ment 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) Dissemination of pediatric information

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.

(e) 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 2013 through 2017.

(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.)

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

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 Health and Human Services, acting through the Director of NIH, (in this subsection referred to as the ''Secretary'') in consultation with the Director of the National Science Foundation, the Secretary of Energy, and other agency heads when necessary, may allocate funds for the national research institutes and national centers to make grants for the purpose of improving the public health through demonstration projects for biomedical research at the interface between the biological, behavioral, and social sciences and the physical, chemical, mathematical, and computational sciences.

(2) Goals, priorities, and methods; interagency collaboration

The Secretary shall establish goals, priorities, and methods of evaluation for research under paragraph (1), and shall provide for interagency collaboration with respect to such research. In developing such goals, priorities, and methods, the Secretary shall ensure that—

(A) the research reflects the vision of innovation and higher risk with long-term payoffs; and

(B) the research includes a wide spectrum of projects, funded at various levels, with varying timeframes.

(3) Peer review

A grant may be made under paragraph (1) only if the application for the grant has undergone technical and scientific peer review under section 289a of this title and has been reviewed by the advisory council under section 282(k) of this title or has been reviewed by an advisory council composed of representatives from appropriate scientific disciplines who can fully evaluate the applicant.

(b) High-risk, high-reward research

(1) In general

From amounts to be appropriated under section 282a(b) of this title, the Secretary, acting through the Director of NIH, may allocate funds for the national research institutes and national centers to make awards of grants or