

“(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—

(A) physicians whose clinical practice includes a significant number of individuals with acquired immune deficiency syndrome;

(B) individuals who are infected with the etiologic agent for such syndrome; and

(C) other individuals with appropriate expertise or experience.

#### (d) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary.

(July 1, 1944, ch. 373, title XXIII, § 2314, as added Pub. L. 100-607, title II, § 201(4), Nov. 4, 1988, 102 Stat. 3069; amended Pub. L. 103-43, title XX, § 2008(d)(3), June 10, 1993, 107 Stat. 212.)

#### PRIOR PROVISIONS

A prior section 300cc-14, act July 1, 1944, § 2315, was successively renumbered by subsequent acts and transferred, see section 238l of this title.

#### AMENDMENTS

1993—Subsec. (a)(1). Pub. L. 103-43 substituted “AIDS Research Advisory Committee” for “Clinical Research Review Committee” in introductory provisions.

### § 300cc-15. Support of international efforts

#### (a) Grants and contracts for research

(1) Under section 242l of this title, the Secretary, acting through the Director of the National Institutes of Health—

(A) shall, for the purpose described in paragraph (2), make grants to, enter into cooperative agreements and contracts with, and provide technical assistance to, international organizations concerned with public health; and

(B) may, for such purpose, provide technical assistance to foreign governments.

(2) The purpose referred to in paragraph (1) is promoting and expediting international research and training concerning the natural history and pathogenesis of the human immunodeficiency virus and the development and evaluation of vaccines and treatments for acquired immune deficiency syndrome and opportunistic infections.

#### (b) Grants and contracts for additional purposes

After consultation with the Administrator of the Agency for International Development, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall under section 242l of this title make grants to, enter into contracts with, and provide technical assistance to, international organizations concerned with public health and may provide technical assistance to foreign governments, in order to support—

(1) projects for training individuals with respect to developing skills and technical expertise for use in the prevention, diagnosis, and treatment of acquired immune deficiency syndrome; and

(2) epidemiological research relating to acquired immune deficiency syndrome.

#### (c) Special Programme of World Health Organization

Support provided by the Secretary pursuant to this section shall be in furtherance of the global