS—Any application or supplement to an application under section 505 proposing a labeling change as a result of any pediatric study conducted pursuant to this section—</p>	

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<p>(A) shall be considered to be a priority supplement; and</p> <p>(B) shall be subject to the performance goals established by the Commissioner for priority drugs.</p> <p>(2) DISPUTE RESOLUTION—</p> <p>(A) REQUEST FOR LABELING CHANGE AND FAILURE TO AGREE—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, not later than 180 days after the date of submission of the application—</p> <p>(i) the Commissioner shall request that the sponsor of the application make any labeling change that the Commissioner determines to be appropriate; and</p> <p>(ii) if the sponsor of the application does not agree to make a labeling change requested by the Commissioner, the Commissioner shall refer the matter to the Pediatric Advisory Committee.</p> <p>(B) ACTION BY THE PEDIATRIC ADVISORY SUBCOMMITTEE OF THE ANTI-INFECTIVE DRUGS ADVISORY COMMITTEE—Not later than 90 days after receiving a referral under subparagraph (A)(ii), the Pediatric Advisory Committee shall—</p> <p>(i) review the pediatric study reports; and</p> <p>(ii) make a recommendation to the Commissioner concerning appropriate labeling changes, if any.</p> <p>(C) CONSIDERATION OF RECOMMENDATIONS—The Commissioner shall consider the recommendations of the Pediatric 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.</p> <p>(D) MISBRANDING—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</p>	<p>ˆ(A) shall be considered to be a priority application or supplement; and</p> <p>ˆ(B) shall be subject to the performance goals established by the Commissioner for priority drugs.</p> <p>ˆ(2) DISPUTE RESOLUTION—</p> <p>ˆ(A) REQUEST FOR LABELING CHANGE AND FAILURE TO AGREE—If, on or after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, the Commissioner determines that the sponsor and the Commissioner have been unable to reach agreement on appropriate changes to the labeling for the drug that is the subject of the application, not later than 180 days after the date of submission of the application—</p> <p>ˆ(i) the Commissioner shall request that the sponsor of the application make any labeling change that the Commissioner determines to be appropriate; and</p> <p>ˆ(ii) if the sponsor of the application does not agree within 30 days after the Commissioner's request to make a labeling change requested by the Commissioner, the Commissioner shall refer the matter to the Pediatric Advisory Committee.</p> <p>ˆ(B) ACTION BY THE PEDIATRIC ADVISORY COMMITTEE—Not later than 90 days after receiving a referral under subparagraph (A)(ii), the Pediatric Advisory Committee shall—</p> <p>ˆ(i) review the pediatric study reports; and</p> <p>ˆ(ii) make a recommendation to the Commissioner concerning appropriate labeling changes, if any.</p> <p>ˆ(C) CONSIDERATION OF RECOMMENDATIONS—The Commissioner shall consider the recommendations of the Pediatric 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.</p> <p>ˆ(D) MISBRANDING—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</p>	<p>Dispute Resolution Removes the current dispute resolution provision requiring labeling to be the only remaining open issue before referral for resolution. Applies the dispute resolution process to all drugs issued study requests, not just those granted exclusivity. Sets a time certain for referral to Pediatric Advisory Committee if sponsor does not make requested label change.</p>

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<p>by the Commissioner, the Commissioner may deem the drug that is the subject of the application to be misbranded.</p> <p>(E) NO EFFECT ON AUTHORITY—Nothing in this subsection limits the authority of the United States to bring an enforcement action under this Act when a drug lacks appropriate pediatric labeling. Neither course of action (the Pediatric Advisory Committee process or an enforcement action referred to in the preceding sentence) shall preclude, delay, or serve as the basis to stay the other course of action.</p> <p>(j) DISSEMINATION OF PEDIATRIC INFORMATION—</p> <p>(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.</p> <p>(2) EFFECT OF SUBSECTION—Nothing in this subsection alters or amends section 301(j) of this Act or section 552 of title 5 or section 1905 of title 18, United States Code.'</p> <p>[The following section on adverse event reporting is from PL107-109. It was never</p>	<p>by the Commissioner, the Commissioner may deem the drug that is the subject of the application to be misbranded.</p> <p>`(E) NO EFFECT ON AUTHORITY— Nothing in this subsection limits the authority of the United States to bring an enforcement action under this Act when a drug lacks appropriate pediatric labeling. Neither course of action (the Pediatric Advisory Committee process or an enforcement action referred to in the preceding sentence) shall preclude, delay, or serve as the basis to stay the other course of action.</p> <p>`(j) OTHER LABELING CHANGES—If, on or after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, the Secretary determines that a pediatric study conducted under this section does or does not demonstrate that the drug that is the subject of the study is safe and effective, including whether such study results are inconclusive, in pediatric populations or subpopulations, the Secretary shall order the labeling of such product to include information about the results of the study and a statement of the Secretary's determination.</p> <p>`(k) DISSEMINATION OF PEDIATRIC INFORMATION—</p> <p>`(1) IN GENERAL—Not later than 210 days after the date of submission of a report on a pediatric study under this section, the Secretary shall make available to the public the medical, statistical, and clinical pharmacology reviews of pediatric studies conducted under subsection (b) or (c).</p> <p>`(2) DISSEMINATION OF INFORMATION REGARDING LABELING CHANGES— Beginning on the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, the Secretary shall include as a requirement of a written request that the sponsors of the studies that result in labeling changes that are reflected in the annual summary developed pursuant to subsection (f)(3)(F) distribute, at least annually (or more frequently if the Secretary determines that it would be beneficial to the public health), such information to physicians and other health care providers.</p> <p>`(3) EFFECT OF SUBSECTION—Nothing in this subsection alters or amends section 301(j) of this Act or section 552 of title 5 or section 1905 of title 18, United States Code.</p>	<p>Labeling Authority Gives FDA explicit authority to indicate on a label when a product has been studied in children.</p> <p>Reviews Made Public Requires Secretary to make publicly available the actual medical, statistical, and clinical pharmacology reviews, not summaries.</p> <p>Dissemination Requirements Requires sponsors who have been granted exclusivity to provide physicians and other health care providers with any new pediatric labeling information.</p>

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<p>codified.]</p> <p>SEC. 17. ADVERSE-EVENT REPORTING.</p> <p>(b) DRUGS WITH PEDIATRIC MARKET EXCLUSIVITY—</p> <p>(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.</p> <p>(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.</p> <p>(k) 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)—If a 180-day period under section 505(j)(5)(B)(iv) overlaps with a 6-month exclusivity period 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 from—</p> <p>(1) the date on which the 180-day period would have expired by the number of days of the overlap, if the 180-day period would, but for the application of this subsection,</p>	<p>(i) ADVERSE EVENT REPORTING—</p> <p>(1) REPORTING IN YEAR ONE— Beginning on the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, during the one-year period beginning on the date a labeling change is approved pursuant to subsection (i), the Secretary shall ensure that all adverse event reports that have been received for such drug (regardless of when such report was received) are referred to the Office of Pediatric Therapeutics established under section 6 of the Best Pharmaceuticals for Children Act (Public Law 107-109). In considering the reports, the Director of such Office shall provide for the review of the reports by the Pediatric Advisory Committee, including obtaining any recommendations of such Committee regarding whether the Secretary should take action under this Act in response to such reports.</p> <p>(2) REPORTING IN SUBSEQUENT YEARS—Following the one-year period described in paragraph (1), the Secretary shall, as appropriate, refer to the Office of Pediatric Therapeutics all pediatric adverse event reports for a drug for which a pediatric study was conducted under this section. In considering such reports, the Director of such Office may provide for the review of such reports by the Pediatric Advisory Committee, including obtaining any recommendation of such Committee regarding whether the Secretary should take action in response to such reports.</p> <p>(3) EFFECT—The requirements of this subsection shall supplement, not supplant, other review of such adverse event reports by the Secretary.</p> <p>(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)—If a 180-day period under section 505(j)(5)(B)(iv) overlaps with a 6-month exclusivity period 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 from—</p> <p>(1) the date on which the 180-day period would have expired by the number of days of the overlap, if the 180-day period would, but for the application of this subsection,</p>	<p>Adverse Event Reporting</p> <p>Continues the requirement that all adverse events be reviewed by the Pediatric Advisory Committee for one year following the awarding of exclusivity. Provides for additional reporting after year one, as needed.</p>

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<p>expire after the 6-month exclusivity period; or</p> <p>(2) the date on which the 6-month exclusivity period expires, by the number of days of the overlap if the 180-day period would, but for the application of this subsection, expire during the six-month exclusivity period.</p>	<p>expire after the 6-month exclusivity period; or</p> <p>(2) the date on which the 6-month exclusivity period expires, by the number of days of the overlap if the 180-day period would, but for the application of this subsection, expire during the six-month exclusivity period.</p> <p>(n) REFERRAL IF PEDIATRIC STUDIES NOT COMPLETED—</p> <p>(1) IN GENERAL- Beginning on the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, if pediatric studies of a drug have not been completed under subsection (d) and if the Secretary, through the committee established under section 505C, 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 carry out the following:</p> <p>(A) For a drug for which a listed patent has not expired, make a determination regarding whether an assessment shall be required to be submitted under section 505B(b). Prior to making such a determination, the Secretary may not take more than 30 days to certify whether the Foundation for the National Institutes of Health has sufficient funding at the time of such certification to initiate and fund all of the studies in the written request in their entirety within the timeframes specified within the written request. Only if the Secretary makes such certification in the affirmative, the Secretary shall refer all pediatric studies in the written request to the Foundation for the National Institutes of Health for the conduct of such studies, and such Foundation shall fund such studies. If no certification has been made at the end of the 30-day period, or if the Secretary certifies that funds are not sufficient to initiate and fund all the studies in their entirety, the Secretary shall consider whether assessments shall be required under section 505B(b) for such drug.</p> <p>(B) For a drug that has no listed patents or has 1 or more listed patents that have expired, 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 studies.</p> <p>(2) PUBLIC NOTICE—The Secretary shall give the public notice of a decision under paragraph (1)(A) not to require an assessment under section 505B and the basis for such decision.</p> <p>(3) EFFECT OF SUBSECTION—Nothing in</p>	<p>Referral to PREA If study is declined by the manufacturer, requires FDA to determine whether the drug should be studied under PREA. If applicable, FDA will report why it did not use PREA.</p> <p>Shorter Period Before Referral Allows only 30 days to determine if private donations are available to completely fund all studies in a declined written request before referral to PREA.</p>

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<p>(I) PROMPT APPROVAL OF DRUGS UNDER SECTION 505(j) WHEN PEDIATRIC INFORMATION IS ADDED TO LABELING—</p> <p>(1) GENERAL RULE—A drug for which an application has been submitted or approved under section 505(j) shall not be considered ineligible for approval under that section or misbranded under section 502 on the basis that the labeling of the drug omits a pediatric indication or any other aspect of labeling pertaining to pediatric use when the omitted indication or other aspect is protected by patent or by exclusivity under clause (iii) or (iv) of section 505(j)(5)(F).</p> <p>(2) LABELING—Notwithstanding clauses (iii) and (iv) of section 505(j)(5)(F), the Secretary may require that the labeling of a drug approved under section 505(j) that omits a pediatric indication or other aspect of labeling as described in paragraph (1) include—</p> <p>(A) a statement that, because of marketing exclusivity for a manufacturer—</p> <p>(i) the drug is not labeled for pediatric use; or</p> <p>(ii) in the case of a drug for which there is an additional pediatric use not referred to in paragraph (1), the drug is not labeled for the pediatric use under paragraph (1); and</p> <p>(B) a statement of any appropriate pediatric contraindications, warnings, or precautions that the Secretary considers necessary.</p> <p>(3) PRESERVATION OF PEDIATRIC EXCLUSIVITY AND OTHER PROVISIONS—This subsection does not affect—</p> <p>(A) the availability or scope of exclusivity under this section;</p> <p>(B) the availability or scope of exclusivity under section 505 for pediatric formulations;</p> <p>(C) the question of the eligibility for approval of any application under section 505(j) that omits any other conditions of approval entitled to exclusivity under clause (iii) or (iv) of section 505(j)(5)(F); or</p> <p>(D) except as expressly provided in paragraphs (1) and (2), the operation of section 505.</p>	<p>this subsection alters or amends section 301(j) of this Act or section 552 of title 5 or section 1905 of title 18, United States Code.</p> <p>^(o) PROMPT APPROVAL OF DRUGS UNDER SECTION 505(J) WHEN PEDIATRIC INFORMATION IS ADDED TO LABELING—</p> <p>^(1) GENERAL RULE—A drug for which an application has been submitted or approved under section 505(j) shall not be considered ineligible for approval under that section or misbranded under section 502 on the basis that the labeling of the drug omits a pediatric indication or any other aspect of labeling pertaining to pediatric use when the omitted indication or other aspect is protected by patent or by exclusivity under clause (iii) or (iv) of section 505(j)(5)(F).</p> <p>^(2) LABELING—Notwithstanding clauses (iii) and (iv) of section 505(j)(5)(F), the Secretary may require that the labeling of a drug approved under section 505(j) that omits a pediatric indication or other aspect of labeling as described in paragraph (1) include—</p> <p>^(A) a statement that, because of marketing exclusivity for a manufacturer—</p> <p>^(i) the drug is not labeled for pediatric use; or</p> <p>^(ii) in the case of a drug for which there is an additional pediatric use not referred to in paragraph (1), the drug is not labeled for the pediatric use under paragraph (1); and</p> <p>^(B) a statement of any appropriate pediatric contraindications, warnings, or precautions that the Secretary considers necessary.</p> <p>^(3) PRESERVATION OF PEDIATRIC EXCLUSIVITY AND OTHER PROVISIONS—This subsection does not affect—</p> <p>^(A) the availability or scope of exclusivity under this section;</p> <p>^(B) the availability or scope of exclusivity under section 505 for pediatric formulations;</p> <p>^(C) the question of the eligibility for approval of any application under section 505(j) that omits any other conditions of approval entitled to exclusivity under clause (iii) or (iv) of section 505(j)(5)(F); or</p> <p>^(D) except as expressly provided in paragraphs (1) and (2), the operation of section 505.</p>	

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<p>(m) REPORT.—The Secretary shall conduct a study and report to Congress not later than January 1, 2001, based on the experience under the program established under this section. The study and report shall examine all relevant issues, including—</p> <p>(1) the effectiveness of the program in improving information about important pediatric uses for approved drugs;</p> <p>(2) the adequacy of the incentive provided under this section;</p> <p>(3) the economic impact of the program on taxpayers and consumers, including the impact of the lack of lower cost generic drugs on patients, including on lower income patients; and</p> <p>(4) any suggestions for modification that the Secretary determines to be appropriate.</p> <p>(n) SUNSET—A drug may not receive any 6-month period under subsection (b) or (c)</p>	<p>(p) INSTITUTE OF MEDICINE STUDY— Not later than 3 years after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, the Secretary shall enter into a contract with the Institute of Medicine to conduct a study and report to Congress regarding the written requests made and the studies conducted pursuant to this section. The Institute of Medicine may devise an appropriate mechanism to review a representative sample of requests made and studies conducted pursuant to this section in order to conduct such study. Such study shall--</p> <p>(1) review such representative written requests issued by the Secretary since 1997 under subsections (b) and (c);</p> <p>(2) review and assess such representative pediatric studies conducted under subsections (b) and (c) since 1997 and labeling changes made as a result of such studies;</p> <p>(3) review the use of extrapolation for pediatric subpopulations, the use of alternative endpoints for pediatric populations, neonatal assessment tools, and ethical issues in pediatric clinical trials;</p> <p>(4) review and assess the pediatric studies of biological products as required under subsections (a) and (b) of section 505B; and</p> <p>(5) make recommendations regarding appropriate incentives for encouraging pediatric studies of biologics.</p> <p>(q) SUNSET—A drug may not receive any 6-month period under subsection (b) or (c)</p>	<p>IOM Study Asks the Institute of Medicine to review past written requests issued by FDA, make recommendations to FDA for future requests, and make recommendations for incentives to encourage the study of biologics in children.</p> <p>Extension Extends BPCA until October 1, 2012.</p>

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<p>unless—</p> <p>(1) on or before October 1, 2007 , the Secretary makes a written request for pediatric studies of the drug;</p> <p>(2) on or before October 1, 2007 , an application for the drug is accepted for filing under section 505(b); and</p> <p>(3) all requirements of this section are met.</p> <p>SEC. 409I. PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.</p> <p>(a) LIST OF DRUGS FOR WHICH PEDIATRIC STUDIES ARE NEEDED.—</p> <p>(1) IN GENERAL.—Not later than one 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—</p> <p>(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));</p> <p>(ii) there is a submitted application that could be approved under the criteria of section 505(j) of the Federal Food, Drug,</p>	<p>unless—</p> <p>(1) on or before October 1, 2012, the Secretary makes a written request for pediatric studies of the drug;</p> <p>(2) on or before October 1, 2012, an application for the drug is accepted for filing under section 505(b); and</p> <p>(3) all requirements of this section are met.'</p> <p>(2) APPLICABILITY—</p> <p>(A) IN GENERAL—The amendment made by this subsection shall apply to written requests under section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) issued on or after the date of the enactment of this Act.</p> <p>(B) CERTAIN WRITTEN REQUESTS—A written request issued under section 505A of the Federal Food, Drug, and Cosmetic Act, as in effect on the day before the date of the enactment of this Act, which has been accepted and for which no determination under subsection (d)(2) of such section has been made before such date of enactment, shall be subject to such section 505A, except that such written requests shall be subject to subsections (d)(2)(A)(ii), (e)(1) and (2), (f), (i)(2)(A), (j), (k)(1), (l)(1), and (n) of section 505A of the Federal Food, Drug, and Cosmetic Act, as in effect on or after the date of the enactment of this Act.</p> <p>(b) PROGRAM FOR PEDIATRIC STUDIES OF DRUGS— Section 409I of the Public Health Service Act (42 U.S.C. 284m) is amended to read as follows:</p> <p>SEC. 409I. PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.</p> <p>(a) LIST OF PRIORITY ISSUES IN PEDIATRIC THERAPEUTICS—</p> <p>(1) IN GENERAL.—Not later than one year after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, 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 and publish a priority list of needs in pediatric therapeutics, including drugs or indications that require study. The list shall be revised every three years.</p>	<p>Needs in Pediatric Therapeutics Provides expanded authority for NIH to examine needs in pediatric therapeutics, including drugs.</p>

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<p>and Cosmetic Act (21 U.S.C. 355(j));</p> <p>(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.); or</p> <p>(iv) there is a referral for inclusion on the list under section 505A(d)(4)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(d)(4)(C)); and</p> <p>(B) in the case of a drug referred to in clause (i), (ii), or (iii) of subparagraph (A), additional studies are needed to assess the safety and effectiveness of the use of the drug in the pediatric population.</p> <p>(2) CONSIDERATION OF AVAILABLE INFORMATION.—In developing and prioritizing the list under paragraph (1), the Secretary shall consider for each drug on the list—</p> <p>(A) the availability of information concerning the safe and effective use of the drug in the pediatric population;</p> <p>(B) whether additional information is needed;</p> <p>(C) whether new pediatric studies concerning the drug may produce health benefits in the pediatric population; and</p> <p>(D) whether reformulation of the drug is necessary.</p> <p>(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).</p> <p>(c) PROCESS FOR CONTRACTS AND LABELING CHANGES.—</p>	<p>^(2) CONSIDERATION OF AVAILABLE INFORMATION- In developing and prioritizing the list under paragraph (1), the Secretary shall consider—</p> <p>^(A) therapeutic gaps in pediatrics that may include developmental pharmacology, pharmacogenetic determinants of drug response, metabolism of drugs and biologics in children, and pediatric clinical trials;</p> <p>^(B) particular pediatric diseases, disorders or conditions where more complete knowledge and testing of therapeutics, including drugs and biologics, may be beneficial in pediatric populations; and</p> <p>^(C) the adequacy of necessary infrastructure to conduct pediatric pharmacological research, including research networks and trained pediatric investigators.</p> <p>^(b) PEDIATRIC STUDIES AND RESEARCH—The Secretary, acting through the National Institutes of Health, shall award funds to entities that have the expertise to conduct pediatric clinical trials or other research (including qualified universities, hospitals, laboratories, contract research organizations, practice groups, federally funded programs such as pediatric pharmacology research units, other public or private institutions, or individuals) to enable the entities to conduct the drug studies or other research on the issues described in subsection (a). The Secretary may use contracts, grants, or other appropriate funding mechanisms to award funds under this subsection.</p> <p>^(c) PROCESS FOR PROPOSED PEDIATRIC STUDY REQUESTS AND LABELING CHANGES—</p>	

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<p>(1) WRITTEN REQUEST TO HOLDERS OF APPROVED APPLICATIONS FOR DRUGS LACKING EXCLUSIVITY.—The Commissioner of Food and Drugs, in consultation with the Director of the 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)(1)(A) (except clause (iv)) 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.</p> <p>(2) REQUESTS FOR CONTRACT PROPOSALS.—If the Commissioner of Food and Drugs does not receive a</p>	<p>“(1) SUBMISSION OF PROPOSED PEDIATRIC STUDY REQUEST—The Director of the National Institutes of Health shall, as appropriate, submit proposed pediatric study requests for consideration by the Commissioner of Food and Drugs for pediatric studies of a specific pediatric indication identified under subsection (a). Such a proposed pediatric study request shall be made in a manner equivalent to a written request made under subsection (b) or (c) of section 505A of the Federal Food, Drug, and Cosmetic Act, including with respect to the information provided on the pediatric studies to be conducted pursuant to the request. The Director of the National Institutes of Health may submit a proposed pediatric study request for a drug for which—</p> <p>“(A)(i) there is an approved application under section 505(j) of the Federal Food, Drug, and Cosmetic Act; or</p> <p>“(ii) there is a submitted application that could be approved under the criteria of such section; and</p> <p>“(B) there is no patent protection or market exclusivity protection for at least one form of the drug under the Federal Food, Drug, and Cosmetic Act; and</p> <p>“(C) additional studies are needed to assess the safety and effectiveness of the use of the drug in the pediatric population.</p> <p>“(2) WRITTEN REQUEST TO HOLDERS OF APPROVED APPLICATIONS FOR DRUGS LACKING EXCLUSIVITY—The Commissioner of Food and Drugs, in consultation with the Director of the National Institutes of Health, may issue a written request based on the proposed pediatric study request for the indication or indications submitted pursuant to paragraph (1) (which shall include a timeframe for negotiations for an agreement) for pediatric studies concerning a drug identified under 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 (b) or (c) of section 505A of such Act, including with respect to information provided on the pediatric studies to be conducted pursuant to the request and using appropriate formulations for each age group for which the study is requested.</p> <p>“(3) REQUESTS FOR PROPOSALS—If the Commissioner of Food and Drugs does not receive a response to a written request</p>	<p>Studies for Drug Labeling Streamlines process by which NIH studies drugs for labeling.</p>

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<p>response to a written request issued under paragraph (1) within 30 days of the date on which a request was issued, or if a referral described in subsection (a)(1)(A)(iv) is made, the Secretary, acting through the Director of the 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.</p> <p>(3) DISQUALIFICATION.—A holder that receives a first right of refusal shall not be entitled to respond to a request for contract proposals under paragraph (2).</p> <p>(4) 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 paragraph (1).</p> <p>(5) 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.</p> <p>(6) REPORTING OF STUDIES.—</p> <p>(A) IN GENERAL.—On 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 the National Institutes of Health and the Commissioner of Food and Drugs. The report shall include all data generated in connection with the study.</p> <p>(B) AVAILABILITY OF REPORTS.—Each report submitted under subparagraph (A) shall be considered to be in the public domain (subject to section 505A(d)(4)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(d)(4)(D)) 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.</p> <p>(C) ACTION BY COMMISSIONER.—The Commissioner of Food and Drugs shall take appropriate action in response to the reports submitted under subparagraph (A) in</p>	<p>issued under paragraph (2) not later than 30 days after the date on which a request was issued, the Secretary, acting through the Director of the National Institutes of Health and in consultation with the Commissioner of Food and Drugs, shall publish a request for proposals to conduct the pediatric studies described in the written request in accordance with subsection (b).</p> <p>(4) DISQUALIFICATION—A holder that receives a first right of refusal shall not be entitled to respond to a request for proposals under paragraph (3).</p> <p>(5) CONTRACTS, GRANTS, OR OTHER FUNDING MECHANISMS—A contract, grant, or other funding may be awarded under this section only if a proposal 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.</p> <p>(6) REPORTING OF STUDIES.—</p> <p>(A) IN GENERAL—On completion of a pediatric study in accordance with an award under this section, a report concerning the study shall be submitted to the Director of the National Institutes of Health and the Commissioner of Food and Drugs. The report shall include all data generated in connection with the study, including a written request if issued.</p> <p>(B) AVAILABILITY OF REPORTS—Each report submitted under subparagraph (A) shall be considered to be in the public domain (subject to section 505A(d)(4) of the Federal Food, Drug, and Cosmetic Act) 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.</p> <p>(C) ACTION BY COMMISSIONER—The Commissioner of Food and Drugs shall take appropriate action in response to the reports submitted under subparagraph (A) in</p>	

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<p>accordance with paragraph (7).</p> <p>(7) REQUESTS FOR LABELING CHANGE.—During the 180-day period after the date on which a report is submitted under paragraph (6)(A), the Commissioner of Food and Drugs shall—</p> <p>(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;</p> <p>(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</p> <p>(C)(i) place in the public docket file a copy of the report and of any requested labeling changes; and</p> <p>(ii) publish in the Federal Register a summary of the report and a copy of any requested labeling changes.</p> <p>(8) DISPUTE RESOLUTION.—</p> <p>(A) REFERRAL TO PEDIATRIC ADVISORY SUBCOMMITTEE OF THE ANTI-INFECTIVE DRUGS ADVISORY COMMITTEE.—If, not later than the end of the 180-day period specified in paragraph (7), 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, the Commissioner of Food and Drugs shall refer the request to the Pediatric Advisory Subcommittee of the Anti-Infective Drugs Advisory Committee.</p> <p>(B) ACTION BY THE PEDIATRIC ADVISORY SUBCOMMITTEE OF THE ANTI-INFECTIVE DRUGS ADVISORY COMMITTEE.—Not later than 90 days after receiving a referral under subparagraph (A), the Pediatric Advisory Subcommittee of the Anti-Infective Drugs Advisory Committee shall—</p> <p>(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</p> <p>(ii) make a recommendation to the Commissioner of Food and Drugs as to appropriate labeling changes, if any.</p> <p>(9) FDA DETERMINATION.—Not later than</p>	<p>accordance with paragraph (7).</p> <p>^(7) REQUESTS FOR LABELING CHANGE—During the 180-day period after the date on which a report is submitted under paragraph (6)(A), the Commissioner of Food and Drugs shall—</p> <p>^(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;</p> <p>^(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</p> <p>^(C)(i) place in the public docket file a copy of the report and of any requested labeling changes; and</p> <p>^(ii) publish in the Federal Register and through a posting on the Web site of the Food and Drug Administration a summary of the report and a copy of any requested labeling changes.</p> <p>^(8) DISPUTE RESOLUTION—</p> <p>^(A) REFERRAL TO PEDIATRIC ADVISORY COMMITTEE—If, not later than the end of the 180-day period specified in paragraph (7), 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, the Commissioner of Food and Drugs shall refer the request to the Pediatric Advisory Committee.</p> <p>^(B) ACTION BY THE PEDIATRIC ADVISORY COMMITTEE—Not later than 90 days after receiving a referral under subparagraph (A), the Pediatric Advisory Committee shall--</p> <p>^(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</p> <p>^(ii) make a recommendation to the Commissioner of Food and Drugs as to appropriate labeling changes, if any.</p> <p>^(9) FDA DETERMINATION—Not later than</p>	

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<p>30 days after receiving a recommendation from the Pediatric Advisory Subcommittee of the Anti-Infective Drugs Advisory Committee under paragraph (8)(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.</p> <p>(10) 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 (9), 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 (21 U.S.C. 301 et seq.).</p> <p>(11) NO EFFECT ON AUTHORITY.—Nothing in this subsection limits the authority of the United States to bring an enforcement action under the Federal Food, Drug, and Cosmetic Act when a drug lacks appropriate pediatric labeling. Neither course of action (the Pediatric Advisory Subcommittee of the Anti-Infective Drugs Advisory Committee process or an enforcement action referred to in the preceding sentence) shall preclude, delay, or serve as the basis to stay the other course of action.</p> <p>(12) 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.</p> <p>(d) AUTHORIZATION OF APPROPRIATIONS.—</p> <p>(1) IN GENERAL.—There are authorized to be appropriated to carry out this section—</p> <p>(A) \$200,000,000 for fiscal year 2002; and</p> <p>(B) such sums as are necessary for each of</p>	<p>30 days after receiving a recommendation from the Pediatric Advisory Committee under paragraph (8)(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.</p> <p>^(10) 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 (9), does not agree to make a requested labeling change, the Commissioner of Food and Drugs may deem the drug to be misbranded under the Federal Food, Drug, and Cosmetic Act.</p> <p>^(11) NO EFFECT ON AUTHORITY—Nothing in this subsection limits the authority of the United States to bring an enforcement action under the Federal Food, Drug, and Cosmetic Act when a drug lacks appropriate pediatric labeling. Neither course of action (the Pediatric Advisory Committee process or an enforcement action referred to in the preceding sentence) shall preclude, delay, or serve as the basis to stay the other course of action.</p> <p>^(d) DISSEMINATION OF PEDIATRIC INFORMATION—Not later than one year after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, the Secretary, acting through the Director of the National Institutes of Health, shall study the feasibility of establishing a compilation of information on pediatric drug use and report the findings to Congress.</p> <p>^(e) AUTHORIZATION OF APPROPRIATIONS—</p> <p>^(1) IN GENERAL—There are authorized to be appropriated to carry out this section—</p> <p>^(A) \$200,000,000 for fiscal year 2008; and</p> <p>^(B) such sums as are necessary for each of</p>	<p>Authorization Extends \$200,000,000 authorization for pediatric research fund.</p>

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<p>the five succeeding fiscal years.</p> <p>(2) AVAILABILITY.—Any amount appropriated under paragraph (1) shall remain available to carry out this section until expended.</p> <p>[The following language is from PL107-109.]</p> <p>SEC. 13. FOUNDATION FOR THE NATIONAL INSTITUTES OF HEALTH.</p> <p>Section 499 of the Public Health Service Act (42 U.S.C. 290b) is amended—</p> <p>(1) in subsection (b), by inserting "(including collection of funds for pediatric pharmacologic research)" after "mission";</p> <p>(2) in subsection (c)(1)—</p> <p>(A) by redesignating subparagraph (C) as subparagraph (D); and</p> <p>(B) by inserting after subparagraph (B) the following:</p> <p>"(C) A program to collect funds for pediatric pharmacologic research and studies listed by the Secretary pursuant to section 409I(a)(1)(A) of this Act and referred under section 505A(d)(4)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(d)(4)(C)).";</p> <p>(3) in subsection (d)—</p> <p>(A) in paragraph (1)—</p> <p>(i) in subparagraph (B)—</p> <p>(I) in clause (ii), by striking "and" at the end;</p> <p>(II) in clause (iii), by striking the period and inserting "; and"; and</p> <p>(III) by adding at the end the following:</p> <p>"(iv) the Commissioner of Food and Drugs."; and</p> <p>(ii) by striking subparagraph (C) and inserting the following:</p> <p>"(C) The ex officio members of the Board under subparagraph (B) shall appoint to the Board individuals from among a list of candidates to be provided by the National Academy of Science. Such appointed members shall include—</p> <p>"(i) representatives of the general biomedical field;</p> <p>"(ii) representatives of experts in pediatric</p>	<p>the four succeeding fiscal years.</p> <p>(2) AVAILABILITY—Any amount appropriated under paragraph (1) shall remain available to carry out this section until expended.'</p> <p>(c) FOUNDATION FOR THE NATIONAL INSTITUTES OF HEALTH—</p> <p>Section 499(c)(1)(C) of the Public Health Service Act (42 U.S.C. 290b(c)(1)(C)) is amended by striking `and studies listed by the Secretary pursuant to section 409I(a)(1)(A) of this Act and referred under section 505A(d)(4)(C) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355(a)(d)(4)(C))' and inserting `and studies for which the Secretary issues a certification in the affirmative under section 505A(n)(1)(A) of the Federal Food, Drug, and Cosmetic Act'.</p>	

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<p>medicine and research;</p> <p>"(iii) representatives of the general biobehavioral field, which may include experts in biomedical ethics; and</p> <p>"(iv) representatives of the general public, which may include representatives of affected industries."; and</p> <p>(B) in paragraph (2), by realigning the margin of subparagraph (B) to align with subparagraph (A);</p> <p>(4) in subsection (k)(9)—</p> <p>(5) by redesignating subsections (f) through (m) as subsections (e) through (l), respectively;</p> <p>(6) in subsection (h)(11) (as so redesignated), by striking "solicit" and inserting "solicit,"; and</p> <p>(7) in paragraphs (1) and (2) of subsection (j) (as so redesignated), by striking "(including those developed under subsection (d)(2)(B)(i)(II))" each place it appears.</p> <p>SEC. 14. PEDIATRIC PHARMACOLOGY ADVISORY COMMITTEE.</p> <p>(a) IN GENERAL—The Secretary of Health and Human Services shall, under section 222 of the Public Health Service Act (42 U.S.C. 217a), convene and consult an advisory committee on pediatric pharmacology (referred to in this section as the "advisory committee").</p> <p>(b) PURPOSE—</p> <p>(1) IN GENERAL—The advisory committee shall advise and make recommendations to the Secretary, through the Commissioner of Food and Drugs and in consultation with the Director of the National Institutes of Health, on matters relating to pediatric pharmacology.</p> <p>(2) MATTERS INCLUDED—The matters referred to in paragraph (1) include—</p> <p>(A) pediatric research conducted under sections 351, 409I, and 499 of the Public Health Service Act and sections 501, 502, 505, and 505A of the Federal Food, Drug, and Cosmetic Act;</p> <p>(B) identification of research priorities related to pediatric pharmacology and the need for additional treatments of specific pediatric diseases or conditions; and</p>	<p>(d) CONTINUATION OF OPERATION OF COMMITTEE—Section 14 of the Best Pharmaceuticals for Children Act (42 U.S.C. 284m note) is amended by adding at the end the following new subsection:</p>	

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<p>(C) the ethics, design, and analysis of clinical trials related to pediatric pharmacology.</p> <p>(c) COMPOSITION—The advisory committee shall include representatives of pediatric health organizations, pediatric researchers, relevant patient and patient-family organizations, and other experts selected by the Secretary.</p> <p>SEC. 15. PEDIATRIC SUBCOMMITTEE OF THE ONCOLOGIC DRUGS ADVISORY COMMITTEE.</p> <p>(a) CLARIFICATION OF AUTHORITIES—</p> <p>(1) IN GENERAL—The Pediatric Subcommittee of the Oncologic Drugs Advisory Committee (referred to in this section as the "Subcommittee"), in carrying out the mission of reviewing and evaluating the data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of pediatric cancers, shall—</p> <p>(A) evaluate and, to the extent practicable, prioritize new and emerging therapeutic alternatives available to treat pediatric cancer;</p> <p>(B) provide recommendations and guidance to help ensure that children with cancer have timely access to the most promising new cancer therapies; and</p> <p>(C) advise on ways to improve consistency in the availability of new therapeutic agents.</p> <p>(2) MEMBERSHIP—</p> <p>(A) IN GENERAL—The Secretary shall appoint not more than 11 voting members to</p>	<p>(d) CONTINUATION OF OPERATION OF COMMITTEE—Notwithstanding section 14 of the Federal Advisory Committee Act, the advisory committee shall continue to operate during the five-year period beginning on the date of the enactment of the Best Pharmaceuticals for Children Act of 2007.'</p> <p>(e) PEDIATRIC SUBCOMMITTEE OF THE ONCOLOGIC DRUGS ADVISORY COMMITTEE—Section 15 of the Best Pharmaceuticals for Children Act (42 U.S.C. 284m note) is amended—</p> <p>(1) in subsection (a)—</p> <p>(A) in paragraph (1)—</p> <p>(i) in subparagraph (B), by striking 'and' after the semicolon;</p> <p>(ii) in subparagraph (C), by striking the period at the end and inserting '; and'; and</p> <p>(iii) by adding at the end the following new subparagraph:</p> <p>(D) provide recommendations to the internal review committee created under section 505B(f) of the Federal Food, Drug, and Cosmetic Act regarding the implementation of amendments to sections 505A and 505B of the Federal Food, Drug, and Cosmetic Act with respect to the treatment of pediatric cancers.'; and</p>	<p>Extension of Pediatric Advisory Committee Extends advisory committee through October 1, 2012.</p> <p>Subcommittee Recommendations Provides for recommendations from the Pediatric Subcommittee of the Oncologic Drugs Advisory Committee on the implementation of BPCA and PREA amendments.</p>

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<p>the Pediatric Subcommittee from the membership of the Pediatric Pharmacology Advisory Committee and the Oncologic Drugs Advisory Committee.</p> <p>(B) REQUEST FOR PARTICIPATION—The Subcommittee shall request participation of the following members in the scientific and ethical consideration of topics of pediatric cancer, as necessary:</p> <p>(i) At least two pediatric oncology specialists from the National Cancer Institute.</p> <p>(ii) At least four pediatric oncology specialists from—</p> <p>(I) the Children's Oncology Group;</p> <p>(II) other pediatric experts with an established history of conducting clinical trials in children; or</p> <p>(III) consortia sponsored by the National Cancer Institute, such as the Pediatric Brain Tumor Consortium, the New Approaches to Neuroblastoma Therapy or other pediatric oncology consortia.</p> <p>(iii) At least two representatives of the pediatric cancer patient and patient-family community.</p> <p>(iv) One representative of the nursing community.</p> <p>(v) At least one statistician.</p> <p>(vi) At least one representative of the pharmaceutical industry.</p> <p>(b) PRE-CLINICAL MODELS TO EVALUATE PROMISING PEDIATRIC CANCER THERAPIES—Section 413 of the Public Health Service Act (42 U.S.C. 285a-2) is amended by adding at the end the following:</p> <p>"(c) PRE-CLINICAL MODELS TO EVALUATE PROMISING PEDIATRIC CANCER THERAPIES—</p> <p>"(1) EXPANSION AND COORDINATION OF ACTIVITIES—The Director of the National Cancer Institute shall expand, intensify, and coordinate the activities of the Institute with respect to research on the development of preclinical models to evaluate which therapies are likely to be effective for treating pediatric cancer.</p> <p>"(2) COORDINATION WITH OTHER INSTITUTES—The Director of the Institute shall coordinate the activities under paragraph (1) with similar activities</p>		

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<p>conducted by other national research institutes and agencies of the National Institutes of Health to the extent that those Institutes and agencies have responsibilities that are related to pediatric cancer."</p> <p>(c) CLARIFICATION OF AVAILABILITY OF INVESTIGATIONAL NEW DRUGS FOR PEDIATRIC STUDY AND USE—</p> <p>(1) AMENDMENT OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT- Section 505(i)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)(1)) is amended—</p> <p>(A) in subparagraph (B), by striking "and" at the end;</p> <p>(B) in subparagraph (C), by striking the period at the end and inserting "; and"; and</p> <p>(C) by adding at the end the following:</p> <p>"(D) the submission to the Secretary by the manufacturer or the sponsor of the investigation of a new drug of a statement of intent regarding whether the manufacturer or sponsor has plans for assessing pediatric safety and efficacy."</p> <p>(2) AMENDMENT OF THE PUBLIC HEALTH SERVICE ACT- Section 402(j)(3)(A) of the Public Health Service Act (42 U.S.C. 282(j)(3)(A)) is amended in the first sentence—</p> <p>(A) by striking "trial sites, and" and inserting "trial sites,"; and</p> <p>(B) by striking "in the trial," and inserting "in the trial, and a description of whether, and through what procedure, the manufacturer or sponsor of the investigation of a new drug will respond to requests for protocol exception, with appropriate safeguards, for single-patient and expanded protocol use of the new drug, particularly in children,".</p> <p>(d) REPORT—Not later than January 31, 2003, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs and in consultation with the Director of the National Institutes of Health, shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on patient access to new therapeutic agents for pediatric cancer, including access to single patient use of new therapeutic agents.</p>	<p>(B) by adding at the end the following new paragraph:</p>	

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	<p>“(3) CONTINUATION OF OPERATION OF SUBCOMMITTEE—Notwithstanding section 14 of the Federal Advisory Committee Act, the Subcommittee shall continue to operate during the five-year period beginning on the date of the enactment of the Best Pharmaceuticals for Children Act of 2007.”; and</p> <p>(2) in subsection (d), by striking “2003” and inserting “2009”.</p> <p>SEC. 503. TRAINING OF PEDIATRIC PHARMACOLOGISTS.</p> <p>(a) INVESTMENT IN TOMORROW'S PEDIATRIC RESEARCHERS—Section 452G(2) of the Public Health Service Act (42 U.S.C. 285g-10(2)) is amended by adding before the period at the end the following: “, including pediatric pharmacological research”.</p> <p>(b) PEDIATRIC RESEARCH LOAN REPAYMENT PROGRAM—Section 487F(a)(1) of the Public Health Service Act (42 U.S.C. 288-6(a)(1)) is amended by inserting “including pediatric pharmacological research,” after “pediatric research,”.</p>	<p>Extension of Subcommittee Extends the Pediatric Subcommittee of the Oncologic Drugs Advisory Committee through October 1, 2012.</p> <p>Pediatric Pharmacologists Includes pediatric pharmacologists in existing NIH career development and loan repayment programs.</p>

**Pediatric Research Equity Act:
Improvements to Existing Law**

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<p>SEC. 505B. [21 U.S.C. 355c] RESEARCH INTO PEDIATRIC USES FOR DRUGS AND BIOLOGICAL PRODUCTS.</p> <p>(a) NEW DRUGS AND BIOLOGICAL PRODUCTS—</p> <p>(1) IN GENERAL—A person that submits an application (or supplement to an application)—</p> <p>(A) under section 505 for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration; or</p> <p>(B) under section 351 of the Public Health Service Act (42 U.S.C. 262) for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration; shall submit with the application the assessments described in paragraph (2).</p> <p>(2) ASSESSMENTS—</p> <p>(A) IN GENERAL—The assessments referred to in paragraph (1) shall contain data, gathered using appropriate formulations for each age group for which the assessment is required, that are adequate—</p> <p>(i) to assess the safety and effectiveness of the drug or the biological product for the claimed indications in all relevant pediatric subpopulations; and</p> <p>(ii) to support dosing and administration for each pediatric subpopulation for which the drug or the biological product is safe and effective.</p> <p>(B) SIMILAR COURSE OF DISEASE OR SIMILAR EFFECT OF DRUG OR BIOLOGICAL PRODUCT—</p> <p>(i) IN GENERAL—If the course of the disease and the effects of the drug are</p>	<p>SEC. 401. SHORT TITLE.</p> <p>This title may be cited as the `Pediatric Research Equity Act of 2007'.</p> <p>SEC. 402. REAUTHORIZATION OF PEDIATRIC RESEARCH EQUITY ACT.</p> <p>(a) In General- Section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c) is amended to read as follows:</p> <p>SEC. 505B. RESEARCH INTO PEDIATRIC USES FOR DRUGS AND BIOLOGICAL PRODUCTS.</p> <p>(a) NEW DRUGS AND BIOLOGICAL PRODUCTS—</p> <p>(1) IN GENERAL- A person that submits, on or after the date of the enactment of the Pediatric Research Equity Act of 2007, an application (or supplement to an application)--</p> <p>(A) under section 505 for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration, or</p> <p>(B) under section 351 of the Public Health Service Act (42 U.S.C. 262) for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration, shall submit with the application the assessments described in paragraph (2).</p> <p>(2) ASSESSMENTS—</p> <p>(A) IN GENERAL—The assessments referred to in paragraph (1) shall contain data, gathered using appropriate formulations for each age group for which the assessment is required, that are adequate—</p> <p>(i) to assess the safety and effectiveness of the drug or the biological product for the claimed indications in all relevant pediatric subpopulations; and</p> <p>(ii) to support dosing and administration for each pediatric subpopulation for which the drug or the biological product is safe and effective.</p> <p>(B) SIMILAR COURSE OF DISEASE OR SIMILAR EFFECT OF DRUG OR BIOLOGICAL PRODUCT—</p> <p>(i) IN GENERAL—If the course of the disease and the effects of the drug are</p>	

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<p>sufficiently similar in adults and pediatric patients, the Secretary may conclude that pediatric effectiveness can be extrapolated from adequate and well-controlled studies in adults, usually supplemented with other information obtained in pediatric patients, such as pharmacokinetic studies.</p> <p>(ii) EXTRAPOLATION BETWEEN AGE GROUPS—A study may not be needed in each pediatric age group if data from 1 age group can be extrapolated to another age group.</p> <p>(3) DEFERRAL—On the initiative of the Secretary or at the request of the applicant, the Secretary may defer submission of some or all assessments required under paragraph (1) until a specified date after approval of the drug or issuance of the license for a biological product if—</p> <p>(A) the Secretary finds that—</p> <p>(i) the drug or biological product is ready for approval for use in adults before pediatric studies are complete;</p> <p>(ii) pediatric studies should be delayed until additional safety or effectiveness data have been collected; or</p> <p>(iii) there is another appropriate reason for deferral; and</p> <p>(B) the applicant submits to the Secretary—</p> <p>(i) certification of the grounds for deferring the assessments;</p> <p>(ii) a description of the planned or ongoing studies; and</p> <p>(iii) evidence that the studies are being conducted or will be conducted with due diligence and at the earliest possible time.</p>	<p>sufficiently similar in adults and pediatric patients, the Secretary may conclude that pediatric effectiveness can be extrapolated from adequate and well-controlled studies in adults, usually supplemented with other information obtained in pediatric patients, such as pharmacokinetic studies.</p> <p>ˆ(ii) EXTRAPOLATION BETWEEN AGE GROUPS—A study may not be needed in each pediatric age group if data from one age group can be extrapolated to another age group.</p> <p>ˆ(iii) INFORMATION ON EXTRAPOLATION—A brief documentation of the scientific data supporting the conclusion under clauses (i) and (ii) shall be included in any pertinent reviews for the application under section 505 of this Act or section 351 of the Public Health Service Act (42 U.S.C. 262).</p> <p>ˆ(3) DEFERRAL—</p> <p>ˆ(A) IN GENERAL—On the initiative of the Secretary or at the request of the applicant, the Secretary may defer submission of some or all assessments required under paragraph (1) until a specified date after approval of the drug or issuance of the license for a biological product if—</p> <p>ˆ(i) the Secretary finds that—</p> <p>ˆ(I) the drug or biological product is ready for approval for use in adults before pediatric studies are complete;</p> <p>ˆ(II) pediatric studies should be delayed until additional safety or effectiveness data have been collected; or</p> <p>ˆ(III) there is another appropriate reason for deferral; and</p> <p>ˆ(ii) the applicant submits to the Secretary--</p> <p>ˆ(I) certification of the grounds for deferring the assessments;</p> <p>ˆ(II) a description of the planned or ongoing studies;</p> <p>ˆ(III) evidence that the studies are being conducted or will be conducted with due diligence and at the earliest possible time; and</p> <p>ˆ(IV) a timeline for the completion of such studies.</p> <p>ˆ(B) ANNUAL REVIEW—</p> <p>ˆ(i) IN GENERAL—On an annual basis following the approval of a deferral under</p>	<p>Annual Deferral Review Requires an annual review from an applicant who has received a deferral.</p>

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<p>(4) WAIVERS—</p> <p>(A) FULL WAIVER—On the initiative of the Secretary or at the request of an applicant, the Secretary shall grant a full waiver, as appropriate, of the requirement to submit assessments for a drug or biological product under this subsection if the applicant certifies and the Secretary finds that—</p> <p>(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients is so small or the patients are geographically dispersed);</p> <p>(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in all pediatric age groups; or</p> <p>(iii) the drug or biological product—</p> <p>(I) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients; and</p> <p>(II) is not likely to be used in a substantial number of pediatric patients.</p> <p>(B) PARTIAL WAIVER—On the initiative of the Secretary or at the request of an applicant, the Secretary shall grant a partial waiver, as appropriate, of the requirement to submit assessments for a drug or biological product under this subsection with respect to a specific pediatric age group if the applicant certifies and the Secretary finds that—</p> <p>(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients in that age group is so small or patients in that age group are geographically dispersed);</p>	<p>subparagraph (A), the applicant shall submit to the Secretary the following information:</p> <p>“(I) Information detailing the progress made in conducting pediatric studies.</p> <p>“(II) If no progress has been made in conducting such studies, evidence and documentation that such studies will be conducted with due diligence and at the earliest possible time.</p> <p>“(ii) PUBLIC AVAILABILITY—The information submitted through the annual review under clause (i) shall promptly be made available to the public in an easily accessible manner, including through the Web site of the Food and Drug Administration.</p> <p>“(4) WAIVERS—</p> <p>“(A) FULL WAIVER—On the initiative of the Secretary or at the request of an applicant, the Secretary shall grant a full waiver, as appropriate, of the requirement to submit assessments for a drug or biological product under this subsection if the applicant certifies and the Secretary finds that--</p> <p>“(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients is so small or the patients are geographically dispersed);</p> <p>“(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in all pediatric age groups; or</p> <p>“(iii) the drug or biological product--</p> <p>“(I) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients; and</p> <p>“(II) is not likely to be used in a substantial number of pediatric patients.</p> <p>“(B) PARTIAL WAIVER—On the initiative of the Secretary or at the request of an applicant, the Secretary shall grant a partial waiver, as appropriate, of the requirement to submit assessments for a drug or biological product under this subsection with respect to a specific pediatric age group if the applicant certifies and the Secretary finds that—</p> <p>“(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients in that age group is so small or patients in that age group are geographically dispersed);</p>	<p>Public Annual Deferral Reviews Requires annual deferral reviews to be made public.</p>

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<p>(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in that age group;</p> <p>(iii) the drug or biological product—</p> <p>(I) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in that age group; and</p> <p>(II) is not likely to be used by a substantial number of pediatric patients in that age group; or</p> <p>(iv) the applicant can demonstrate that reasonable attempts to produce a pediatric formulation necessary for that age group have failed</p> <p>(C) PEDIATRIC FORMULATION NOT POSSIBLE—If a waiver is granted on the ground that it is not possible to develop a pediatric formulation, the waiver shall cover only the pediatric groups requiring that formulation.</p> <p>(D) LABELING REQUIREMENT—If the Secretary grants a full or partial waiver because there is evidence that a drug or biological product would be ineffective or unsafe in pediatric populations, the information shall be included in the labeling for the drug or biological product.</p> <p>(b) MARKETED DRUGS AND BIOLOGICAL PRODUCTS—</p> <p>(1) IN GENERAL—After providing notice in the form of a letter and an opportunity for written response and a meeting, which may include an advisory committee meeting, the Secretary may (by order in the form of a letter) require the holder of an approved application for a drug under section 505 or the holder of a license for a biological product under section 351 of the Public Health Service Act (42 U.S.C. 262) to submit by a specified date the assessments described in subsection (a)(2) if the Secretary finds that—</p> <p>(A)(i) the drug or biological product is used</p>	<p>ˆ(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in that age group;</p> <p>ˆ(iii) the drug or biological product--</p> <p>ˆ(I) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in that age group; and</p> <p>ˆ(II) is not likely to be used by a substantial number of pediatric patients in that age group; or</p> <p>ˆ(iv) the applicant can demonstrate that reasonable attempts to produce a pediatric formulation necessary for that age group have failed.</p> <p>ˆ(C) PEDIATRIC FORMULATION NOT POSSIBLE—If a waiver is granted on the ground that it is not possible to develop a pediatric formulation, the waiver shall cover only the pediatric groups requiring that formulation. An applicant seeking either a full or partial waiver shall submit to the Secretary documentation detailing why a pediatric formulation cannot be developed and, if the waiver is granted, the applicant's submission shall promptly be made available to the public in an easily accessible manner, including through posting on the Web site of the Food and Drug Administration.</p> <p>ˆ(D) LABELING REQUIREMENT—If the Secretary grants a full or partial waiver because there is evidence that a drug or biological product would be ineffective or unsafe in pediatric populations, the information shall be included in the labeling for the drug or biological product.</p> <p>ˆ(b) MARKETED DRUGS AND BIOLOGICAL PRODUCTS—</p> <p>ˆ(1) IN GENERAL—After providing notice in the form of a letter (that, for a drug approved under section 505, references a declined written request under section 505A for a labeled indication which written request is not referred under section 505A(n)(1)(A) to the Foundation of the National Institutes of Health for the pediatric studies), the Secretary may (by order in the form of a letter) require the sponsor or holder of an approved application for a drug under section 505 or the holder of a license for a biological product under section 351 of the Public Health Service Act to submit by a specified date the assessments described in subsection (a)(2), if the Secretary finds that—</p> <p>ˆ(A)(i) the drug or biological product is used</p>	<p>Pediatric Formulations Requires manufacturers that have tried but been unable to produce a pediatric formulation to submit to FDA the reasons why the formulation cannot be developed.</p>

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<p>for a substantial number of pediatric patients for the labeled indications; and</p> <p>(ii) the absence of adequate labeling could pose significant risks to pediatric patients; or</p> <p>(B)(i) there is reason to believe that the drug or biological product would represent a meaningful therapeutic benefit over existing therapies for pediatric patients for 1 or more of the claimed indications; and</p> <p>(ii) the absence of adequate labeling could pose significant risks to pediatric patients.</p> <p>(2) WAIVERS—</p> <p>(A) FULL WAIVER—At the request of an applicant, the Secretary shall grant a full waiver, as appropriate, of the requirement to submit assessments under this subsection if the applicant certifies and the Secretary finds that—</p> <p>(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients in that age group is so small or patients in that age group are geographically dispersed); or</p> <p>(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in all pediatric age groups.</p> <p>(B) PARTIAL WAIVER—At the request of an applicant, the Secretary shall grant a partial waiver, as appropriate, of the requirement to submit assessments under this subsection with respect to a specific pediatric age group if the applicant certifies and the Secretary finds that—</p> <p>(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients in that age group is so small or patients in that age group are geographically dispersed);</p> <p>(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in that age group;</p> <p>(iii)(I) the drug or biological product—</p> <p>(aa) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in that age group; and</p> <p>(bb) is not likely to be used in a substantial number of pediatric patients in that age group; and</p> <p>(II) the absence of adequate labeling could</p>	<p>for a substantial number of pediatric patients for the labeled indications; and</p> <p>ˆ(ii) adequate pediatric labeling could confer a benefit on pediatric patients;</p> <p>ˆ(B) there is reason to believe that the drug or biological product would represent a meaningful therapeutic benefit over existing therapies for pediatric patients for 1 or more of the claimed indications; or</p> <p>ˆ(C) the absence of adequate pediatric labeling could pose a risk to pediatric patients.</p> <p>ˆ(2) WAIVERS—</p> <p>ˆ(A) FULL WAIVER—At the request of an applicant, the Secretary shall grant a full waiver, as appropriate, of the requirement to submit assessments under this subsection if the applicant certifies and the Secretary finds that—</p> <p>ˆ(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients in that age group is so small or patients in that age group are geographically dispersed); or</p> <p>ˆ(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in all pediatric age groups.</p> <p>ˆ(B) PARTIAL WAIVER—At the request of an applicant, the Secretary shall grant a partial waiver, as appropriate, of the requirement to submit assessments under this subsection with respect to a specific pediatric age group if the applicant certifies and the Secretary finds that—</p> <p>ˆ(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients in that age group is so small or patients in that age group are geographically dispersed);</p> <p>ˆ(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in that age group;</p> <p>ˆ(iii)(I) the drug or biological product--</p> <p>ˆ(aa) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in that age group; and</p> <p>ˆ(bb) is not likely to be used in a substantial number of pediatric patients in that age group; and</p> <p>ˆ(II) the absence of adequate labeling could</p>	<p>Post-Market Standard Changes the criteria for applying PREA to already marketed drugs. New language allows FDA to use a “benefit” standard as opposed to a “risk” standard.</p>

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<p>not pose significant risks to pediatric patients; or</p> <p>(iv) the applicant can demonstrate that reasonable attempts to produce a pediatric formulation necessary for that age group have failed.</p> <p>(C) PEDIATRIC FORMULATION NOT POSSIBLE—If a waiver is granted on the ground that it is not possible to develop a pediatric formulation, the waiver shall cover only the pediatric groups requiring that formulation.</p> <p>(D) LABELING REQUIREMENT—If the Secretary grants a full or partial waiver because there is evidence that a drug or biological product would be ineffective or unsafe in pediatric populations, the information shall be included in the labeling for the drug or biological product.</p> <p>(3) RELATIONSHIP TO OTHER PEDIATRIC PROVISIONS—</p> <p>(A) NO ASSESSMENT WITHOUT WRITTEN REQUEST—No assessment may be required under paragraph (1) for a drug subject to an approved application under section 505 unless—</p> <p>(i) the Secretary has issued a written request for a related pediatric study under section 505A(c) of this Act or section 409I of the Public Health Service Act (42 U.S.C. 284m);</p> <p>(ii)(I) if the request was made under section 505A(c)—</p> <p>(aa) the recipient of the written request does not agree to the request; or</p> <p>(bb) the Secretary does not receive a response as specified under section 505A(d)(4)(A); or</p> <p>(II) if the request was made under section 409I of the Public Health Service Act (42 U.S.C. 284m)—</p>	<p>not pose significant risks to pediatric patients; or</p> <p>`(iv) the applicant can demonstrate that reasonable attempts to produce a pediatric formulation necessary for that age group have failed.</p> <p>`(C) PEDIATRIC FORMULATION NOT POSSIBLE—If a waiver is granted on the ground that it is not possible to develop a pediatric formulation, the waiver shall cover only the pediatric groups requiring that formulation. An applicant seeking either a full or partial waiver shall submit to the Secretary documentation detailing why a pediatric formulation cannot be developed and, if the waiver is granted, the applicant's submission shall promptly be made available to the public in an easily accessible manner, including through posting on the Web site of the Food and Drug Administration.</p> <p>`(D) LABELING REQUIREMENT—If the Secretary grants a full or partial waiver because there is evidence that a drug or biological product would be ineffective or unsafe in pediatric populations, the information shall be included in the labeling for the drug or biological product.</p> <p>`(3) EFFECT OF SUBSECTION—Nothing in this subsection alters or amends section 301(j) of this Act or section 552 of title 5 or section 1905 of title 18, United States Code.</p>	<p>Pediatric Formulations Requires a manufacturer that has tried but been unable to produce a pediatric formulation to submit to FDA the reasons why the formulation cannot be developed.</p> <p>“Exhaustion” Process Eliminates “exhaustion” provision in favor of expedited 30-day review of private funding before referral to PREA. See subsection (n) of BPCA.</p>

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<p>(aa) the recipient of the written request does not agree to the request; or</p> <p>(bb) the Secretary does not receive a response as specified under section 409I(c)(2) of that Act; and</p> <p>(iii)(I) the Secretary certifies under subparagraph (B) that there are insufficient funds under sections 409I and 499 of the Public Health Service Act (42 U.S.C. 284m, 290b) to conduct the study; or</p> <p>(II) the Secretary publishes in the Federal Register a certification that certifies that—</p> <p>(aa) no contract or grant has been awarded under section 409I or 499 of the Public Health Service Act (42 U.S.C. 284m, 290b); and</p> <p>(bb) not less than 270 days have passed since the date of a certification under subparagraph (B) that there are sufficient funds to conduct the study.</p> <p>(B) NO AGREEMENT TO REQUEST—Not later than 60 days after determining that no holder will agree to the written request (including a determination that the Secretary has not received a response specified under section 505A(d) of this Act or section 409I of the Public Health Service Act (42 U.S.C. 284m), the Secretary shall certify whether the Secretary has sufficient funds to conduct the study under section 409I or 499 of the Public Health Service Act (42 U.S.C. 284m, 290b), taking into account the prioritization under section 409I.</p> <p>(c) MEANINGFUL THERAPEUTIC BENEFIT—For the purposes of paragraph (4)(A)(iii)(I) and (4)(B)(iii)(I) of subsection (a) and paragraphs (1)(B)(i) and (2)(B)(iii)(I)(aa) of subsection (b), a drug or biological product shall be considered to represent a meaningful therapeutic benefit over existing therapies if the Secretary estimates that—</p> <p>(1) if approved, the drug or biological product would represent a significant improvement in the treatment, diagnosis, or prevention of a disease, compared with marketed products adequately labeled for that use in the relevant pediatric population; or</p> <p>(2) the drug or biological product is in a class of products or for an indication for which there is a need for additional options.</p> <p>(d) SUBMISSION OF ASSESSMENTS—If a person fails to submit an assessment described in subsection (a)(2), or a request</p>	<p>ˆ(c) MEANINGFUL THERAPEUTIC BENEFIT—For the purposes of paragraph (4)(A)(iii)(I) and (4)(B)(iii)(I) of subsection (a) and paragraphs (1)(B) and (2)(B)(iii)(I)(aa) of subsection (b), a drug or biological product shall be considered to represent a meaningful therapeutic benefit over existing therapies if the Secretary determines that—</p> <p>ˆ(1) if approved, the drug or biological product could represent an improvement in the treatment, diagnosis, or prevention of a disease, compared with marketed products adequately labeled for that use in the relevant pediatric population; or</p> <p>ˆ(2) the drug or biological product is in a class of products or for an indication for which there is a need for additional options.</p> <p>ˆ(d) SUBMISSION OF ASSESSMENTS—If a person fails to submit an assessment described in subsection (a)(2), or a request</p>	

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<p>for approval of a pediatric formulation described in subsection (a) or (b), in accordance with applicable provisions of subsections (a) and (b)—</p> <p>(1) the drug or biological product that is the subject of the assessment or request may be considered misbranded solely because of that failure and subject to relevant enforcement action (except that the drug or biological product shall not be subject to action under section 303); but</p> <p>(2) the failure to submit the assessment or request shall not be the basis for a proceeding—</p> <p>(A) to withdraw approval for a drug under section 505(e); or</p> <p>(B) to revoke the license for a biological product under section 351 of the Public Health Service Act (42 U.S.C. 262).</p> <p>(e) MEETINGS—Before and during the investigational process for a new drug or biological product, the Secretary shall meet at appropriate times with the sponsor of the new drug or biological product to discuss—</p> <p>(1) information that the sponsor submits on plans and timelines for pediatric studies; or</p> <p>(2) any planned request by the sponsor for waiver or deferral of pediatric studies.</p>	<p>for approval of a pediatric formulation described in subsection (a) or (b), in accordance with applicable provisions of subsections (a) and (b)—</p> <p>`(1) the drug or biological product that is the subject of the assessment or request may be considered misbranded solely because of that failure and subject to relevant enforcement action (except that the drug or biological product shall not be subject to action under section 303); but</p> <p>`(2) the failure to submit the assessment or request shall not be the basis for a proceeding--</p> <p>`(A) to withdraw approval for a drug under section 505(e); or</p> <p>`(B) to revoke the license for a biological product under section 351 of the Public Health Service Act.</p> <p>`(e) MEETINGS—Before and during the investigational process for a new drug or biological product, the Secretary shall meet at appropriate times with the sponsor of the new drug or biological product to discuss--</p> <p>`(1) information that the sponsor submits on plans and timelines for pediatric studies; or</p> <p>`(2) any planned request by the sponsor for waiver or deferral of pediatric studies.</p> <p>`(f) REVIEW OF PEDIATRIC PLANS, ASSESSMENTS, DEFERRALS, AND WAIVERS—</p> <p>`(1) REVIEW—Beginning not later than 30 days after the date of the enactment of the Pediatric Research Equity Act of 2007, the Secretary shall utilize the internal committee established under section 505C to provide consultation to reviewing divisions on all pediatric plans and assessments prior to approval of an application or supplement for which a pediatric assessment is required under this section and all deferral and waiver requests granted pursuant to this section.</p> <p>`(2) ACTIVITY BY COMMITTEE—The committee referred to in paragraph (1) may operate using appropriate members of such committee and need not convene all members of the committee.</p> <p>`(3) DOCUMENTATION OF COMMITTEE ACTION—For each drug or biological product, the committee referred to in paragraph (1) shall document, for each activity described in paragraph (4) or (5), which members of the committee</p>	<p>Internal Review Requires internal committee to review study plans and assessments, as well as deferrals and waivers.</p>

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	<p>participated in such activity.</p> <p>`(4) REVIEW OF PEDIATRIC PLANS, ASSESSMENTS, DEFERRALS, AND WAIVERS—Consultation on pediatric plans and assessments by the committee referred to in paragraph (1) pursuant to this section shall occur prior to approval of an application or supplement for which a pediatric assessment is required under this section. The committee shall review all requests for deferrals and waivers from the requirement to submit a pediatric assessment granted under this section and shall provide recommendations as needed to reviewing divisions, including with respect to whether such a supplement, when submitted, shall be considered for priority review.</p> <p>`(5) RETROSPECTIVE REVIEW OF PEDIATRIC ASSESSMENTS, DEFERRALS, AND WAIVERS—Not later than 1 year after the date of the enactment of the Pediatric Research Equity Act of 2007, the committee referred to in paragraph (1) shall conduct a retrospective review and analysis of a representative sample of assessments submitted and deferrals and waivers approved under this section since the enactment of the Pediatric Research Equity Act of 2003. Such review shall include an analysis of the quality and consistency of pediatric information in pediatric assessments and the appropriateness of waivers and deferrals granted. Based on such review, the Secretary shall issue recommendations to the review divisions for improvements and initiate guidance to industry related to the scope of pediatric studies required under this section.</p> <p>`(6) TRACKING OF ASSESSMENTS AND LABELING CHANGES—The Secretary, in consultation with the committee referred to in paragraph (1), shall track and make available to the public in an easily accessible manner, including through posting on the Web site of the Food and Drug Administration—</p> <p>`(A) the number of assessments conducted under this section;</p> <p>`(B) the specific drugs and biological products and their uses assessed under this section;</p> <p>`(C) the types of assessments conducted under this section, including trial design, the number of pediatric patients studied, and the number of centers and countries involved;</p>	<p>Tracking Requires FDA to track the number and type of studies completed, as well as labeling changes and other data resulting from PREA.</p>

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	<p>`(D) the total number of deferrals requested and granted under this section and, if granted, the reasons for such deferrals, the timeline for completion, and the number completed and pending by the specified date, as outlined in subsection (a)(3);</p> <p>`(E) the number of waivers requested and granted under this section and, if granted, the reasons for the waivers;</p> <p>`(F) the number of pediatric formulations developed and the number of pediatric formulations not developed and the reasons any such formulation was not developed;</p> <p>`(G) the labeling changes made as a result of assessments conducted under this section;</p> <p>`(H) an annual summary of labeling changes made as a result of assessments conducted under this section for distribution pursuant to subsection (h)(2);</p> <p>`(I) an annual summary of information submitted pursuant to subsection (a)(3)(B); and</p> <p>`(J) the number of times the committee referred to in paragraph (1) made a recommendation to the Secretary under paragraph (4) regarding priority review, the number of times the Secretary followed or did not follow such a recommendation, and, if not followed, the reasons why such a recommendation was not followed.</p> <p>`(g) LABELING CHANGES—</p> <p>`(1) DISPUTE RESOLUTION—</p> <p>`(A) REQUEST FOR LABELING CHANGE AND FAILURE TO AGREE—If, on or after the date of the enactment of the Pediatric Research Equity Act of 2007, the Commissioner determines that a sponsor and the Commissioner have been unable to reach agreement on appropriate changes to the labeling for the drug that is the subject of the application or supplement, not later than 180 days after the date of the submission of the application or supplement—</p> <p>`(i) the Commissioner shall request that the sponsor of the application make any labeling change that the Commissioner determines to be appropriate; and</p> <p>`(ii) if the sponsor does not agree within 30 days after the Commissioner's request to make a labeling change requested by the Commissioner, the Commissioner shall refer the matter to the Pediatric Advisory Committee.</p>	<p>Dispute Resolution The dispute resolution provision previously only applied to BPCA. The BPCA dispute resolution process was modified and applied to PREA. The modified language reduces the overall time period for dispute resolution over labeling and removes the provision requiring labeling to be the only remaining open issue before referral for resolution.</p>

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	<p>“(B) ACTION BY THE PEDIATRIC ADVISORY COMMITTEE- Not later than 90 days after receiving a referral under subparagraph (A)(ii), the Pediatric Advisory Committee shall—</p> <p>“(i) review the pediatric study reports; and</p> <p>“(ii) make a recommendation to the Commissioner concerning appropriate labeling changes, if any.</p> <p>“(C) CONSIDERATION OF RECOMMENDATIONS—The Commissioner shall consider the recommendations of the Pediatric Advisory Committee and, if appropriate, not later than 30 days after receiving the recommendation, make a request to the sponsor of the application or supplement to make any labeling changes that the Commissioner determines to be appropriate.</p> <p>“(D) MISBRANDING—If the sponsor of the application or supplement, 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 or supplement to be misbranded.</p> <p>“(E) NO EFFECT ON AUTHORITY— Nothing in this subsection limits the authority of the United States to bring an enforcement action under this Act when a drug lacks appropriate pediatric labeling. Neither course of action (the Pediatric Advisory Committee process or an enforcement action referred to in the preceding sentence) shall preclude, delay, or serve as the basis to stay the other course of action.</p> <p>“(2) OTHER LABELING CHANGES—If, on or after the date of the enactment of the Pediatric Research Equity Act of 2007, the Secretary makes a determination that a pediatric assessment conducted under this section does or does not demonstrate that the drug that is the subject of such assessment is safe and effective in pediatric populations or subpopulations, including whether such assessment results are inconclusive, the Secretary shall order the label of such product to include information about the results of the assessment and a statement of the Secretary’s determination.</p> <p>“(h) DISSEMINATION OF PEDIATRIC INFORMATION—</p> <p>“(1) IN GENERAL—Not later than 210 days</p>	

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	<p>after the date of submission of a pediatric assessment under this section, the Secretary shall make available to the public in an easily accessible manner the medical, statistical, and clinical pharmacology reviews of such pediatric assessments, and shall post such assessments on the Web site of the Food and Drug Administration.</p> <p>`(2) DISSEMINATION OF INFORMATION REGARDING LABELING CHANGES— Beginning on the date of the enactment of the Pediatric Research Equity Act of 2007, the Secretary shall require that the sponsors of the assessments that result in labeling changes that are reflected in the annual summary developed pursuant to subsection (f)(6)(H) distribute such information to physicians and other health care providers.</p> <p>`(3) EFFECT OF SUBSECTION—Nothing in this subsection shall alter or amend section 301(j) of this Act or section 552 of title 5 or section 1905 of title 18, United States Code.</p> <p>`(i) ADVERSE EVENT REPORTING—</p> <p>`(1) REPORTING IN YEAR ONE— Beginning on the date of the enactment of the Pediatric Research Equity Act of 2007, during the one-year period beginning on the date a labeling change is made pursuant to subsection (g), the Secretary shall ensure that all adverse event reports that have been received for such drug (regardless of when such report was received) are referred to the Office of Pediatric Therapeutics. In considering such reports, the Director of such Office shall provide for the review of such reports by the Pediatric Advisory Committee, including obtaining any recommendations of such committee regarding whether the Secretary should take action under this Act in response to such reports.</p> <p>`(2) REPORTING IN SUBSEQUENT YEARS—Following the one-year period described in paragraph (1), the Secretary shall, as appropriate, refer to the Office of Pediatric Therapeutics all pediatric adverse event reports for a drug for which a pediatric study was conducted under this section. In considering such reports, the Director of such Office may provide for the review of such reports by the Pediatric Advisory Committee, including obtaining any recommendation of such Committee regarding whether the Secretary should take action in response to such reports.</p> <p>`(3) EFFECT—The requirements of this subsection shall supplement, not supplant, other review of such adverse event reports by the Secretary.</p>	<p>Reviews Made Public Requires Secretary to make publicly available the medical, statistical, and clinical pharmacology reviews.</p> <p>Dissemination Requirements Requires sponsors to provide physicians and other health care providers with new pediatric labeling information.</p> <p>Adverse Event Reporting Requires drugs studied under PREA to report adverse events and provides for review by the Pediatric Advisory Committee.</p>

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<p>(f) SCOPE OF AUTHORITY—Nothing in this section provides to the Secretary any authority to require a pediatric assessment of any drug or biological product, or any assessment regarding other populations or uses of a drug or biological product, other than the pediatric assessments described in this section.</p> <p>(g) ORPHAN DRUGS—Unless the Secretary requires otherwise by regulation, this section does not apply to any drug for an indication for which orphan designation has been granted under section 526.</p> <p>(h) INTEGRATION WITH OTHER PEDIATRIC STUDIES—The authority under this section shall remain in effect so long as an application subject to this section may be accepted for filing by the Secretary on or before the date specified in section 505A(n).</p>	<p>`(j) SCOPE OF AUTHORITY—Nothing in this section provides to the Secretary any authority to require a pediatric assessment of any drug or biological product, or any assessment regarding other populations or uses of a drug or biological product, other than the pediatric assessments described in this section.</p> <p>`(k) ORPHAN DRUGS—Unless the Secretary requires otherwise by regulation, this section does not apply to any drug for an indication for which orphan designation has been granted under section 526.</p> <p>`(l) INSTITUTE OF MEDICINE STUDY—</p> <p>`(1) IN GENERAL—Not later than three years after the date of the enactment of the Pediatric Research Equity Act of 2007, the Secretary shall contract with the Institute of Medicine to conduct a study and report to Congress regarding the pediatric studies conducted pursuant to this section or precursor regulations since 1997 and labeling changes made as a result of such studies.</p> <p>`(2) CONTENT OF STUDY—The study under paragraph (1) shall review and assess the use of extrapolation for pediatric subpopulations, the use of alternative endpoints for pediatric populations, neonatal assessment tools, the number and type of pediatric adverse events, and ethical issues in pediatric clinical trials.</p> <p>`(3) REPRESENTATIVE SAMPLE—The Institute of Medicine may devise an appropriate mechanism to review a representative sample of studies conducted pursuant to this section from each review division within the Center for Drug Evaluation and Research in order to make the requested assessment.</p> <p>`(m) INTEGRATION WITH OTHER PEDIATRIC STUDIES—The authority under this section shall remain in effect so long as an application subject to this section may be accepted for filing by the Secretary on or before the date specified in section 505A(q).'</p> <p>(b) APPLICABILITY—</p> <p>(1) IN GENERAL—Notwithstanding subsection (h) of section 505B of the Federal Food, Drug and Cosmetic Act, as in effect on the day before the date of the enactment of this Act, a pending assessment, including a deferred assessment, required under such section 505B shall be deemed to have been</p>	<p>IOM Study Asks the Institute of Medicine to review past study requests issued by FDA and make recommendations to FDA for future requests.</p> <p>PREA Extended Continues linkage of PREA to expiration (sunset) of BPCA on October 1, 2012.</p>

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<p>[Original GAO report from PL108-155. Only included BPCA.]</p> <p>SEC. 16. REPORT ON PEDIATRIC EXCLUSIVITY PROGRAM.</p> <p>Not later than October 1, 2006, the Comptroller General of the United States, in consultation with the Secretary of Health and Human Services, shall submit to Congress a report that addresses the following issues, using publicly available data or data otherwise available to the Government that may be used and disclosed under applicable law:</p>	<p>required under section 505B of the Federal Food, Drug and Cosmetic Act as in effect on or after the date of the enactment of this Act.</p> <p>(2) CERTAIN ASSESSMENTS AND WAIVER REQUESTS—An assessment pending on or after the date that is 1 year prior to the date of the enactment of this Act shall be subject to the tracking and disclosure requirements established under such section 505B, as in effect on or after such date of enactment, except that any such assessments submitted or waivers of such assessments requested before such date of enactment shall not be subject to subsections (a)(4)(C), (b)(2)(C), (f)(6)(F), and (h) of such section 505B.</p> <p>SEC. 403. ESTABLISHMENT OF INTERNAL COMMITTEE.</p> <p>Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 505B the following:</p> <p>SEC. 505C. INTERNAL COMMITTEE FOR REVIEW OF PEDIATRIC PLANS, ASSESSMENTS, DEFERRALS, AND WAIVERS.</p> <p>The Secretary shall establish an internal committee within the Food and Drug Administration to carry out the activities as described in sections 505A(f) and 505B(f). Such internal committee shall include employees of the Food and Drug Administration, with expertise in pediatrics (including representation from the Office of Pediatric Therapeutics), biopharmacology, statistics, chemistry, legal issues, pediatric ethics, and the appropriate expertise pertaining to the pediatric product under review, such as expertise in child and adolescent psychiatry, and other individuals designated by the Secretary.</p> <p>SEC. 404. GOVERNMENT ACCOUNTABILITY OFFICE REPORT.</p> <p>Not later than January 1, 2011, the Comptroller General of the United States, in consultation with the Secretary of Health and Human Services, shall submit to the Congress a report that addresses the effectiveness of sections 505A and 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a, 355c) and section 409I of the Public Health Service Act (42 U.S.C. 284m) in ensuring that medicines used by children are tested and properly labeled.</p>	<p>Coordinated Internal Review Committee</p> <p>New language establishes a coordinated internal review committee for BPCA and PREA.</p> <p>GAO Report</p> <p>Requires the GAO to produce a report on the results of BPCA and PREA with recommendations for improving the programs.</p>

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<p>(1) The effectiveness of section 505A of the Federal Food, Drug, and Cosmetic Act and section 409I of the Public Health Service Act (as added by this Act) in ensuring that medicines used by children are tested and properly labeled, including—</p> <p>(A) the number and importance of drugs for children that are being tested as a result of this legislation and the importance for children, health care providers, parents, and others of labeling changes made as a result of such testing;</p> <p>(B) the number and importance of drugs for children that are not being tested for their use notwithstanding the provisions of this legislation, and possible reasons for the lack of testing; and</p> <p>(C) the number of drugs for which testing is being done, exclusivity granted, and labeling changes required, including the date pediatric exclusivity is granted and the date labeling changes are made and which labeling changes required the use of the dispute resolution process established pursuant to the amendments made by this Act, together with a description of the outcomes of such process, including a description of the disputes and the recommendations of the Pediatric Advisory Subcommittee of the Anti-Infective Drugs Advisory Committee.</p> <p>(2) The economic impact of section 505A of the Federal Food, Drug, and Cosmetic Act and section 409I of the Public Health Service Act (as added by this Act), including an estimate of—</p> <p>(A) the costs to taxpayers in the form of higher expenditures by medicaid and other Government programs;</p> <p>(B) sales for each drug during the 6-month period for which exclusivity is granted, as attributable to such exclusivity;</p> <p>(C) costs to consumers and private insurers as a result of any delay in the availability of lower cost generic equivalents of drugs tested and granted exclusivity under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), and loss of revenue by the generic drug industry and retail pharmacies as a result of any such delay; and</p> <p>(D) the benefits to the government, to private insurers, and to consumers resulting from decreased health care costs, including—</p>	<p>Such report shall include—</p> <p>(1) the number and importance of drugs and biological products for children that are being tested as a result of the amendments made by this title and title V and the importance for children, health care providers, parents, and others of labeling changes made as a result of such testing;</p> <p>(2) the number and importance of drugs and biological products for children that are not being tested for their use notwithstanding the provisions of this title and title V and possible reasons for the lack of testing;</p> <p>(3) the number of drugs and biological products for which testing is being done and labeling changes required, including the date labeling changes are made and which labeling changes required the use of the dispute resolution process established pursuant to the amendments made by this title, together with a description of the outcomes of such process, including a description of the disputes and the recommendations of the Pediatric Advisory Committee;</p> <p>(4) any recommendations for modifications to the programs established under sections 505A and 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) and section 409I of the Public Health Service Act (42 U.S.C. 284m) that the Secretary determines to be appropriate, including a detailed rationale for each recommendation; and</p> <p>(5)(A) the efforts made by the Secretary to increase the number of studies conducted in the neonate population; and</p> <p>(B) the results of those efforts, including efforts made to encourage the conduct of appropriate studies in neonates by companies with products that have sufficient safety and other information to make the conduct of the studies ethical and safe.</p>	

Existing Law	2007 Reauthorization	Improvements
<p>(i) decreased hospitalizations and fewer medical errors, due to more appropriate and more effective use of medications in children as a result of testing and re-labeling because of the amendments made by this Act;</p> <p>(ii) direct and indirect benefits associated with fewer physician visits not related to hospitalization;</p> <p>(iii) benefits to children from missing less time at school and being less affected by chronic illnesses, thereby allowing a better quality of life;</p> <p>(iv) benefits to consumers from lower health insurance premiums due to lower treatment costs and hospitalization rates; and</p> <p>(v) benefits to employers from reduced need for employees to care for family members.</p> <p>(3) The nature and type of studies in children for each drug granted exclusivity under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), including—</p> <p>(A) a description of the complexity of the studies;</p> <p>(B) the number of study sites necessary to obtain appropriate data;</p> <p>(C) the number of children involved in any clinical studies; and</p> <p>(D) the estimated cost of each of the studies.</p> <p>(4) Any recommendations for modifications to the programs established under section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) and section 409l of the Public Health Service Act (as added by section 3) that the Secretary determines to be appropriate, including a detailed rationale for each recommendation.</p> <p>(5) The increased private and Government-funded pediatric research capability associated with this Act and the amendments made by this Act.</p> <p>(6) The number of written requests and additional letters of recommendation that the Secretary issues.</p> <p>(7) The prioritized list of off-patent drugs for which the Secretary issues written requests.</p> <p>(8)(A) The efforts made by the Secretary to increase the number of studies conducted in</p>		

Existing Law	2007 Reauthorization	Improvements
<p>the neonate population; and</p> <p>(B) the results of those efforts, including efforts made to encourage the conduct of appropriate studies in neonates by companies with products that have sufficient safety and other information to make the conduct of studies ethical and safe.</p>		