''(12) Since the late 1960s, spending for general clinical research centers has declined from approximately 3 percent to 1 percent of the National Institutes of Health budget.

''(13) In fiscal year 1999, there were 77 general clinical research centers in operation, supplying patients in the areas in which such centers operate with access to the most modern clinical research and clinical research facilities and technologies.

''(b) PURPOSE.—It is the purpose of this title [see Short Title of 2000 Amendments note set out under section 201 of this title] to provide additional support for and to expand clinical research programs.''

OVERSIGHT BY GAO

Pub. L. 106–505, title II, §207, Nov. 13, 2000, 114 Stat. 2330, provided that, not later than 18 months after Nov. 13, 2000, the Comptroller General was to submit to Congress a report describing the extent to which the National Institutes of Health had complied with the amendments made by title II of Pub. L. 106–505.

§284*l*. Enhancement awards

(a) Mentored Patient-Oriented Research Career Development Awards

(1) Grants

(A) In general

The Director of the National Institutes of Health shall make grants (to be referred to as ''Mentored Patient-Oriented Research Career Development Awards'') to support individual careers in clinical research 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 support clinical investigators in the 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 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, 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