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.

**Statutory Notes and Related Subsidiaries**

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), 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) 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.)

**Editorial Notes**

PRIOR PROVISIONS

A prior section 300cc–14, act July 1, 1944, § 2315, was successively renumbered by subsequent acts and transferred, see section 238*l* 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 242*l* of this title, the Secretary, acting through the Director of the National Institutes of Health—