recommended expanded support for existing National Institutes of Health clinical research programs and the creation of new initiatives to recruit and retain clinical investigators.

''(7) The current level of training and support for health professionals in clinical research is fragmented, undervalued, and underfunded.

''(8) Young investigators are not only apprentices for future positions but a crucial source of energy, enthusiasm, and ideas in the day-to-day research that constitutes the scientific enterprise. Serious questions about the future of life-science research are raised by the following:

''(A) The number of young investigators applying for grants dropped by 54 percent between 1985 and 1993.

''(B) The number of physicians applying for first-time National Institutes of Health research project grants fell from 1226 in 1994 to 963 in 1998, a 21 percent reduction.

''(C) Newly independent life-scientists are expected to raise funds to support their new research programs and a substantial proportion of their own salaries.

''(9) The following have been cited as reasons for the decline in the number of active clinical researchers, and those choosing this career path:

''(A) A medical school graduate incurs an average debt of $85,619, as reported in the Medical School Graduation Questionnaire by the Association of American Medical Colleges (AAMC).

''(B) The prolonged period of clinical training required increases the accumulated debt burden.

''(C) The decreasing number of mentors and role models.

''(D) The perceived instability of funding from the National Institutes of Health and other Federal agencies.

''(E) The almost complete absence of clinical research training in the curriculum of training grant awardees.

''(F) Academic Medical Centers are experiencing difficulties in maintaining a proper environment for research in a highly competitive health care marketplace, which are compounded by the decreased willingness of third party payers to cover health care costs for patients engaged in research studies and research procedures.

''(10) In 1960, general clinical research centers were established under the Office of the Director of the National Institutes of Health with an initial appropriation of $3,000,000.

''(11) Appropriations for general clinical research centers in fiscal year 1999 equaled $200,500,000.

''(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 sti-

pend, 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; amended Pub. L. 109–482, title I, §103(b)(13), Jan. 15, 2007, 120 Stat. 3687.)

Editorial Notes

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.''

Statutory Notes and Related Subsidiaries

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,