early phases of their independent careers by providing salary and such other support for a period of supervised study.

(2) Applications

An application for a grant under this subsection shall be submitted by an individual scientist at such time as the Director may require.

(b) Mid-Career Investigator Awards in Patient-Oriented Research

(1) Grants

(A) In general

The Director of the National Institutes of Health shall make grants (to be referred to as ''Mid-Career Investigator Awards in Patient-Oriented Research'') to support individual clinical research projects at general clinical research centers or at other institutions that have the infrastructure and resources deemed appropriate for conducting patient-oriented clinical research.

(B) Use

Grants under subparagraph (A) shall be used to provide support for mid-career level clinicians to allow such clinicians to devote time to clinical research and to act as mentors for beginning clinical investigators.

(2) Applications

An application for a grant under this subsection shall be submitted by an individual scientist at such time as the Director requires.

(c) Graduate Training in Clinical Investigation Award

(1) In general

The Director of the National Institutes of Health shall make grants (to be referred to as ''Graduate Training in Clinical Investigation Awards'') to support individuals pursuing master's or doctoral degrees in clinical investigation.

(2) Applications

An application for a grant under this subsection shall be submitted by an individual scientist at such time as the Director may require.

(3) Limitations

Grants under this subsection shall be for terms of 2 years or more and shall provide stipend, tuition, and institutional support for individual advanced degree programs in clinical investigation.

(4) Definition

As used in this subsection, the term ''advanced degree programs in clinical investigation'' means programs that award a master's or Ph.D. degree in clinical investigation after 2 or more years of training in areas such as the following:

(A) Analytical methods, biostatistics, and study design.

(B) Principles of clinical pharmacology and pharmacokinetics.

(C) Clinical epidemiology.

(D) Computer data management and medical informatics.

(E) Ethical and regulatory issues.

(F) Biomedical writing.

(d) Clinical Research Curriculum Awards

(1) In general

The Director of the National Institutes of Health shall make grants (to be referred to as ''Clinical Research Curriculum Awards'') to institutions for the development and support of programs of core curricula for training clinical investigators, including medical students. Such core curricula may include training in areas such as the following:

(A) Analytical methods, biostatistics, and study design.

(B) Principles of clinical pharmacology and pharmacokinetics.

(C) Clinical epidemiology.

(D) Computer data management and medical informatics.

(E) Ethical and regulatory issues.

(F) Biomedical writing.

(2) Applications

An application for a grant under this subsection shall be submitted by an individual institution or a consortium of institutions at such time as the Director may require. An institution may submit only one such application.

(3) Limitations

Grants under this subsection shall be for terms of up to 5 years and may be renewable.

(July 1, 1944, ch. 373, title IV, § 409H, formerly § 409D, as added Pub. L. 106–505, title II, § 204(b), Nov. 13, 2000, 114 Stat. 2327; renumbered § 409H, Pub. L. 107–109, § 3(2), Jan. 4, 2002, 115 Stat. 1408; Pub. L. 109–482, title I, § 103(b)(13), Jan. 15, 2007, 120 Stat. 3687.)

AMENDMENTS

2007—Subsec. (a)(3). Pub. L. 109–482, § 103(b)(13)(A), struck out heading and text of par. (3). 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. (b)(3). Pub. L. 109–482, § 103(b)(13)(B), struck out heading and text of par. (3). 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. (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 Direc-

tor 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 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.

(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.

(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], 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

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

(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 [21 U.S.C. 301 et seq.]; 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 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 [21 U.S.C. 355]. 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 [21 U.S.C. 355a], 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

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 shall be assigned a

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

(C) Action by Commissioner

The Commissioner of Food and Drugs shall take appropriate action in response to the reports submitted under subparagraph (A) in accordance with paragraph (7).

(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—

(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) place in the public docket file a copy of the report and of any requested labeling changes; and

(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.

(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) 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—

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

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

(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.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (c)(1)(B), (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

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.

PEDIATRIC ADVISORY COMMITTEE

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, provided that:

''(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) 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 351, 409I, and 499 of the Public Health Service Act [42 U.S.C. 262, 284m, and 290b] and sections 501, 502, 505, 505A, 505B, 510(k), 515, and 520(m) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 351, 352, 355, 355a, 355c, 360(k), 360e, and 360j(m)];

''(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; [and]

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

''(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 [5 U.S.C. App.], 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 [Sept. 27, 2007].''

§ 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 contracts or to engage in other transactions for demonstration projects for high-impact, cutting-edge research that fosters scientific creativity and increases fundamental biological understanding leading to the prevention, diagnosis, and treatment of diseases and disorders. The head of a national research institute or national center may conduct or support such high-impact, cutting-edge research (with funds allocated under the preceding sentence or otherwise available for such purpose) if the institute or center gives notice to the Director of NIH beforehand and submits a report to the Director of NIH on an annual basis on the activities of the institute or center relating to such research.

(2) Special consideration

In carrying out the program under paragraph (1), the Director of NIH shall give special consideration to coordinating activities with national research institutes whose budgets are substantial relative to a majority of the other institutes.

(3) Administration of program

Activities relating to research described in paragraph (1) shall be designed by the Director of NIH or the head of a national research institute or national center, as applicable, to enable such research to be carried out with maximum flexibility and speed.

(4) Public-private partnerships

In providing for research described in paragraph (1), the Director of NIH or the head of a national research institute or national center, as applicable, shall seek to facilitate partner-