described in subsection (a) of this section and with respect to which an exemption is in effect for purposes of section 355(i) of title 21, the Secretary shall—

(A) as appropriate, encourage the sponsor of the investigation of the new drug to submit to the Secretary, in accordance with regulations issued under such section, an application to use the drug in the treatment of individuals—

(i) who are infected with the etiologic agent for acquired immune deficiency syndrome; and

(ii) who are not participating in the clinical trials conducted pursuant to such exemption; and

(B) if such an application is approved, encourage, as appropriate, licensed medical practitioners to obtain, in accordance with such regulations, the new drug from such sponsor for the purpose of treating such individuals.

(2) If the sponsor of the investigation of a new drug described in paragraph (1) does not submit to the Secretary an application described in such paragraph (relating to treatment use), the Secretary shall, through statements published in the Federal Register, encourage, as appropriate, licensed medical practitioners to submit to the Secretary such applications in accordance with regulations described in such paragraph.

(c) Technical assistance with respect to treatment use

In the case of a new drug with respect to which the Secretary has made a determination described in subsection (a) of this section, the Secretary may, directly or through grants or contracts, provide technical assistance with respect to the process of—

(1) submitting to the Secretary applications for exemptions described in paragraph (1)(B) of such subsection;

(2) submitting to the Secretary applications described in subsection (b) of this section; and

(3) with respect to sponsors of investigations of new drugs, facilitating the transfer of new drugs from such sponsors to licensed medical practitioners.

(d) "New drug" defined

For purposes of this section, the term ''new drug'' has the meaning given such term in section 321 of title 21.

(July 1, 1944, ch. 373, title XXIII, § 2312, as added Pub. L. 100–607, title II, § 201(4), Nov. 4, 1988, 102 Stat. 3066; amended Pub. L. 103–43, title XX, § 2008(d)(2), June 10, 1993, 107 Stat. 212.)

PRIOR PROVISIONS

A prior section 300cc–12, act July 1, 1944, § 2313, was successively renumbered by subsequent acts and transferred, see section 238j of this title.

AMENDMENTS

1993—Subsec. (a)(2)(A). Pub. L. 103–43 substituted ''AIDS Research Advisory Committee'' for ''AIDS Clinical Research Review Committee''.

§ 300cc–13. Terry Beirn Community-Based AIDS Research Initiative

(a) In general

After consultation with the Commissioner of Food and Drugs, the Director of the National Institutes of Health, acting through the Director of the National Institute of Allergy and Infectious Diseases, may make grants to public entities and nonprofit private entities concerned with acquired immune deficiency syndrome, and may enter into contracts with public and private such[1] entities, for the purpose of planning and conducting, in the community involved, clinical trials of experimental treatments for infection with the etiologic agent for such syndrome that are approved by the Commissioner of Food and Drugs for investigational use under regulations issued under section 355 of title 21.

(b) Requirement of certain projects

(1) Financial assistance under subsection (a) of this section shall include such assistance to community-based organizations and community health centers for the purpose of—

(A) retaining appropriate medical supervision;

(B) assisting with administration, data collection and record management; and

(C) conducting training of community physicians, nurse practitioners, physicians' assistants and other health professionals for the purpose of conducting clinical trials.

(2)(A) Financial assistance under subsection (a) of this section shall include such assistance for demonstration projects designed to implement and conduct community-based clinical trials in order to provide access to the entire scope of communities affected by infections with the etiologic agent for acquired immune deficiency syndrome, including minorities, hemophiliacs and transfusion-exposed individuals, women, children, users of intravenous drugs, and individuals who are asymptomatic with respect to such infection.

(B) The Director of the National Institutes of Health may not provide financial assistance under this paragraph unless the application for such assistance is approved—

(i) by the Commissioner of Food and Drugs;

(ii) by a duly constituted Institutional Review Board that meets the requirements of part 56 of title 21, Code of Federal Regulations; and

(iii) by the Director of the National Institute of Allergy and Infectious Diseases.

(c) Participation of private industry, schools of medicine and primary providers

Programs carried out with financial assistance provided under subsection (a) of this section shall be designed to encourage private industry and schools of medicine, osteopathic medicine, and existing consortia of primary care providers organized to conduct clinical research concerning acquired immune deficiency syndrome to participate in, and to support, the clinical trials conducted pursuant to the programs.

(d) Requirement of application

The Secretary may not provide financial assistance under subsection (a) of this section unless—

(1) an application for the assistance is submitted to the Secretary;

[1] So in original.

(2) with respect to carrying out the purpose for which the assistance is to be made, the application provides assurances of compliance satisfactory to the Secretary; and

(3) the application otherwise is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(e) Authorization of appropriations

(1) For the purpose of carrying out subsection (b)(1) of this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1989 through 1996.

(2) For the purpose of carrying out subsection (b)(2) of this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1989 through 1996.

(July 1, 1944, ch. 373, title XXIII, § 2313, as added Pub. L. 100–607, title II, § 201(4), Nov. 4, 1988, 102 Stat. 3068; amended Pub. L. 100–690, title II, § 2617(b), Nov. 18, 1988, 102 Stat. 4240; Pub. L. 101–93, § 6, Aug. 16, 1989, 103 Stat. 615; Pub. L. 102–96, § 3, Aug. 14, 1991, 105 Stat. 481.)

PRIOR PROVISIONS

A prior section 300cc–13, act July 1, 1944, § 2314, was successively renumbered by subsequent acts and transferred, see section 238k of this title.

AMENDMENTS

1991—Pub. L. 102–96, § 3(1), substituted ''Terry Beirn Community-Based AIDS Research Initiative'' for ''Community-based evaluations of experimental therapies'' in section catchline.

Subsec. (c). Pub. L. 102–96, § 3(2), substituted '', schools of medicine and primary providers'' for ''and schools of medicine'' in heading and substituted ''schools of medicine, osteopathic medicine, and existing consortia of primary care providers organized to conduct clinical research concerning acquired immune deficiency syndrome'' for ''schools of medicine and osteopathic medicine''.

Subsec. (e). Pub. L. 102–96, § 3(3), substituted ''1996'' for ''1991'' in pars. (1) and (2).

1989—Subsec. (c). Pub. L. 101–93 inserted ''and osteopathic medicine'' after ''schools of medicine''.

1988—Subsec. (a). Pub. L. 100–690, § 2617(b)(1), which directed substitution of ''through the Director of the National Institute of Allergy'' for ''through the National Institutes of Allergy'', was executed by making substitution for ''through the National Institute of Allergy'' as the probable intent of Congress.

Subsec. (b)(2)(B)(iii). Pub. L. 100–690, § 2617(b)(2), which directed substitution of ''Institute'' for ''Institutes'', could not be executed because ''Institute'' was singular in original.

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100–690 effective immediately after enactment of Pub. L. 100–607, which was approved Nov. 4, 1988, see section 2600 of Pub. L. 100–690, set out as a note under section 242m of this title.

REFERENCE TO COMMUNITY, MIGRANT, PUBLIC HOUSING, OR HOMELESS HEALTH CENTER CONSIDERED REFERENCE TO HEALTH CENTER

Reference to community health center, migrant health center, public housing health center, or homeless health center considered reference to health center, see section 4(c) of Pub. L. 104–299, set out as a note under section 254b of this title.

FINDINGS AND SENSE OF CONGRESS

Pub. L. 102–96, § 2, Aug. 14, 1991, 105 Stat. 481, provided that:

''(a) FINDINGS.—Congress finds that—

''(1) community-based clinical trials complement the National Institute of Allergy and Infectious Diseases' university-based research in order to provide increased access to experimental therapies;

''(2) community-based clinical trials provide an efficient and cost-effective means to develop new HIV-related treatments, benefiting all people living with HIV disease and other illnesses; and

''(3) because the community-based clinical trials model has a proven ability to conduct rapid trials that meet the very highest standards of scientific inquiry, this program should be reauthorized and significantly expanded.

''(b) SENSE OF CONGRESS.—It is the sense of Congress that, because of Terry Beirn's tireless efforts to foster a partnership among all parties invested in AIDS research (including the National Institutes of Health university-based research system, primary care physicians practicing in the community, and patients), the community-based clinical trials program should be renamed as the 'Terry Beirn Community-Based AIDS Research Initiative' in his honor.''

§ 300cc–14. Evaluation of certain treatments

(a) Establishment of program

(1) After consultation with the AIDS Research Advisory Committee established pursuant to section 300cc–3 of this title, the Secretary shall establish a program for the evaluation of drugs that—

(A) are not approved by the Commissioner of Food and Drugs for the purpose of treatments with respect to acquired immune deficiency syndrome; and

(B) are being utilized for such purpose by individuals infected with the etiologic agent for such syndrome.

(2) The program established under paragraph (1) shall include evaluations of the effectiveness and the risks of the treatment involved, including the risks of foregoing treatments with respect to acquired immune deficiency syndrome that are approved by the Commissioner of Food and Drugs.

(b) Authority with respect to grants and contracts

(1) For the purpose of conducting evaluations required in subsection (a) of this section, the Secretary may make grants to, and enter into cooperative agreements and contracts with, public and nonprofit private entities.

(2) Nonprofit private entities under paragraph (1) may include nonprofit private organizations that—

(A) are established for the purpose of evaluating treatments with respect to acquired immune deficiency syndrome; and

(B) consist primarily of individuals infected with the etiologic agent for such syndrome.

(c) Scientific and ethical guidelines

(1) The Secretary shall establish appropriate scientific and ethical guidelines for the conduct of evaluations carried out pursuant to this section. The Secretary may not provide financial assistance under subsection (b)(1) of this section unless the applicant for such assistance agrees to comply with such guidelines.

(2) The Secretary may establish the guidelines described in paragraph (1) only after consulting with—