Subsec. (c)(5). Pub. L. 109–482, §103(b)(13)(C), struck out heading and text of par. (5). Text read as follows: ''For the purpose of carrying out this subsection, there are authorized to be appropriated such sums as may be necessary for each fiscal year.''

Subsec. (d)(4). Pub. L. 109–482, §103(b)(13)(D), struck out heading and text of par. (4). Text read as follows: ''For the purpose of carrying out this subsection, there are authorized to be appropriated such sums as may be necessary for each fiscal year.''

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

§ 284m. Program for pediatric studies of drugs

(a) List of priority issues in pediatric therapeutics

(1) In general

Not later than one year after September 27, 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, biological products, or indications that require study. The list shall be revised every three years.

(2) Consideration of available information

In developing and prioritizing the list under paragraph (1), the Secretary—

(A) shall consider—

(i) 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;

(ii) particular pediatric diseases, disorders or conditions where more complete knowledge and testing of therapeutics, including drugs and biologics, and identification of biomarkers for such diseases, disorders, or conditions, may be beneficial in pediatric populations; and

(iii) the adequacy of necessary infrastructure to conduct pediatric pharmacological research, including research networks and trained pediatric investigators; and

(B) may consider the availability of qualified countermeasures (as defined in section 247d–6a of this title), security countermeasures (as defined in section 247d–6b of this title), and qualified pandemic or epidemic products (as defined in section 247d–6d of this title) to address the needs of pediatric populations, in consultation with the Assistant Secretary for Preparedness and Response, consistent with the purposes of this section.

(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 paragraphs (1) and (2)(A) of subsection (a). The Secretary may use contracts, grants, or other appropriate funding mechanisms to award funds under this subsection.

(c) Process for proposed pediatric study requests and labeling changes

(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 [21 U.S.C. 355a], or section 262(m) of this title, 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—

(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)] or section 262(k) of this title; or

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

(B) there remains no patent listed pursuant to section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355(b)(1)], and every three-year and five-year period referred to in subsection (c)(3)(E)(ii), (c)(3)(E)(iii), (c)(3)(E)(iv), (j)(5)(F)(ii), (j)(5)(F)(iii), or (j)(5)(F)(iv) of section 505 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355], or applicable twelve-year period referred to in section 262(k)(7) of this title, and any seven-year period referred to in section 527 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360cc] has ended for at least one form of the drug; and

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

(2) Written request to holders of approved applications

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. 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 the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355a] or section 262(m) of this title, 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.

(3) Requests for proposals

If the Commissioner of Food and Drugs does not receive a response to a written request 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).

(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).

(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.

(6) Reporting of studies

(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.

(B) Availability of reports

(i) In general

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 [21 U.S.C. 355a(d)(4)]) and not later than 90 days after submission of such report, shall be—

(I) posted on the internet website of the National Institutes of Health in a manner that is accessible and consistent with all applicable Federal laws and regulations, including such laws and regulations for the protection of—

(aa) human research participants, including with respect to privacy, security, informed consent, and protected health information; and

(bb) proprietary interests, confidential commercial information, and intellectual property rights; and

(II) assigned a docket number by the Commissioner of Food and Drugs and made available for the submission of public comments.

(ii) Submission of comments

An interested person may submit written comments concerning such pediatric studies to the Commissioner of Food and Drugs, and the submitted comments shall become part of the docket file with respect to each of the drugs.

(C) Action by Commissioner

The Commissioner of Food and Drugs shall take action in a timely and appropriate manner in response to the reports submitted under subparagraph (A), and shall begin such action upon receipt of the report under subparagraph (A), in accordance with paragraph (7).

(7) Requests for labeling change

Within the 180-day period after the date on which a report is submitted under paragraph (6)(A), the Commissioner of Food and Drugs shall—

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

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

(C)(i) include in the public docket file a reference to the location of the report on the internet website of the National Institutes of Health and a copy of any requested labeling changes; and

(ii) publish 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.

(8) Dispute resolution

(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.

(B) Action by the Pediatric Advisory Committee

Not later than 90 days after receiving a referral under subparagraph (A), the Pediatric Advisory Committee shall—

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

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

(9) FDA determination

Not later than 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.

(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 [21 U.S.C. 301 et seq.].

(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 [21 U.S.C. 301 et seq.] 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.

(d) Authorization of appropriations

(1) In general

There are authorized to be appropriated to carry out this section, $25,000,000 for each of fiscal years 2018 through 2022.

(2) Availability

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

(July 1, 1944, ch. 373, title IV, §409I, as added Pub. L. 107–109, §3(3), Jan. 4, 2002, 115 Stat. 1408; amended Pub. L. 108–155, §3(b)(6), Dec. 3, 2003, 117 Stat. 1942; Pub. L. 109–482, title I, §103(b)(14), Jan. 15, 2007, 120 Stat. 3687; Pub. L. 110–85, title V, §502(b), Sept. 27, 2007, 121 Stat. 886; Pub. L. 111–148, title VII, §7002(g)(2)(A), Mar. 23, 2010, 124 Stat. 820; Pub. L. 112–144, title V, §§507(d), 509(d), July 9, 2012, 126 Stat. 1045, 1049; Pub. L. 113–5, title III, §307(b), Mar. 13, 2013, 127 Stat. 192; Pub. L. 115–52, title V, §501, Aug. 18, 2017, 131 Stat. 1036.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (c)(10), (11), is act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to chapter 9 (§301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

AMENDMENTS

2017—Subsec. (a)(2)(A)(ii). Pub. L. 115–52, §501(1), inserted ''and identification of biomarkers for such diseases, disorders, or conditions,'' after ''biologics,''.

Subsec. (c)(6)(B). Pub. L. 115–52, §501(2)(A)(i), amended subpar. (B) generally. Prior to amendment, text read as follows: ''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.''

Subsec. (c)(6)(C). Pub. L. 115–52, §501(2)(A)(ii), substituted ''action in a timely and appropriate manner in response to the reports submitted under subparagraph (A), and shall begin such action upon receipt of the report under subparagraph (A), in accordance with paragraph (7).'' for ''appropriate action in response to the reports submitted under subparagraph (A) in accordance with paragraph (7).''

Subsec. (c)(7). Pub. L. 115–52, §501(2)(B)(i), substituted ''Within'' for ''During'' in introductory provisions.

Subsec. (c)(7)(C)(i). Pub. L. 115–52, §501(2)(B)(ii), substituted ''include in the public docket file a reference to the location of the report on the internet website of the National Institutes of Health and a copy of'' for ''place in the public docket file a copy of the report and of''.

Subsec. (c)(7)(C)(ii). Pub. L. 115–52, §501(2)(B)(iii), struck out ''in the Federal Register and'' after ''publish''.

Subsec. (d). Pub. L. 115–52, §501(3), (4), redesignated subsec. (e) as (d) and struck out former subsec. (d). Prior to amendment, text of subsec. (d) read as follows: ''Not later than one year after September 27, 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.''

Subsec. (d)(1). Pub. L. 115–52, §501(5), substituted ''2018 through 2022'' for ''2013 through 2017''.

Subsec. (e). Pub. L. 115–52, §501(4), redesignated subsec. (e) as (d).

2013—Subsec. (a)(2). Pub. L. 113–5, §307(b)(1), added par. (2) and struck out former par. (2). Prior to amendment, text read as follows: ''In developing and prioritizing the list under paragraph (1), the Secretary shall consider—

''(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;

''(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

''(C) the adequacy of necessary infrastructure to conduct pediatric pharmacological research, including research networks and trained pediatric investigators.''

Subsec. (b). Pub. L. 113–5, §307(b)(2), substituted ''paragraphs (1) and (2)(A) of subsection (a)'' for ''subsection (a)''.

2012—Subsec. (c)(1). Pub. L. 112–144, §509(d)(1)(A), inserted ''or section 262(m) of this title,'' after ''Cosmetic Act,''.

Subsec. (c)(1)(A)(i). Pub. L. 112–144, §509(d)(1)(B), inserted ''or section 262(k) of this title'' after ''Cosmetic Act''.

Subsec. (c)(1)(B). Pub. L. 112–144, §509(d)(1)(C), amended subpar. (B) generally. Prior to amendment, subpar. (B) read as follows: ''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''.

Subsec. (c)(2). Pub. L. 112–144, §509(d)(2), struck out ''for drugs lacking exclusivity'' after ''applications'' in heading, and in text struck out ''under section 505 of the Federal Food, Drug, and Cosmetic Act'' after ''for the drug'' and substituted ''505A of the Federal Food, Drug, and Cosmetic Act or section 262(m) of this title'' for ''505A of such Act''.

Subsec. (e)(1). Pub. L. 112–144, §507(d), substituted ''to carry out this section, $25,000,000 for each of fiscal years 2013 through 2017.'' for ''to carry out this section—

''(A) $200,000,000 for fiscal year 2008; and

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

2010—Subsec. (a)(1). Pub. L. 111–148 inserted '', biological products,'' after ''including drugs''.

2007—Pub. L. 110–85 amended section generally. Prior to amendment, section related to development of list of drugs for which pediatric studies are needed, award of

contracts for pediatric studies, process for requesting contract proposals to conduct certain pediatric studies, reporting of completed studies, requests for labeling changes and dispute resolution, and recommendation by the Secretary for formulation changes.

Subsec. (d). Pub. L. 109–482 struck out subsec. (d) which related to authorization and availability of appropriations.

2003—Subsec. (c)(8), (9), (11). Pub. L. 108–155 struck out ''Advisory Subcommittee of the Anti-Infective Drugs'' before ''Advisory Committee'' wherever appearing.

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

EFFECTIVE DATE OF 2003 AMENDMENT

Amendment by Pub. L. 108–155 effective Dec. 3, 2003, except as otherwise provided, see section 4 of Pub. L. 108–155, set out as an Effective Date note under section 355c of Title 21, Food and Drugs.

§ 284m–1. Pediatric Advisory Committee

(a) In general

The Secretary of Health and Human Services shall, under section 217a of this title or other appropriate authority, convene and consult an advisory committee on pediatric therapeutics (including drugs and biological products) and medical devices (referred to in this section as the ''advisory committee'').

(b) Purpose

(1) In general

The advisory committee shall advise and make recommendations to the Secretary, through the Commissioner of Food and Drugs, on matters relating to pediatric therapeutics (including drugs and biological products) and medical devices.

(2) Matters included

The matters referred to in paragraph (1) include—

(A) pediatric research conducted under sections 262, 284m, and 290b of this title and sections 351, 352, 355, 355a, 355c, 360(k), 360e, and 360j(m) of title 21;

(B) identification of research priorities related to therapeutics (including drugs and biological products) and medical devices for pediatric populations and the need for additional diagnostics and treatments for specific pediatric diseases or conditions;

(C) the ethics, design, and analysis of clinical trials related to pediatric therapeutics (including drugs and biological products) and medical devices; and

(D) the development of countermeasures (as defined in section 360bbb–4(a) of title 21) for pediatric populations.

(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.

(d) Continuation of Operation of Committee

Notwithstanding section 14 of the Federal Advisory Committee Act, the advisory committee shall continue to operate to carry out the advisory committee's responsibilities under sections 355a, 355c, and 360j(m) of title 21.

(Pub. L. 107–109, § 14, Jan. 4, 2002, 115 Stat. 1419, as amended by Pub. L. 108–155, § 3(b)(2), Dec. 3, 2003, 117 Stat. 1941; Pub. L. 110–85, title III, § 306(b), title V, § 502(d), Sept. 27, 2007, 121 Stat. 865, 889; Pub. L. 112–144, title V, § 507(a), July 9, 2012, 126 Stat. 1045; Pub. L. 113–5, title III, § 307(c), Mar. 13, 2013, 127 Stat. 192.)

REFERENCES IN TEXT

Section 14 of the Federal Advisory Committee Act, referred to in subsec. (d), is section 14 of Pub. L. 92–463, which is set out in the Appendix to Title 5, Government Organization and Employees.

CODIFICATION

Section was formerly set out as a note under section 284m of this title.

Section was enacted as part of the Best Pharmaceuticals for Children Act, and not as part of the Public Health Service Act which comprises this chapter.

AMENDMENTS

2013—Subsec. (b)(2)(D). Pub. L. 113–5 added subpar. (D).

2012—Subsec. (d). Pub. L. 112–144 substituted ''to carry out the advisory committee's responsibilities under sections 355a, 355c, and 360j(m) of title 21'' for ''during the five-year period beginning on September 27, 2007''.

2007—Subsec. (a). Pub. L. 110–85, § 306(b)(1), inserted ''(including drugs and biological products) and medical devices'' after ''therapeutics''.

Subsec. (b)(1). Pub. L. 110–85, § 306(b)(2)(A), inserted ''(including drugs and biological products) and medical devices'' after ''therapeutics''.

Subsec. (b)(2)(A). Pub. L. 110–85, § 306(b)(2)(B)(i), substituted ''355c, 360(k), 360e, and 360j(m)'' for ''and 355c''.

Subsec. (b)(2)(B). Pub. L. 110–85, § 306(b)(2)(B)(ii), added subpar. (B) and struck out former subpar. (B) which read as follows: ''identification of research priorities related to pediatric therapeutics and the need for additional treatments of specific pediatric diseases or conditions; and''.

Subsec. (b)(2)(C). Pub. L. 110–85, § 306(b)(2)(B)(iii), inserted ''(including drugs and biological products) and medical devices'' after ''therapeutics''.

Subsec. (d). Pub. L. 110–85, § 502(d), added subsec. (d).

2003—Pub. L. 108–155, § 3(b)(2)(A), struck out ''Pharmacology'' after ''Pediatric'' in section catchline.

Subsec. (a). Pub. L. 108–155, § 3(b)(2)(D), substituted ''therapeutics'' for ''pharmacology''.

Pub. L. 108–155, § 3(b)(2)(B), inserted ''or other appropriate authority'' after ''217a of this title''.

Subsec. (b)(1). Pub. L. 108–155, § 3(b)(2)(D), substituted ''therapeutics'' for ''pharmacology''.

Pub. L. 108–155, § 3(b)(2)(C)(i), struck out ''and in consultation with the Director of the National Institutes of Health'' after ''Commissioner of Food and Drugs''.

Subsec. (b)(2). Pub. L. 108–155, § 3(b)(2)(C)(ii), substituted ''355a, and 355c'' for ''and 355a''.

Subsec. (b)(2)(B), (C). Pub. L. 108–155, § 3(b)(2)(D), substituted ''therapeutics'' for ''pharmacology''.

EFFECTIVE DATE OF 2003 AMENDMENT

Amendment by Pub. L. 108–155 effective Dec. 3, 2003, except as otherwise provided, see section 4 of Pub. L. 108–155, set out as an Effective Date note under section 355c of Title 21, Food and Drugs.

§ 284n. Certain demonstration projects

(a) Bridging the sciences

(1) In general

From amounts to be appropriated under section 282a(b) of this title, the Secretary of