PREEMPTION

Pub. L. 110–85, title VIII, §801(d), Sept. 27, 2007, 121 Stat. 922, provided that:

''(1) IN GENERAL.—Upon the expansion of the registry and results data bank under section 402(j)(3)(D) of the Public Health Service Act [42 U.S.C. 282(j)(3)(D)], as added by this section, no State or political subdivision of a State may establish or continue in effect any requirement for the registration of clinical trials or for the inclusion of information relating to the results of clinical trials in a database.

''(2) RULE OF CONSTRUCTION.—The fact of submission of clinical trial information, if submitted in compliance with subsection (j) of section 402 of the Public Health Service Act (as amended by this section), that relates to a use of a drug or device not included in the official labeling of the approved drug or device shall not be construed by the Secretary of Health and Human Services or in any administrative or judicial proceeding, as evidence of a new intended use of the drug or device that is different from the intended use of the drug or device set forth in the official labeling of the drug or device. The availability of clinical trial information through the registry and results data bank under such subsection (j), if submitted in compliance with such subsection, shall not be considered as labeling, adulteration, or misbranding of the drug or device under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).''

COLLABORATION AND REPORT

Pub. L. 105–115, title I, §113(b), Nov. 21, 1997, 111 Stat. 2312, directed the Secretary of Health and Human Services, the Director of the National Institutes of Health, and the Commissioner of Food and Drugs to collaborate to determine the feasibility of including device investigations within the scope of the data bank under subsec. (j) of this section, with the Secretary to report to Congress, not later than two years after Nov. 21, 1997, on the public health need, if any, for inclusion of device investigations within the scope of the data bank under subsec. (j), and on the adverse impact, if any, on device innovation and research in the United States if information relating to such device investigations was required to be publicly disclosed.

CHRONIC FATIGUE SYNDROME; EXPERTS AND RESEARCH REPRESENTATIVES ON ADVISORY COMMITTEES AND BOARDS

Pub. L. 103–43, title IX, §902(c), June 10, 1993, 107 Stat. 164, provided that: ''The Secretary of Health and Human Services, acting through the Director of the National Institutes of Health, shall ensure that appropriate individuals with expertise in chronic fatigue syndrome or neuromuscular diseases and representative of a variety of disciplines and fields within the research community are appointed to appropriate National Institutes of Health advisory committees and boards.''

THIRD-PARTY PAYMENTS REGARDING CERTAIN CLINICAL TRIALS AND CERTAIN LIFE-THREATENING ILLNESSES

Pub. L. 103–43, title XIX, §1901(a), June 10, 1993, 107 Stat. 200, provided that: ''The Secretary of Health and Human Services, acting through the Director of the National Institutes of Health, shall conduct a study for the purpose of—

''(1) determining the policies of third-party payors regarding the payment of the costs of appropriate health services that are provided incident to the participation of individuals as subjects in clinical trials conducted in the development of drugs with respect to acquired immune deficiency syndrome, cancer, and other life-threatening illnesses; and

''(2) developing recommendations regarding such policies.''

PERSONNEL STUDY OF RECRUITMENT, RETENTION AND TURNOVER

Pub. L. 103–43, title XIX, §1905, June 10, 1993, 107 Stat. 203, directed Secretary of Health and Human Services, acting through Director of National Institutes of Health, to conduct a study to review the retention, recruitment, vacancy and turnover rates of support staff, including firefighters, law enforcement, procurement officers, technicians, nurses and clerical employees, to ensure that National Institutes of Health is adequately supporting conduct of efficient, effective and high quality research for the American public, and to submit a report to Congress on results of such study not later than 1 year after June 10, 1993.

CHRONIC PAIN CONDITIONS

Pub. L. 103–43, title XIX, §1907, June 10, 1993, 107 Stat. 204, directed Director of the National Institutes of Health to submit to Congress, not later than 2 years after June 10, 1993, a report and study on the incidence in the United States of cases of chronic pain, including chronic pain resulting from back injuries, reflex sympathetic dystrophy syndrome, temporomandibular joint disorder, post-herpetic neuropathy, painful diabetic neuropathy, phantom pain, and post-stroke pain, and the effect of such cases on the costs of health care in the United States.

SUPPORT FOR BIOENGINEERING RESEARCH

Pub. L. 103–43, title XIX, §1912, June 10, 1993, 107 Stat. 206, directed Secretary of Health and Human Services, acting through Director of the National Institutes of Health, to conduct a study for the purpose of determining the sources and amounts of public and private funding devoted to basic research in bioengineering, including biomaterials sciences, cellular bioprocessing, tissue and rehabilitation engineering, evaluating whether that commitment is sufficient to maintain the innovative edge that the United States has in these technologies, evaluating the role of the National Institutes of Health or any other Federal agency to achieve a greater commitment to innovation in bioengineering, and evaluating the need for better coordination and collaboration among Federal agencies and between the public and private sectors, and, not later than 1 year after June 10, 1993, to prepare and submit to Committee on Labor and Human Resources of Senate, and Committee on Energy and Commerce of House of Representatives, a report containing the findings of the study together with recommendations concerning the enactment of legislation to implement the results of such study.

MASTER PLAN FOR PHYSICAL INFRASTRUCTURE FOR RESEARCH

Pub. L. 103–43, title XX, §2002, June 10, 1993, 107 Stat. 208, directed Secretary of Health and Human Services, acting through Director of the National Institutes of Health, not later than June 1, 1994, to present to Congress a master plan to provide for replacement or refurbishment of less than adequate buildings, utility equipment and distribution systems (including the resources that provide electrical and other utilities, chilled water, air handling, and other services that the Secretary, acting through the Director, deemed necessary), roads, walkways, parking areas, and grounds that underpin the laboratory and clinical facilities of the National Institutes of Health, and provided that the plan could make recommendations for the undertaking of new projects that are consistent with the objectives of this section, such as encircling the National Institutes of Health Federal enclave with an adequate chilled water conduit.

§ 282a. Authorization of appropriations

(a) In general

(1) This subchapter

For purposes of carrying out this subchapter, there are authorized to be appropriated—

(A) $30,331,309,000 for fiscal year 2007;

(B) $32,831,309,000 for fiscal year 2008;
(C) such sums as may be necessary for fiscal year 2009;
(D) $34,851,000,000 for fiscal year 2018;
(E) $35,585,871,000 for fiscal year 2019; and
(F) $36,472,442,775 for fiscal year 2020.

(2) Funding for 10-year pediatric research initiative through Common Fund

For the purpose of carrying out section 282(b)(7)(B)(ii) of this title, there is authorized to be appropriated to the Common Fund, out of the 10-Year Pediatric Research Initiative Fund described in section 9008 of title 26, and in addition to amounts otherwise made available under paragraph (1) of this subsection and reserved under subsection (c)(1)(B)(i) of this section, $12,600,000 for each of fiscal years 2014 through 2023.

(b) Office of the Director

Of the amount authorized to be appropriated under subsection (a) for a fiscal year, there are authorized to be appropriated for programs and activities under this subchapter carried out through the Office of the Director of NIH such sums as may be necessary for each of the fiscal years 2007 through 2009.

(c) Trans-NIH research

(1) Common Fund

(A) Account

For the purpose of allocations under section 282(b)(7)(B) of this title (relating to research identified by the Division of Program Coordination, Planning, and Strategic Initiatives), there is established an account to be known as the Common Fund.

(B) Reservation

(i) In general

Of the total amount appropriated under subsection (a)(1) for fiscal year 2007 or any subsequent fiscal year, the Director of NIH shall reserve an amount for the Common Fund, subject to any applicable provisions in appropriations Acts.

(ii) Minimum amount

For each fiscal year, the percentage constituted by the amount reserved under clause (i) relative to the total amount appropriated under subsection (a)(1) for such year may not be less than the percentage constituted by the amount so reserved for the preceding fiscal year relative to the total amount appropriated under subsection (a)(1) for such preceding fiscal year, subject to any applicable provisions in appropriations Acts.

(C) Common Fund strategic planning report

As part of the National Institutes of Health Strategic Plan required under section 282(m) of this title, the Secretary, acting through the Director of NIH, shall submit a report to the Congress containing a strategic plan for funding research described in section 282(b)(7)(A)(i) of this title (including personnel needs) through the Common Fund. Each such plan shall include the following:

(i) An estimate of the amounts determined by the Director of NIH to be appropriate for maximizing the potential of such research.
(ii) An estimate of the amounts determined by the Director of NIH to be sufficient only for continuing to fund research activities previously identified by the Division of Program Coordination, Planning, and Strategic Initiatives.
(iii) An estimate of the amounts determined by the Director of NIH to be necessary to fund research described in section 282(b)(7)(A)(i) of this title—
(I) that is in addition to the research activities described in clause (ii); and
(II) for which there is the most substantial need.

(D) Evaluation

During the 6-month period following the end of the first fiscal year for which the total amount reserved under subparagraph (B) is equal to 5 percent of the total amount appropriated under subsection (a)(1) for such fiscal year, the Secretary, acting through the Director of NIH, in consultation with the advisory council established under section 282(k) of this title, shall submit recommendations to the Congress for changes regarding amounts for the Common Fund.

(2) Trans-NIH research reporting

(A) Limitation

With respect to the total amount appropriated under subsection (a) for fiscal year 2008 or any subsequent fiscal year, if the head of a national research institute or national center fails to submit the report required by subparagraph (B) for the preceding fiscal year, the amount made available for the institute or center for the fiscal year involved may not exceed the amount made available for the institute or center for fiscal year 2006.

(B) Reporting

Not later than 2 years after December 13, 2016, the head of each national research institute or national center shall submit to the Director of the National Institutes of Health a report, to be included in the triennial report under section 283 of this title, on the amount made available by the institute or center for conducting or supporting research that involves collaboration between the institute or center and 1 or more other national research institutes or national centers.

(C) Determination

For purposes of determining the amount or percentage of funds to be reported under subparagraph (B), any amounts made available to an institute or center under section 282(b)(7)(B) of this title shall be included.

(D) Verification of amounts

Upon receipt of each report submitted under subparagraph (B), the Director of NIH shall review and, in cases of discrepancy, verify the accuracy of the amounts specified in the report.

(E) Waiver

At the request of any national research institute or national center, the Director of NIH may waive the application of this paragraph to such institute or center if the Director finds that the conduct or support of research described in subparagraph (B) is inconsistent with the mission of such institute or center.

(d) Transfer authority

Of the total amount appropriated under subsection (a)(1) for a fiscal year, the Director of NIH may (in addition to the reservation under subsection (c)(1) for such year) transfer not more than 1 percent for programs or activities that are authorized in this subchapter and identified by the Director to receive funds pursuant to this subsection. In making such transfers, the Director may not decrease any appropriation account under subsection (a)(1) by more than 1 percent.

(e) Rule of construction

This section may not be construed as affecting the authorities of the Director of NIH under section 281 of this title.

(July 1, 1944, ch. 373, title IV, § 402A, as added Pub. L. 109–482, title I, § 103(a), Jan. 15, 2007, 120 Stat. 3685; amended Pub. L. 113–94, § 3(b), Apr. 3, 2014, 128 Stat. 1087; Pub. L. 114–255, div. A, title II, §§ 2001, 2031(b), 2042(a), Dec. 13, 2016, 130 Stat. 1047, 1056, 1073.)

AMENDMENTS

2016—Subsec. (a)(1)(D) to (F). Pub. L. 114–255, § 2001, added subpars. (D) to (F).

Subsec. (c)(1)(C). Pub. L. 114–255, § 2031(b), substituted ''As part of the National Institutes of Health Strategic Plan required under section 282(m) of this title,'' for ''Not later than June 1, 2007, and every 2 years thereafter,''.

Subsec. (c)(2)(B). Pub. L. 114–255, § 2042(a)(1), amended subpar. (B) generally. Prior to amendment, text read as follows: ''Not later than January 1, 2008, and each January 1st thereafter—

''(i) the head of each national research institute or national center shall submit to the Director of NIH a report on the amount made available by the institute or center for conducting or supporting research that involves collaboration between the institute or center and 1 or more other national research institutes or national centers; and

''(ii) the Secretary shall submit a report to the Congress identifying the percentage of funds made available by each national research institute and national center with respect to such fiscal year for conducting or supporting research described in clause (i).''

Subsec. (c)(2)(D), (E). Pub. L. 114–255, § 2042(a)(2), substituted ''(B)'' for ''(B)(i)''.

2014—Subsec. (a). Pub. L. 113–94, § 3(b)(1)(B), which directed amendment of subsec. (a) by striking ''For purposes of carrying out this subchapter'' and inserting par. (1) designation, heading, and ''For purposes of carrying out this subchapter'', was executed by striking ''For the purpose of carrying out this subchapter'' and making the insertions as directed, to reflect the probable intent of Congress.

Pub. L. 113–94, § 3(b)(1)(A), redesignated pars. (1) to (3) as subpars. (A) to (C), respectively, and realigned margins.

Subsec. (a)(2). Pub. L. 113–94, § 3(b)(1)(C), added par. (2). Former par. (2) redesignated subpar. (B) of par. (1).

Subsecs. (c)(1)(B), (D), (d). Pub. L. 113–94, § 3(b)(2), substituted ''subsection (a)(1)'' for ''subsection (a)'' wherever appearing.

EFFECTIVE DATE

Section 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 an Effective Date of 2007 Amendment note under section 281 of this title.

SUPPLEMENT, NOT SUPPLANT; PROHIBITION AGAINST TRANSFER

Pub. L. 113–94, § 3(c), Apr. 3, 2014, 128 Stat. 1087, provided that: ''Funds appropriated pursuant to section 402A(a)(2) of the Public Health Service Act [42 U.S.C. 282a(a)(2)], as added by subsection (b)—

''(1) shall be used to supplement, not supplant, the funds otherwise allocated by the National Institutes of Health for pediatric research; and

''(2) notwithstanding any transfer authority in any appropriation Act, shall not be used for any purpose other than allocating funds for making grants as described in section 402(b)(7)(B)(ii) of the Public Health Service Act [42 U.S.C. 282(b)(7)(B)(ii)], as added by subsection (a).''

§ 282b. Electronic coding of grants and activities

The Secretary, acting through the Director of NIH, shall establish an electronic system to uniformly code research grants and activities of the Office of the Director and of all the national research institutes and national centers. The electronic system shall be searchable by a variety of codes, such as the type of research grant, the research entity managing the grant, and the public health area of interest. When permissible, the Secretary, acting through the Director of NIH, shall provide information on relevant literature and patents that are associated with research activities of the National Institutes of Health.

(July 1, 1944, ch. 373, title IV, § 402B, as added Pub. L. 109–482, title I, § 104(a)(3), Jan. 15, 2007, 120 Stat. 3689.)

EFFECTIVE DATE

Section 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 an Effective Date of 2007 Amendment note under section 281 of this title.

§ 282c. Public access to funded investigators' final manuscripts

The Director of the National Institutes of Health (''NIH'') shall require in the current fiscal year and thereafter that all investigators funded by the NIH submit or have submitted for them to the National Library of Medicine's PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication: *Provided*, That the NIH shall implement the public access policy in a manner consistent with copyright law.

(Pub. L. 111–8, div. F, title II, § 217, Mar. 11, 2009, 123 Stat. 782.)

CODIFICATION

Section was enacted as part of the Department of Health and Human Services Appropriations Act, 2009, and also as part of the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2009, and the Omnibus Appro-