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112TH CONGRESS
2D SESSION

H. R. 4274

To amend title IV of the Public Health Service Act and title V of the Federal Food, Drug, and Cosmetic Act to permanently extend the provisions of the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act of 2003.

IN THE HOUSE OF REPRESENTATIVES

MARCH 28, 2012

Mr. ROGERS of Michigan (for himself, Ms. ESHOO, and Mr. MARKEY) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend title IV of the Public Health Service Act and title V of the Federal Food, Drug, and Cosmetic Act to permanently extend the provisions of the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act of 2003.

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

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''BPCA and PREA Reauthorization Act of 2012''.

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

SEC. 2. PERMANENT EXTENSION OF BEST PHARMACEUTICALS FOR CHILDREN ACT AND PEDIATRIC RESEARCH EQUITY ACT.

(a) PROGRAM FOR PEDIATRIC STUDY OF DRUGS IN PHSA.—Section 409I(e)(1)(B) of the Public Health Service Act (42 U.S.C. 284m(e)(1)(B)) is amended by striking ''of the four succeeding fiscal years'' and inserting ''succeeding fiscal year''.

(b) PEDIATRIC STUDIES OF DRUGS IN FFDCA.—Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended—

(1) in subsection (d)(1)(A), by adding at the end the following: ''If a request under this subparagraph does not request studies in neonates, such request shall include a statement describing the rationale for not requesting studies in neonates.'';

(2) by amending subsection (h) to read as follows:

''(h) RELATIONSHIP TO PEDIATRIC RESEARCH REQUIREMENTS.—Exclusivity under this section shall only be granted for the completion of a study or studies that are

the subject of a written request and for which reports are submitted and accepted in accordance with subsection (d)(3). Written requests under this section may consist of a study or studies required under section 505B.'';

(3) in subsection (k)(2), by striking ''subsection (f)(3)(F)'' and inserting ''subsection (f)(6)(F)'';

(4) in subsection (l)—

(A) in paragraph (1)—

(i) in the paragraph heading, by striking ''YEAR ONE'' and inserting ''FIRST 18-MONTH PERIOD''; and

(ii) by striking ''one-year'' and inserting ''18-month'';

(B) in paragraph (2)—

(i) in the paragraph heading, by striking ''YEARS'' and inserting ''PERIODS''; and

(ii) by striking ''one-year period'' and inserting ''18-month period'';

(C) by redesignating paragraph (3) as paragraph (4); and

(D) by inserting after paragraph (2) the following:

''(3) PRESERVATION OF AUTHORITY.—Nothing in this subsection shall prohibit the Office of Pedi-

atric Therapeutics from providing for the review of adverse event reports by the Pediatric Advisory Committee prior to the 18-month period referred to in paragraph (1), if such review is necessary to ensure safe use of a drug in a pediatric population.'';

(5) in subsection (n)—

(A) in the subsection heading, by striking ''COMPLETED'' and inserting ''SUBMITTED''; and

(B) in paragraph (1)—

(i) in the text preceding subparagraph (A), by striking ''have not been completed'' and inserting ''have not been submitted by the date specified in the written request issued and agreed upon''; and

(ii) by revising subparagraphs (A) and (B) to read as follows:

''(A) For a drug for which there remains any listed patent or exclusivity protection, make a determination regarding whether an assessment shall be required to be submitted under section 505B(b).

''(B) For a drug that has no remaining listed patents or exclusivity protection, 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.'';

(6) in subsection (o)(2), by amending subparagraph (B) to read as follows:

''(B) a statement of any appropriate pediatric contraindications, warnings, precautions, or other information that the Secretary considers necessary to assure safe use.''; and

(7) by striking subsection (q) (relating to a sunset).

(c) RESEARCH INTO PEDIATRIC USES FOR DRUGS AND BIOLOGICAL PROJECTS IN FFDCA.—Section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c) is amended—

(1) in subsection (a)—

(A) in paragraph (1), in the matter before subparagraph (A), by inserting ''for a drug'' after ''(or supplement to an application)'';

(B) in paragraph (3)—

(i) by redesignating subparagraph (B) as subparagraph (D); and

(ii) by inserting after subparagraph (A) the following:

''(B) DEFERRAL EXTENSION.—On the initiative of the Secretary or at the request of the

applicant, the Secretary may grant an extension of a deferral under subparagraph (A) if—

''(i) the Secretary finds that the criteria specified in subclause (II) or (III) of subparagraph (A)(i) continue to be met; and

''(ii) the applicant submits the materials required under subparagraph (A)(ii).

''(C) CONSIDERATION DURING DEFERRAL PERIOD.—If the Secretary has under this paragraph deferred the date by which an assessment must be submitted, then until the date specified in the deferral under subparagraph (A) (including any extension of such date under subparagraph (B))—

''(i) the assessment shall not be considered late or delayed;

''(ii) the Secretary shall not classify the assessment as late or delayed in any report, database, or public posting.''; and

(iii) in subparagraph (D), as redesignated, by amending clause (ii) to read as follows:

''(ii) PUBLIC AVAILABILITY.—Not later than 60 days after the submission to

the Secretary of the information submitted through the annual review under clause (i), the Secretary shall make available to the public in an easily accessible manner, including through the Web site of the Food and Drug Administration—

''(I) such information;

''(II) the name of the applicant for the product subject to the assessment;

''(III) the date on which the product was approved; and

''(IV) the date of each deferral or deferral extension under this paragraph for the product.''; and

(C) in paragraph (4)(C)—

(i) in the first sentence, by inserting ''partial'' before ''waiver is granted''; and

(ii) in the second sentence, by striking ''either a full or partial waiver'' and inserting ''a partial waiver'';

(2) in subsection (b)(1), by striking ''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 in-

dication 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'' and inserting ''The Secretary'';

(3) by amending subsection (d) to read as follows:

''(d) FAILURE TO MEET REQUIREMENTS.—If a person fails to submit a required assessment described in subsection (a)(2), fails to meet the applicable requirements in subsection (a)(3), or fails to submit a request for approval of a pediatric formulation described in subsection (a) or (b), in accordance with applicable provisions of subsections (a) and (b)—

''(1)(A) the Secretary shall issue a letter to such person informing such person of such failure;

''(B) not later than 30 calendar days after the issuance of a letter under subparagraph (A), the person who receives such letter shall submit to the Secretary a written response to such letter; and

''(C) not later than 45 calendar days after the issuance of a letter under subparagraph (A), the Secretary shall make such letter, and any response to such letter under subparagraph (B), available to the public on the Web site of the Food and Drug Administration, with appropriate redactions made to

protect trade secrets and confidential commercial information, except that, if the Secretary determines that the letter under subparagraph (A) was issued in error, the requirements of this subparagraph shall not apply with respect to such letter; and

''(2)(A) the drug or biological product that is the subject of the required assessment, applicable requirements in subsection (a)(3), or required request for approval of a pediatric formulation 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

''(B) the failure to submit the required assessment, meet the applicable requirements in subsection (a)(3), or submit the required request for approval of a pediatric formulation shall not be the basis for a proceeding—

''(i) to withdraw approval for a drug under section 505(e); or

''(ii) to revoke the license for a biological product under section 351 of the Public Health Service Act.'';

(4) by amending subsection (e) to read as follows:

''(e) INITIAL PEDIATRIC PLAN.—

''(1) IN GENERAL.—

''(A) SUBMISSION.—An applicant who is required to submit an assessment under subsection (a)(1) shall submit an initial pediatric plan.

''(B) TIMING.—An applicant shall submit the initial pediatric plan under paragraph (1)—

''(i) before the date on which the applicant submits the assessments under subsection (a)(2); and

''(ii) not later than—

''(I) 60 calendar days after the date of end-of-Phase 2 meeting (as such term is used in section 312.47 of title 21, Code of Federal Regulations, or successor regulations); or

''(II) such other time as may be agreed upon between the Secretary and the applicant.

Nothing in this section shall preclude the Secretary from accepting the submission of an initial pediatric plan earlier than the date otherwise applicable under this subparagraph.

"(C) CONTENTS.—The initial pediatric plan shall include—

"(i) an outline of the pediatric studies that the applicant plans to conduct;

"(ii) any request for a deferral, partial waiver, or waiver under this section, along with supporting information; and

"(iii) other information the Secretary determines necessary, including any information specified in regulations under paragraph (5).

"(2) MEETING.—

"(A) IN GENERAL.—Subject to subparagraph (B), not later than 60 calendar days after receiving an initial pediatric plan under paragraph (1), the Secretary shall meet with the applicant to discuss the plan.

"(B) WRITTEN RESPONSE.—If the Secretary determines that a written response to the initial pediatric plan is sufficient to communicate comments on the initial pediatric plan, and that no meeting is necessary the Secretary shall, not later than 60 days after receiving an initial pediatric plan under paragraph (1)—

"(i) notify the applicant of such determination; and

"(ii) provide to the applicant the Secretary's written comments on the plan.

"(3) AGREED PEDIATRIC PLAN.—

"(A) SUBMISSION.—The applicant shall submit to the Secretary a document reflecting the agreement between the Secretary and the applicant on the initial pediatric plan (referred to in this subsection as an 'agreed pediatric plan').

"(B) CONFIRMATION.—Not later than 30 days after receiving the agreed pediatric plan under subparagraph (A), the Secretary shall provide written confirmation to the applicant that such plan reflects the agreement of the Secretary.

"(C) DEFERRAL AND WAIVER.—If the agreed pediatric plan contains a request from the applicant for a deferral, partial waiver, or waiver under this section, the written confirmation under subparagraph (B) shall include a recommendation from the Secretary as to whether such request meets the standards under paragraphs (3) or (4) of subsection (a).

"(D) AMENDMENTS TO THE PLAN.—At the initiative of the Secretary or the applicant, the agreed pediatric plan may be amended at any time. The requirements of paragraph (2) shall apply to any such proposed amendment in the same manner and to the same extent as such requirements apply to an initial pediatric plan under paragraph (1). The requirements of subparagraphs (A) through (C) of this paragraph shall apply to any agreement resulting from such proposed amendment in the same manner and to the same extent as such requirements apply to an agreed pediatric plan.

"(4) INTERNAL COMMITTEE.—The Secretary shall consult the internal committee under section 505C on the review of the initial pediatric plan, agreed pediatric plan, and any amendments to such plans.

"(5) MANDATORY RULEMAKING.—Not later than one year after the date of enactment of the BPCA and PREA Reauthorization Act of 2012, the Secretary shall promulgate proposed regulations and guidance to implement the provisions of this subsection.

''(6) EFFECTIVE DATE.—The provisions of this subsection shall take effect 180 calendar days after the date of enactment of the BPCA and PREA Reauthorization Act of 2012, irrespective of whether the Secretary has promulgated final regulations to carry out this subsection by such date.'';

(5) in subsection (f)—

(A) in the subsection heading, by inserting ''DEFERRAL EXTENSIONS,'' after ''DEFERRALS,'';

(B) in paragraph (4)—

(i) in the paragraph heading, by inserting ''DEFERRAL EXTENSIONS,'' after ''DEFERRALS,''; and

(ii) in the second sentence, by inserting '', deferral extensions,'' after ''deferrals''; and

(C) in paragraph (6)(D)—

(i) by inserting ''and deferral extensions'' before ''requested and granted''; and

(ii) by inserting ''and deferral extensions'' after ''the reasons for such deferrals'';

(6) in subsection (g)—

(A) in paragraph (1)(A), by striking ''after the date of the submission of the application or supplement'' and inserting ''after the date of the submission of an application or supplement that receives a priority review or 330 days after the date of the submission of an application or supplement that receives a standard review''; and

(B) in paragraph (2), by striking ''the label of such product'' and inserting ''the labeling of such product'';

(7) in subsection (h)(1)—

(A) by inserting ''an application (or supplement to an application) that contains'' after ''date of submission of''; and

(B) by inserting ''if the application (or supplement) receives a priority review, or not later than 300 days after the date of submission of an application (or supplement to an application) that contains a pediatric assessment under this section, if the application (or supplement) receives a standard review,'' after ''under this section,'';

(8) in subsection (i)—

(A) in paragraph (1)—

(i) in the paragraph heading, by striking ''YEAR ONE'' and inserting ''FIRST 18-MONTH PERIOD''; and

(ii) by striking ''one-year'' and inserting ''18-month'';

(B) in paragraph (2)—

(i) in the paragraph heading, by striking ''YEARS'' and inserting ''PERIODS''; and

(ii) by striking ''one-year period'' and inserting ''18-month period'';

(C) by redesignating paragraph (3) as paragraph (4); and

(D) by inserting after paragraph (2) the following:

''(3) PRESERVATION OF AUTHORITY.—Nothing in this subsection shall prohibit the Office of Pediatric Therapeutics from providing for the review of adverse event reports by the Pediatric Advisory Committee prior to the 18-month period referred to in paragraph (1), if such review is necessary to ensure safe use of a drug in a pediatric population.'';

(9) by striking subsection (m) (relating to integration with other pediatric studies); and

(10) by redesignating subsection (n) as subsection (m).

(d) PEDIATRIC STUDIES OF BIOLOGICAL PRODUCTS IN PHSA.—Section 351(m)(1) of the Public Health Service Act (42 U.S.C. 262(m)(1)) is amended by striking ''(f), (i), (j), (k), (l), (p), and (q)'' and inserting ''(f), (h), (i), (j), (k), (l), and (p)''.

(e) APPLICATION; TRANSITION RULE.—

(1) APPLICATION.—Notwithstanding any provision of section 505A and 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a, 355c) stating that a provision applies beginning on the date of the enactment of the Best Pharmaceuticals for Children Act of 2007 or the date of the enactment of the Pediatric Research Equity Act of 2007, any amendment made by this Act to such a provision applies beginning on the date of the enactment of this Act.

(2) TRANSITIONAL RULE FOR ADVERSE EVENT REPORTING.—With respect to a drug for which a labeling change described under section 505A(l)(1) or 505B(i)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(l)(1); 355c(i)(1)) is approved or made, respectively, during the one-year period that ends on the day before the date of enactment

of this Act, the Secretary shall apply section 505A(l) and section 505B(i), as applicable, to such drug, as such sections were in effect on such day.

(f) CONFORMING AMENDMENT.—Section 499(c)(1)(C) of the Public Health Service Act (42 U.S.C. 290b(c)(1)(C)) is amended by striking ''for which the Secretary issues a certification in the affirmative under section 505A(n)(1)(A) of the Federal Food, Drug, and Cosmetic Act''.

SEC. 3. GOVERNMENT ACCOUNTABILITY OFFICE REPORT.

(a) IN GENERAL.—Not later than January 1, 2016, and the end of each subsequent 5-year period, 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 evaluates 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 in pediatric populations and properly labeled for use in children.

(b) CONTENTS.—The report under subsection (a) shall include—

(1) the number and importance of drugs and biological products for children that are being tested

as a result of the programs established under sections 505A and 505B of the Federal Food, Drug, and Cosmetic Act and section 409I of the Public Health Service Act;

(2) a description of the importance for children, health care providers, parents, and others of labeling changes made as a result of such testing;

(3) the number and importance of drugs and biological products for children that are not being tested for their use in pediatric populations, notwithstanding the existence of such programs;

(4) the possible reasons for the lack of testing reported under paragraph (3);

(5) the number of drugs and biological products for which testing is being done and labeling changes are required under the programs established by this Act, including—

(A) the date labeling changes are made;

(B) which labeling changes required the use of the dispute resolution process; and

(C) for labeling changes that required such dispute resolution process, a description of—

(i) the disputes;

(ii) the recommendations of the Pediatric Advisory Committee; and

(iii) the outcomes of such process;

(6) any recommendations for modifications to the programs established under sections 505A and 505B of the Federal Food, Drug, and Cosmetic Act and section 409I of the Public Health Service Act that the Secretary determines to be appropriate, including a detailed rationale for each recommendation;

(7)(A) the efforts made by the Secretary to increase the number of studies conducted in the neonate population (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); and

(B) the results of such efforts; and

(8)(A) the number and importance of drugs and biological products for children with cancer that are being tested as a result of the programs established under sections 505A and 505B of the Federal Food, Drug, and Cosmetic Act and section 409I of the Public Health Service Act; and

(B) any recommendations for modifications to the programs under such sections that would lead to new and better therapies for children with cancer,

including a detailed rationale for each recommendation.

SEC. 4. INTERNAL COMMITTEE FOR REVIEW OF PEDIATRIC PLANS, ASSESSMENTS, DEFERRALS, DEFERRAL EXTENSIONS, AND WAIVERS.

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

(1) in the section heading, by inserting ''**DEFERRAL EXTENSIONS,**'' after ''**DEFERRALS,**''; and

(2) by inserting ''neonatology'' after ''pediatric ethics''.

SEC. 5. STAFF OF OFFICE OF PEDIATRIC THERAPEUTICS.

Section 6(c) of the Best Pharmaceuticals for Children Act (21 U.S.C. 393a(c)) is amended—

(1) in paragraph (1), by striking ''and'' at the end;

(2) by redesignating paragraph (2) as paragraph (4);

(3) by inserting after paragraph (1) the following:

''(2) one or more additional individuals with expertise in neonatology;

''(3) one or more additional individuals with expertise in pediatric epidemiology; and''.

SEC. 6. CONTINUATION OF OPERATION OF PEDIATRIC ADVISORY COMMITTEE.

Section 14(d) of the Best Pharmaceuticals for Children Act (42 U.S.C. 284m note) is amended by striking ''during the five-year period beginning on the date of the enactment of the Best Pharmaceuticals for Children Act of 2007'' and inserting ''to carry out the advisory committee's responsibilities under sections 505A, 505B, and 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a, 355c, and 360j(m))''.

SEC. 7. PEDIATRIC SUBCOMMITTEE OF THE ONCOLOGIC DRUGS ADVISORY COMMITTEE.

Section 15(a) of the Best Pharmaceuticals for Children Act (Public Law 107–109), as amended by section 502(e) of the Food and Drug Administration Amendments Act of 2007 (Public Law 110–85), is amended—

(1) in paragraph (1)(D), by striking ''section 505B(f)'' and inserting ''section 505C''; and

(2) in paragraph (3), by striking ''during the five-year period beginning on the date of the enactment of the Best Pharmaceuticals for Children Act of 2007'' and inserting ''to carry out the Subcommittee's responsibilities under this section''.

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