Population Assessment of Tobacco and Health (PATH) Study (NIDA)



1980—Subsec. (a). Pub. L. 96–180, §16(a), substituted: in first sentence "biomedical, behavioral, and social issues related to alcoholism and alcohol abuse" for "alcohol problems"; in par. (1)(B) "facilities (including laboratory, reference, and data analysis facilities) to carry out the research plan contained in the application" for "laboratory facilities and reference services (including reference services that will afford access to scientific alcohol literature)"; and in par. (1)(E) "medical and osteopathic, nursing, social work, and other specialized graduate students; and" for "medical and osteopathic students and physicians;", and added par. (1)(F).

Subsec. (b). Pub. L. 96-180, \$16(b), increased annual grant limitation to \$1,500,000 from \$1,000,000.

Subsec. (c). Pub. L. 96–180, §16(c), authorized appropriation of \$8,000,000 and \$9,000,000 for fiscal years ending Sept. 30, 1980, and 1981.

1978—Subsec. (a). Pub. L. 95–622 inserted provision following par. (2) relating to approval of applications under this subsection by the Secretary in a manner which results in equitable geographic distribution of Centers.

#### Effective Date of 1992 Amendments

Amendment by Pub. L. 102–352 effective immediately upon effectuation of amendment made by Pub. L. 102–321, see section 3(1) of Pub. L. 102–352, set out as a note under section 285n of this title.

Amendment by Pub. L. 102–321 effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102–321, set out as a note under section 236 of this title.

SUBPART 15—NATIONAL INSTITUTE ON DRUG ABUSE

#### § 2850. Purpose of Institute

#### (a) In general

The general purpose of the National Institute on Drug Abuse (hereafter in this subpart referred to as the "Institute") is the conduct and support of biomedical and behavioral research, health services research, research training, and health information dissemination with respect to the prevention of drug abuse and the treatment of drug abusers.

## (b) Research program

The research program established under this subpart shall encompass the social, behavioral, and biomedical etiology, mental and physical health consequences, and social and economic consequences of drug abuse. In carrying out the program, the Director of the Institute shall give special consideration to projects relating to drug abuse among women (particularly with respect to pregnant women).

# (c) Collaboration

The Director of the Institute shall collaborate with the Substance Abuse and Mental Health Services Administration in focusing the services research activities of the Institute and in disseminating the results of such research to health professionals and the general public.

(July 1, 1944, ch. 373, title IV, §464L, as added Pub. L. 102–321, title I, §123(a), July 10, 1992, 106 Stat. 360; amended Pub. L. 102–352, §2(a)(3), Aug. 26, 1992, 106 Stat. 938; Pub. L. 109–482, title I, §103(b)(33), Jan. 15, 2007, 120 Stat. 3688.)

### AMENDMENTS

2007—Subsec. (d). Pub. L. 109–482 struck out subsec. (d) which related to authorization of appropriations and allocation for health services research.

1992—Subsec. (d)(1). Pub. L. 102–352 inserted "other than section 2850–4 of this title," after "this subpart,".

#### 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 1992 AMENDMENT

Amendment by Pub. L. 102–352 effective immediately upon effectuation of amendment made by Pub. L. 102–321, see section 3(1) of Pub. L. 102–352, set out as a note under section 285n of this title.

#### EFFECTIVE DATE

Section effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102–321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

#### § 2850-1. Associate Director for Prevention

#### (a) In general

There shall be in the Institute an Associate Director for Prevention who shall be responsible for the full-time coordination and promotion of the programs in the Institute concerning the prevention of drug abuse. The Associate Director shall be appointed by the Director of the Institute from individuals who because of their professional training or expertise are experts in drug abuse and the prevention of such abuse.

### (b) Report

The Associate Director for Prevention shall prepare for inclusion in the biennial report made under section  $284b^{\, 1}$  of this title a description of the prevention activities of the Institute, including a description of the staff and resources allocated to those activities.

(July 1, 1944, ch. 373, title IV, §464M, as added Pub. L. 102–321, title I, §123(b), July 10, 1992, 106 Stat. 361.)

# References in Text

Section 284b of this title, referred to in subsec. (b), was repealed by Pub. L. 109-482, title I, \$104(b)(1)(C), Jan. 15, 2007, 120 Stat. 3693.

## EFFECTIVE DATE

Section effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102–321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

# § 2850-2. Drug Abuse Research Centers

# (a) Authority

The Director of the Institute may designate National Drug Abuse Research Centers for the purpose of interdisciplinary research relating to drug abuse and other biomedical, behavioral, and social issues related to drug abuse. No entity may be designated as a Center unless an application therefore has been submitted to, and approved by, the Secretary. Such an application shall be submitted in such manner and contain such information as the Secretary may reasonably require. The Secretary may not approve such an application unless—

(1) the application contains or is supported by reasonable assurances that—

<sup>&</sup>lt;sup>1</sup> See References in Text note below.

- (A) the applicant has the experience, or capability, to conduct, through biomedical, behavioral, social, and related disciplines, long-term research on drug abuse and to provide coordination of such research among such disciplines:
- (B) the applicant has available to it sufficient facilities (including laboratory, reference, and data analysis facilities) to carry out the research plan contained in the application:
- (C) the applicant has facilities and personnel to provide training in the prevention and treatment of drug abuse;
- (D) the applicant has the capacity to train predoctoral and postdoctoral students for careers in research on drug abuse;
- (E) the applicant has the capacity to conduct courses on drug abuse problems and research on drug abuse for undergraduate and graduate students, and medical and osteopathic, nursing, social work, and other specialized graduate students; and
- (F) the applicant has the capacity to conduct programs of continuing education in such medical, legal, and social service fields as the Secretary may require.<sup>1</sup>
- (2) the application contains a detailed fiveyear plan for research relating to drug abuse.

#### (b) Grants

The Director of the Institute shall, under such conditions as the Secretary may reasonably require, make annual grants to Centers which have been designated under this section. No funds provided under a grant under this subsection may be used for the purchase of any land or the purchase, construction, preservation, or repair of any building. For the purposes of the preceding sentence, the term "construction" has the meaning given that term by section 292a(1)<sup>2</sup> of this title.

# (c) Drug abuse and addiction research

# (1) Grants or cooperative agreements

The Director of the Institute may make grants or enter into cooperative agreements to expand the current and ongoing interdisciplinary research and clinical trials with treatment centers of the National Drug Abuse Treatment Clinical Trials Network relating to drug abuse and addiction, including related biomedical, behavioral, and social issues.

### (2) Use of funds

Amounts made available under a grant or cooperative agreement under paragraph (1) for drug abuse and addiction may be used for research and clinical trials relating to—

- (A) the effects of drug abuse on the human body, including the brain;
- (B) the addictive nature of drugs and how such effects differ with respect to different individuals;
- (C) the connection between drug abuse and mental health;
- (D) the identification and evaluation of the most effective methods of prevention of drug abuse and addiction;

- (E) the identification and development of the most effective methods of treatment of drug addiction, including pharmacological treatments;
  - (F) risk factors for drug abuse;
- (G) effects of drug abuse and addiction on pregnant women and their fetuses; and
- (H) cultural, social, behavioral, neurological, and psychological reasons that individuals abuse drugs, or refrain from abusing drugs.

#### (3) Research results

The Director shall promptly disseminate research results under this subsection to Federal, State, and local entities involved in combating drug abuse and addiction.

(July 1, 1944, ch. 373, title IV, §464N, as added Pub. L. 102–321, title I, §123(b), July 10, 1992, 106 Stat. 361; amended Pub. L. 102–352, §2(a)(4), Aug. 26, 1992, 106 Stat. 938; Pub. L. 106–310, div. B, title XXXVI, §3631, Oct. 17, 2000, 114 Stat. 1235; Pub. L. 107–273, div. B, title II, §2203, Nov. 2, 2002, 116 Stat. 1794; Pub. L. 109–482, title I, §103(b)(34), Jan. 15, 2007, 120 Stat. 3688.)

#### REFERENCES IN TEXT

Section 292a of this title, referred to in subsec. (b), was in the original a reference to section 701 of act July 1, 1944. Section 701 of that Act was omitted in the general revision of subchapter V of this chapter by Pub. L. 102–408, title I,  $\S$ 102, Oct. 13, 1992, 106 Stat. 1994. Pub. L. 102–408 enacted a new section 701 of act July 1, 1944, relating to statement of purpose, and a new section 702, relating to scope and duration of loan insurance program, which are classified to sections 292 and 292a, respectively, of this title. For provisions relating to definitions, see sections 292o and 295p of this title.

# AMENDMENTS

2007—Subsec. (c)(4). Pub. L. 109–482 struck out par. (4) which authorized appropriations and provided they were supplemental to other funding of research on drug abuse.

2002—Subsec. (c). Pub. L. 107–273 amended heading and text of subsec. (c) generally, substituting provisions relating to grants or cooperative agreements for research and clinical trials relating to drug abuse and addiction for similar provisions relating to grants or cooperative agreements for research and clinical trials relating to methamphetamine abuse and addiction.

2000—Subsec. (c). Pub. L. 106–310 added subsec. (c). 1992—Subsec. (b). Pub. L. 102–352 substituted "292a(1)" for "292a(2)".

## 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 1992 AMENDMENT

Amendment by Pub. L. 102–352 effective immediately upon effectuation of amendment made by Pub. L. 102–321, see section 3(1) of Pub. L. 102–352, set out as a note under section 285n of this title.

# EFFECTIVE DATE

Section effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102–321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

# § 2850-3. Office on AIDS

The Director of the Institute shall establish within the Institute an Office on AIDS. The Of-

<sup>&</sup>lt;sup>1</sup>So in original. The period probably should be ": and".

<sup>&</sup>lt;sup>2</sup> See References in Text note below.

fice shall be responsible for the coordination of research and determining the direction of the Institute with respect to AIDS research related to—

- (1) primary prevention of the spread of HIV, including transmission via drug abuse;
  - (2) drug abuse services research; and
- (3) other matters determined appropriate by the Director.

(July 1, 1944, ch. 373, title IV, §464O, as added Pub. L. 102–321, title I, §123(b), July 10, 1992, 106 Stat. 362.)

#### EFFECTIVE DATE

Section effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102–321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

#### STUDY BY NATIONAL ACADEMY OF SCIENCES

Section 706 of Pub. L. 102–321 directed Secretary of Health and Human Services to contract for a study or studies relating to programs that provide both sterile hypodermic needles and bleach to individuals in order to reduce the risk of contracting acquired immune deficiency syndrome or related conditions, in order to determine extent to which such programs promote the abuse of drugs or otherwise altered any behaviors constituting a substantial risk of contracting AIDS or hepatitus, or of transmitting such conditions, and further directed Secretary to ensure that a report is submitted to Congress on the results of this study not later than 18 months after July 10, 1992.

#### § 2850-4. Medication Development Program

#### (a) Establishment

There is established in the Institute a Medication Development Program through which the Director of such Institute shall—

- (1) conduct periodic meetings with the Commissioner of Food and Drugs to discuss measures that may facilitate the approval process of drug abuse treatments:
- (2) encourage and promote (through grants, contracts, international collaboration, or otherwise) expanded research programs, investigations, experiments, community trials, and studies, into the development and use of medications to treat drug addiction;
- (3) establish or provide for the establishment of research facilities;
- (4) report on the activities of other relevant agencies relating to the development and use of pharmacotherapeutic treatments for drug addiction:
- (5) collect, analyze, and disseminate data useful in the development and use of pharmacotherapeutic treatments for drug addiction and collect, catalog, analyze, and disseminate through international channels, the results of such research;
- (6) directly or through grants, contracts, or cooperative agreements, support training in the fundamental sciences and clinical disciplines related to the pharmacotherapeutic treatment of drug abuse, including the use of training stipends, fellowships, and awards where appropriate; and
- (7) coordinate the activities conducted under this section with related activities conducted within the National Institute on Alcohol Abuse and Alcoholism, the National Institute

of Mental Health, and other appropriate institutes and shall consult with the Directors of such Institutes.

#### (b) Duties

In carrying out the activities described in subsection (a) of this section, the Director of the Institute—

- (1) shall collect and disseminate through publications and other appropriate means, information pertaining to the research and other activities under this section;
- (2) shall make grants to or enter into contracts and cooperative agreements with individuals and public and private entities to further the goals of the program;
- (3) may, in accordance with section 289e of this title, and in consultation with the National Advisory Council on Drug Abuse, acquire, construct, improve, repair, operate, and maintain pharmacotherapeutic research centers, laboratories, and other necessary facilities and equipment, and such other real or personal property as the Director determines necessary, and may, in consultation with such Advisory Council, make grants for the construction or renovation of facilities to carry out the purposes of this section;
- (4) may accept voluntary and uncompensated services:
- (5) may accept gifts, or donations of services, money, or property, real, personal, or mixed, tangible or intangible; and
- (6) shall take necessary action to ensure that all channels for the dissemination and exchange of scientific knowledge and information are maintained between the Institute and the other scientific, medical, and biomedical disciplines and organizations nationally and internationally.

### (c) Report

# (1) In general

Not later than December 31, 1992, and each December 31 thereafter, the Director of the Institute shall submit to the Office of National Drug Control Policy established under section 1501¹ of title 21 a report, in accordance with paragraph (3), that describes the objectives and activities of the program assisted under this section.

# (2) National Drug Control Strategy

The Director of National Drug Control Policy shall incorporate, by reference or otherwise, each report submitted under this subsection in the National Drug Control Strategy submitted the following February 1 under section 1504 of title 21.

# (d) "Pharmacotherapeutics" defined

For purposes of this section, the term "pharmacotherapeutics" means medications used to treat the symptoms and disease of drug abuse, including medications to—

- (1) block the effects of abused drugs;
- (2) reduce the craving for abused drugs;
- (3) moderate or eliminate withdrawal symptoms;
- (4) block or reverse the toxic effect of abused drugs; or

<sup>&</sup>lt;sup>1</sup> See References in Text note below.

(5) prevent relapse in persons who have been detoxified from drugs of abuse.

(July 1, 1944, ch. 373, title IV, §464P, as added Pub. L. 102–321, title I, §123(b), July 10, 1992, 106 Stat. 362; amended Pub. L. 103–43, title XX, §2008(b)(10), June 10, 1993, 107 Stat. 211; Pub. L. 109–482, title I, §103(b)(35), Jan. 15, 2007, 120 Stat. 3688.)

#### REFERENCES IN TEXT

Sections 1501 and 1504 of title 21, referred to in subsec. (c), were repealed by Pub. L. 100-690, title I, \$1009, Nov. 18, 1988, 102 Stat. 4188, as amended.

#### AMENDMENTS

2007—Subsec. (e). Pub. L. 109–482 struck out heading and text of subsec. (e). Text read as follows: "For the purpose of carrying out this section, there are authorized to be appropriated \$85,000,000 for fiscal year 1993, and \$95,000,000 for fiscal year 1994."

1993—Subsec. (b)(6). Pub. L. 103–43 substituted "Institute" for "Administration".

#### 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

Section effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102–321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

### REPORT BY INSTITUTE ON MEDICINE

Section 701 of Pub. L. 102-321 directed Secretary of Health and Human Services to enter into a contract with a public or nonprofit private entity to conduct a study concerning (1) role of the private sector in development of anti-addiction medications, including legislative proposals designed to encourage private sector development of such medications, (2) process by which anti-addiction medications receive marketing approval from Food and Drug Administration, including an assessment of feasibility of expediting marketing approval process in a manner consistent with maintaining safety and effectiveness of such medications, (3) with respect to pharmacotherapeutic treatments for drug addiction (A) recommendations with respect to a national strategy for developing such treatments and improvements in such strategy, (B) state of the scientific knowledge concerning such treatments, and (C) assessment of progress toward development of safe, effective pharmacological treatments for drug addiction, and (4) other related information determined appropriate by the authors of the study, and to submit to Congress a report of the results of such study not later than 18 months after July 10, 1992.

# SUBPART 16—NATIONAL INSTITUTE OF MENTAL HEALTH

## §285p. Purpose of Institute

### (a) In general

The general purpose of the National Institute of Mental Health (hereafter in this subpart referred to as the "Institute") is the conduct and support of biomedical and behavioral research, health services research, research training, and health information dissemination with respect to the cause, diagnosis, treatment, control and prevention of mental illness.

# (b) Research program

The research program established under this subpart shall include support for biomedical and

behavioral neuroscience and shall be designed to further the treatment and prevention of mental illness, the promotion of mental health, and the study of the psychological, social and legal factors that influence behavior.

#### (c) Collaboration

The Director of the Institute shall collaborate with the Administrator of the Substance Abuse and Mental Health Services Administration in focusing the services research activities of the Institute and in disseminating the results of such research to health professionals and the general public.

## (d) Information with respect to suicide

#### (1) In general

The Director of the Institute shall—

- (A) develop and publish information with respect to the causes of suicide and the means of preventing suicide; and
- (B) make such information generally available to the public and to health professionals.

#### (2) Youth suicide

Information described in paragraph (1) shall especially relate to suicide among individuals under 24 years of age.

# (e) Associate Director for Special Populations (1) In general

The Director of the Institute shall designate an Associate Director for Special Populations.

#### (2) Duties

The Associate Director for Special Populations shall—

- (A) develop and coordinate research policies and programs to assure increased emphasis on the mental health needs of women and minority populations;
- (B) support programs of basic and applied social and behavioral research on the mental health problems of women and minority populations:
- (C) study the effects of discrimination on institutions and individuals, including majority institutions and individuals:
- (D) support and develop research designed to eliminate institutional discrimination; and
- (E) provide increased emphasis on the concerns of women and minority populations in training programs, service delivery programs, and research endeavors of the Institute.

(July 1, 1944, ch. 373, title IV, §464R, as added Pub. L. 102–321, title I, §124(a), July 10, 1992, 106 Stat. 364; amended Pub. L. 102–352, §2(a)(5), Aug. 26, 1992, 106 Stat. 938; Pub. L. 109–482, title I, §103(b)(36), Jan. 15, 2007, 120 Stat. 3688.)

# AMENDMENTS

2007—Subsec. (f). Pub. L. 109–482 struck out subsec. (f) which authorized appropriations and provided that at least 15% of the appropriated amounts were to carry out health services research relating to mental health. 1992—Subsec. (f)(1). Pub. L. 102–352 struck out "other than section 2850–4 of this title" after "this subpart".

## Effective Date of 2007 Amendment

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or