PUBLIC HEALTH SERVICE ACT

[As Amended Through P.L. 112–240, Enacted January 2, 2013]

[Currency: This publication is a compilation of the text of title XXIII of Chapter 373 of the 78th Congress. It was last amended by the public law listed in the As Amended Through note above and below at the bottom of each page of the pdf version and reflects current law through the date of the enactment of the public law listed at https://www.govinfo.gov/app/collection/comps/]

[Note: While this publication does not represent an official version of any Federal statute, substantial efforts have been made to ensure the accuracy of its contents. The official version of Federal law is found in the United States Statutes at Large and in the United States Code. The legal effect to be given to the Statutes at Large and the United States Code is established by statute (1 U.S.C. 112, 204).]

[References in brackets [] are to title 42, United States Code]

TITLE XXIII—RESEARCH WITH RESPECT TO ACQUIRED IMMUNE DEFICIENCY SYNDROME [1]

PART A—ADMINISTRATION OF RESEARCH PROGRAMS

SEC. 2302. [300cc–1] REQUIREMENT OF EXPEDITING AWARDS OF GRANTS AND CONTRACTS FOR RESEARCH.

(a) IN GENERAL.—The Secretary shall expedite the award of grants, contracts, and cooperative agreements for research projects relating to acquired immune deficiency syndrome (including such research projects initiated independently of any solicitation by the Secretary for proposals for such research projects).

(b) TIME LIMITATIONS WITH RESPECT TO CERTAIN APPLICATIONS.—

(1) With respect to programs of grants, contracts, and cooperative agreements described in subsection (a), any application submitted in response to a solicitation by the Secretary for proposals pursuant to such a program—

(A) may not be approved if the application is submitted after the expiration of the 3-month period beginning on the date on which the solicitation is issued; and

(B) shall be awarded, or otherwise finally acted upon, not later than the expiration of the 6-month period beginning on the expiration of the period described in subparagraph (A).

(2) If the Secretary makes a determination that it is not practicable to administer a program referred to in paragraph (1) in accordance with the time limitations described in such paragraph, the Secretary may adjust the time limitations accordingly.

[1] Subtitle E of title II of Public Law 100–607 (102 Stat. 3108) established various authorities regarding acquired immune deficiency syndrome.

Section 2301 was repealed by section 104(b)(2)(C) of Public Law 109–482.

(c) REQUIREMENTS WITH RESPECT TO ADJUSTMENTS IN TIME LIMITATIONS.—With respect to any program for which a determination described in subsection (b)(2) is made, the Secretary shall—

(1) if the determination is made before the Secretary issues a solicitation for proposals pursuant to the program, ensure that the solicitation describes the time limitations as adjusted by the determination; and

(2) if the determination is made after the Secretary issues such a solicitation for proposals, issue a statement describing the time limitations as adjusted by the determination and individually notify, with respect to the determination, each applicant whose application is submitted before the expiration of the 3-month period beginning on the date on which the solicitation was issued.

(d) ANNUAL REPORTS TO CONGRESS.—Except as provided in subsection (e), the Secretary shall annually prepare, for inclusion in the comprehensive report required in section 2301, a report—

(A)[2] summarizing programs for which the Secretary has made a determination described in subsection (b)(2), including a description of the time limitations as adjusted by the determination and including a summary of the solicitation issued by the Secretary for proposals pursuant to the program; and

(B) summarizing applications that—

(i) were submitted pursuant to a program of grants, contracts, or cooperative agreements referred to in paragraph (1) of subsection (b) for which a determination described in paragraph (2) of such subsection has not been made; and

(ii) were not processed in accordance with the time limitations described in such paragraph (1).

(e) QUARTERLY REPORTS FOR FISCAL YEAR 1989.—For fiscal year 1989, the report required in subsection (d) shall, not less than quarterly, be prepared and submitted to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate.

SEC. 2303. [300cc–2] REQUIREMENTS WITH RESPECT TO PROCESSING OF REQUESTS FOR PERSONNEL AND ADMINISTRATIVE SUPPORT.

(a) IN GENERAL.—The Director of the Office of Personnel Management or the Administrator of General Services, as the case may be, shall respond to any priority request made by the Administrator of the Alcohol, Drug Abuse, and Mental Health Administration, the Director of the Centers for Disease Control and Prevention, the Commissioner of Food and Drugs, or the Director of the National Institutes of Health, not later than 21 days after the date on which such request is made. If the Director of the Office of Personnel Management or the Administrator of General Services, as the case may be, does not disapprove a priority request during the 21-day period, the request shall be deemed to be approved.

[2] Designations are so in law. Subparagraphs (A) and (B) should probably be designated paragraphs (1) and (2), respectively. Similarly, clauses (i) and (ii) of subparagraph (B) should probably be designated subparagraphs (A) and (B), respectively.

(b) NOTICE TO SECRETARY AND TO ASSISTANT SECRETARY FOR HEALTH.—The Administrator of the Substance Abuse and Mental Health Services Administration, the Director of the Centers for Disease Control and Prevention, the Commissioner of Food and Drugs, and the Director of the National Institutes of Health, shall, respectively, transmit to the Secretary and the Assistant Secretary for Health a copy of each priority request made under this section by the agency head involved. The copy shall be transmitted on the date on which the priority request involved is made.

(c) DEFINITION OF PRIORITY REQUEST.—For purposes of this section, the term "priority request" means any request that—

(1) is designated as a priority request by the Administrator of the Substance Abuse and Mental Health Services Administration, the Director of the Centers for Disease Control and Prevention, the Commissioner of Food and Drugs, or the Director of the National Institutes of Health; and

(2)(A) is made to the Director of the Office of Personnel Management for the allocation of personnel to carry out activities with respect to acquired immune deficiency syndrome; or

(B) is made to the Administrator of General Services for administrative support or space in carrying out such activities.

SEC. 2304. [300cc–3] ESTABLISHMENT OF RESEARCH ADVISORY COMMITTEE.

(a) IN GENERAL.—After consultation with the Commissioner of Food and Drugs, the Secretary, acting through the Director of the National Institute of Allergy and Infectious Diseases, shall establish within such Institute an advisory committee to be known as the AIDS Research Advisory Committee (hereafter in this section referred to as the "Committee").

(b) COMPOSITION.—The Committee shall be composed of physicians whose clinical practice includes a significant number of patients with acquired immune deficiency syndrome.

(c) DUTIES.—The Committee shall—

(1) advise the Director of such Institute (and may provide advice to the Directors of other agencies of the National Institutes of Health, as appropriate) on appropriate research activities to be undertaken with respect to clinical treatment of such syndrome, including advice with respect to—

(A) research on drugs for preventing or minimizing the development of symptoms or conditions arising from infection with the etiologic agent for such syndrome, including recommendations on the projects of research with respect to diagnosing immune deficiency and with respect to predicting, diagnosing, preventing, and treating opportunistic cancers and infectious diseases; and

(B) research on the effectiveness of treating such symptoms or conditions with drugs that—

(i) are not approved by the Commissioner of Food and Drugs for the purpose of treating such symptoms or conditions; and

(ii) are being utilized for such purpose by individuals infected with such etiologic agent;

(2)(A) review ongoing publicly and privately supported research on clinical treatment for acquired immune deficiency

syndrome, including research on drugs described in paragraph (1); and

(B) periodically issue, and make available to health care professionals, reports describing and evaluating such research;

(3) conduct studies and convene meetings for the purpose of determining the recommendations among physicians in clinical practice on clinical treatment of acquired immune deficiency syndrome, including treatment with the drugs described in paragraph (1); and

(4) conduct a study for the purpose of developing, with respect to individuals infected with the etiologic agent for acquired immune deficiency syndrome, a consensus among health care professionals on clinical treatments for preventing or minimizing the development of symptoms or conditions arising from infection with such etiologic agent.

PART B—RESEARCH AUTHORITY

SEC. 2311. [300cc–11] CLINICAL EVALUATION UNITS AT NATIONAL INSTITUTES OF HEALTH.

(a) IN GENERAL.—The Secretary, acting through the Director of the National Cancer Institute and the Director of the National Institute of Allergy and Infectious Diseases, shall for each such Institute establish a clinical evaluation unit at the Clinical Center at the National Institutes of Health. Each of the clinical evaluation units—

(1) shall conduct clinical evaluations of experimental treatments for acquired immune deficiency syndrome developed within the preclinical drug development program, including evaluations of methods of diagnosing immune deficiency and evaluations of methods of predicting, diagnosing, preventing, and treating opportunistic cancers and infectious diseases; and

(2) may conduct clinical evaluations of experimental treatments for such syndrome that are developed by any other national research institute of the National Institutes of Health or by any other entity.

(b) PERSONNEL AND ADMINISTRATIVE SUPPORT.—

(1) For the purposes described in subsection (a), the Secretary, acting through the Director of the National Institutes of Health, shall provide each of the clinical evaluation units required in such subsection—

(A)(i) with not less than 50 beds; or

(ii) with an outpatient clinical capacity equal to not less than twice the outpatient clinical capacity, with respect to acquired immune deficiency syndrome, possessed by the Clinical Center of the National Institutes of Health on June 1, 1988; and

(B) with such personnel, such administrative support, and such other support services as may be necessary.

(2) Facilities, personnel, administrative support, and other support services provided pursuant to paragraph (1) shall be in addition to the number or level of facilities, personnel, administrative support, and other support services that otherwise would be available at the Clinical Center at the National Insti-

tutes of Health for the provision of clinical care for individuals with diseases or disorders.

(c) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary.

SEC. 2312. [300cc–12] USE OF INVESTIGATIONAL NEW DRUGS WITH RESPECT TO ACQUIRED IMMUNE DEFICIENCY SYNDROME.

(a) ENCOURAGEMENT OF APPLICATIONS WITH RESPECT TO CLINICAL TRIALS.—

(1) If, in the determination of the Secretary, there is preliminary evidence that a new drug has effectiveness in humans with respect to the prevention or treatment of acquired immune deficiency syndrome, the Secretary shall, through statements published in the Federal Register—

(A) announce the fact of such determination; and

(B) with respect to the new drug involved, encourage an application for an exemption for investigational use of the new drug under regulations issued under section 505(i) of the Federal Food, Drug, and Cosmetic Act.

(2)(A) The AIDS Research Advisory Committee established pursuant to section 2304 shall make recommendations to the Secretary with respect to new drugs appropriate for determinations described in paragraph (1).

(B) The Secretary shall, as soon as is practicable, determine the merits of recommendations received by the Secretary pursuant to subparagraph (A).

(b) ENCOURAGEMENT OF APPLICATIONS WITH RESPECT TO TREATMENT USE IN CIRCUMSTANCES OTHER THAN CLINICAL TRIALS.—

(1) In the case of a new drug with respect to which the Secretary has made a determination described in subsection (a) and with respect to which an exemption is in effect for purposes of section 505(i) of the Federal Food, Drug, and Cosmetic Act, 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), 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); 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) DEFINITION.—For purposes of this section, the term "new drug" has the meaning given such term in section 201 of the Federal Food, Drug, and Cosmetic Act.

SEC. 2313. [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 National Institute[3] 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 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 505 of the Federal Food, Drug, and Cosmetic Act.

(b) REQUIREMENT OF CERTAIN PROJECTS.—

(1) Financial assistance under subsection (a) 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) 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.

[3] So in law. Probably should be "acting through the Director of the National Institute". (Section 2617(b)(1) of Public Law 100–690 expressed the intent to so amend the provision; however, the amendment cannot be executed because the amendatory instructions are to strike "through the National Institutes of Allergy", and this term does not appear in subsection (a) (above).)

(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) 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) unless—

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

(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), 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), there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1989 through 1996.

SEC. 2314. [300cc–14] EVALUATION OF CERTAIN TREATMENTS.

(a) ESTABLISHMENT OF PROGRAM.—

(1) After consultation with the AIDS Research Advisory Committee established pursuant to section 2304, 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.

SEC. 2315. [300cc–15] SUPPORT OF INTERNATIONAL EFFORTS.

(a) GRANTS AND CONTRACTS FOR RESEARCH.—

(1) Under section 307, 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 307 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 strategy of the World Health Organization Special Programme on Acquired Immunodeficiency Syndrome.

(d) PREFERENCES.—In providing grants, cooperative agreements, contracts, and technical assistance under subsections (a) and (b), the Secretary shall—

(1) give preference to activities under such subsections conducted by, or in cooperation with, the World Health Organization; and

(2) with respect to activities carried out under such subsections in the Western Hemisphere, give preference to activities conducted by, or in cooperation with, the Pan American Health Organization or the World Health Organization.

(e) REQUIREMENT OF APPLICATION.—The Secretary may not make a grant or enter into a cooperative agreement or contract under this section unless—

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

(2) with respect to carrying out the purpose for which such assistance is to be provided, 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.

(f) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each fiscal year.

SEC. 2316. [300cc–16] RESEARCH CENTERS.

(a) IN GENERAL.—

(1) The Secretary, acting through the Director of the National Institute of Allergy and Infectious Diseases, may make grants to, and enter into contracts with, public and nonprofit private entities to assist such entities in planning, establishing, or strengthening, and providing basic operating support for, centers for basic and clinical research into, and training in, advanced diagnostic, prevention, and treatment methods for acquired immune deficiency syndrome.

(2) A grant or contract under paragraph (1) shall be provided in accordance with policies established by the Secretary, acting through the Director of the National Institutes of Health, and after consultation with the advisory council for the National Institute of Allergy and Infectious Diseases.

(3) The Secretary shall ensure that, as appropriate, clinical research programs carried out under paragraph (1) include as research subjects women, children, hemophiliacs, and minorities.

(b) USE OF FINANCIAL ASSISTANCE.—

(1) Financial assistance under subsection (a) may be expended for—

(A) the renovation or leasing of space;

(B) staffing and other basic operating costs, including such patient care costs as are required for clinical research;

(C) clinical training with respect to acquired immune deficiency syndrome (including such training for allied health professionals); and

(D) demonstration purposes, including projects in the long-term monitoring and outpatient treatment of individuals infected with the etiologic agent for such syndrome.

(2) Financial assistance under subsection (a) may not be expended to provide research training for which National Research Service Awards may be provided under section 487.

(c) DURATION OF SUPPORT.—Support of a center under subsection (a) may be for not more than five years. Such period may be extended by the Director for additional periods of not more than five years each if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

(d) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary.

SEC. 2317. [300cc–17] INFORMATION SERVICES.

(a) ESTABLISHMENT OF PROGRAM.—The Secretary shall establish, maintain, and operate a program with respect to information on research, treatment, and prevention activities relating to infection with the etiologic agent for acquired immune deficiency syndrome. The program shall, with respect to the agencies of the Department of Health and Human Services, be integrated and coordinated.

(b) TOLL-FREE TELEPHONE COMMUNICATIONS FOR HEALTH CARE ENTITIES.—

(1) After consultation with the Director of the Office of AIDS Research, the Administrator of the Health Resources and Services Administration, and the Director of the Centers for Disease Control and Prevention, the Secretary shall provide for toll-free telephone communications to provide medical and technical information with respect to acquired immune deficiency syndrome to health care professionals, allied health care providers, and to professionals providing emergency health services.

(2) Information provided pursuant to paragraph (1) shall include—

(A) information on prevention of exposure to, and the transmission of, the etiologic agent for acquired immune deficiency syndrome; and

(B) information contained in the data banks established in subsections (c) and (d).

(c) DATA BANK ON RESEARCH INFORMATION.—

(1) After consultation with the Director of the Office of AIDS Research, the Director of the Centers for Disease Control and Prevention, and the National Library of Medicine, the Secretary shall establish a data bank of information on the results of research with respect to acquired immune deficiency syndrome conducted in the United States and other countries.

(2) In carrying out paragraph (1), the Secretary shall collect, catalog, store, and disseminate the information described in such paragraph. To the extent practicable, the Secretary shall make such information available to researchers, physicians, and other appropriate individuals, of countries other than the United States.

(d) DATA BANK ON CLINICAL TRIALS AND TREATMENTS.—

(1) After consultation with the Commissioner of Food and Drugs, the AIDS Research Advisory Committee established under section 2304, and the Director of the Office of AIDS Research, the Secretary shall, in carrying out subsection (a), establish a data bank of information on clinical trials and treatments with respect to infection with the etiologic agent for acquired immune deficiency syndrome (hereafter in this section referred to as the "Data Bank").

(2) In carrying out paragraph (1), the Secretary shall collect, catalog, store, and disseminate the information described in such paragraph. The Secretary shall disseminate such information through information systems available to individuals infected with the etiologic agent for acquired immune deficiency syndrome, to other members of the public, to health care providers, and to researchers.

(e) REQUIREMENTS WITH RESPECT TO DATA BANK ON CLINICAL TRIALS AND TREATMENTS.—The Data Bank shall include the following:

(1) A registry of clinical trials of experimental treatments for acquired immune deficiency syndrome and related illnesses conducted under regulations promulgated pursuant to section 505 of the Federal Food, Drug and Cosmetic Act that provides a description of the purpose of each experimental drug protocol either with the consent of the protocol sponsor, or when a trial to test efficacy begins. Information provided shall include eligibility criteria and the location of trial sites, and must be forwarded to the Data Bank by the sponsor of the trial not later than 21 days after the approval by the Food and Drug Administration.

(2) Information pertaining to experimental treatments for acquired immune deficiency syndrome that may be available under a treatment investigational new drug application that has been submitted to the Food and Drug Administration pursuant to part 312 of title 21, Code of Federal Regulations. The Data Bank shall also include information pertaining to the results of clinical trials of such treatments, with the consent of the sponsor, of such experimental treatments, including information concerning potential toxicities or adverse effects associated with the use or administration of such experimental treatment.

SEC. 2318. [300cc–18] DEVELOPMENT OF MODEL PROTOCOLS FOR CLINICAL CARE OF INFECTED INDIVIDUALS.

(a) IN GENERAL.—

(1) The Secretary, acting through the Director of the National Institutes of Health and after consultation with the Administrator for Health Care Policy and Research, may make grants to public and nonprofit private entities for the establishment of projects to develop model protocols for the clinical care of individuals infected with the etiologic agent for acquired immune deficiency syndrome, including treatment and prevention of HIV infection and related conditions among women.

(2) The Secretary may not make a grant under paragraph (1) unless—

(A) the applicant for the grant is a provider of comprehensive primary care; or

(B) the applicant for the grant agrees, with respect to the project carried out pursuant to paragraph (1), to enter into a cooperative arrangement with an entity that is a provider of comprehensive primary care.

(b) REQUIREMENT OF PROVISION OF CERTAIN SERVICES.—The Secretary may not make a grant under subsection (a) unless the applicant for the grant agrees that, with respect to patients participating in the project carried out with the grant, services provided pursuant to the grant will include—

(1) monitoring, in clinical laboratories, of the condition of such patients;

(2) clinical intervention for infection with the etiologic agent for acquired immune deficiency syndrome, including measures for the prevention of conditions arising from the infection;

(3) information and counseling on the availability of treatments for such infection approved by the Commissioner of Food and Drugs, on the availability of treatments for such infection not yet approved by the Commissioner, and on the reports issued by the AIDS Research Advisory Committee under section 2304(c)(2)(B);

(4) support groups; and

(5) information on, and referrals to, entities providing appropriate social support services.

(c) LIMITATION ON IMPOSITION OF CHARGES FOR SERVICES.—The Secretary may not make a grant under subsection (a) unless the applicant for the grant agrees that, if the applicant will routinely impose a charge for providing services pursuant to the grant, the applicant will not impose the charge on any individual seeking such services who is unable to pay the charge.

(d) EVALUATION AND REPORTS.—

(1) The Secretary may not make a grant under subsection (a) unless the applicant for the grant agrees, with respect to the project carried out pursuant to subsection (a), to submit to the Secretary—

(A) information sufficient to assist in the replication of the model protocol developed pursuant to the project; and

(B) such reports as the Secretary may require.

(2) The Secretary shall provide for evaluations of projects carried out pursuant to subsection (a) and shall annually submit to the Congress a report describing such projects. The report shall include the findings made as a result of such evaluations and may include any recommendations of the Secretary for appropriate administrative and legislative initiatives with respect to the program established in this section.

(e) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1989 through 1991, and such sums as may be necessary for each of the fiscal years 1994 through 1996.

SEC. 2319. [300cc–19] NATIONAL BLOOD RESOURCE EDUCATION PROGRAM.

After consultation with the Director of the National Heart, Lung, and Blood Institute and the Commissioner of Food and Drugs, the Secretary shall establish a program of research and education regarding blood donations and transfusions to maintain and improve the safety of the blood supply. Education programs shall be directed at health professionals, patients, and the community to—

(1) in the case of the public and patients undergoing treatment—

(A) increase awareness that the process of donating blood is safe;

(B) promote the concept that blood donors are contributors to a national need to maintain an adequate and safe blood supply;

(C) encourage blood donors to donate more than once a year; and

(D) encourage repeat blood donors to recruit new donors;

(2) in the case of health professionals—

(A) improve knowledge, attitudes, and skills of health professionals in the appropriate use of blood and blood components;

(B) increase the awareness and understanding of health professionals regarding the risks versus benefits of blood transfusion; and

(C) encourage health professionals to consider alternatives to the administration of blood or blood components for their patients; and

(3) in the case of the community, increase coordination, communication, and collaboration among community, professional, industry, and government organizations regarding blood donation and transfusion issues.

SEC. 2320. [300cc–20] ADDITIONAL AUTHORITY WITH RESPECT TO RESEARCH.

(a) DATA COLLECTION WITH RESPECT TO NATIONAL PREVALENCE.—

(1) The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may, through representative sampling and other appropriate methodologies, pro-

vide for the continuous collection of data on the incidence in the United States of cases of acquired immune deficiency syndrome and of cases of infection with the etiologic agent for such syndrome. The Secretary may carry out the program of data collection directly or through cooperative agreements and contracts with public and nonprofit private entities.

(2) The Secretary shall encourage each State to enter into a cooperative agreement or contract under paragraph (1) with the Secretary in order to facilitate the prompt collection of the most recent accurate data on the incidence of cases described in such paragraph.

(3) The Secretary shall ensure that data collected under paragraph (1) includes data on the demographic characteristics of the population of individuals with cases described in paragraph (1), including data on specific subpopulations at risk of infection with the etiologic agent for acquired immune deficiency syndrome.

(4) In carrying out this subsection, the Secretary shall, for the purpose of assuring the utility of data collected under this section, request entities with expertise in the methodologies of data collection to provide, as soon as is practicable, assistance to the Secretary and to the States with respect to the development and utilization of uniform methodologies of data collection.

(5) The Secretary shall provide for the dissemination of data collected pursuant to this subsection. In carrying out this paragraph, the Secretary may publish such data as frequently as the Secretary determines to be appropriate with respect to the protection of the public health. The Secretary shall publish such data not less than once each year.

(b) EPIDEMIOLOGICAL AND DEMOGRAPHIC DATA.—

(1) The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall develop an epidemiological data base and shall provide for long-term studies for the purposes of—

(A) collecting information on the demographic characteristics of the population of individuals infected with the etiologic agent for acquired immune deficiency syndrome and the natural history of such infection; and

(B) developing models demonstrating the long-term domestic and international patterns of the transmission of such etiologic agent.

(2) The Secretary may carry out paragraph (1) directly or through grants to, or cooperative agreeements[4] or contracts with, public and nonprofit private entities, including Federal agencies.

(c) LONG-TERM RESEARCH.—The Secretary may make grants to public and nonprofit private entities for the purpose of assisting grantees in conducting long-term research into treatments for acquired immune deficiency syndrome developed from knowledge of the genetic nature of the etiologic agent for such syndrome.

[4] So in law. Probably should be "agreements".

(d) SOCIAL SCIENCES RESEARCH.—The Secretary, acting through the Director of the National Institute of Mental Health, may make grants to public and nonprofit private entities for the purpose of assisting grantees in conducting scientific research into the psychological and social sciences as such sciences relate to acquired immune deficiency syndrome.

(e) AUTHORIZATION OF APPROPRIATIONS.—

(1) For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each fiscal year.

(2) Amounts appropriated pursuant to paragraph (1) to carry out subsection (c) shall remain available until expended.

PART C—RESEARCH TRAINING

SEC. 2341. [300cc–31] FELLOWSHIPS AND TRAINING.

(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control[5], shall establish fellowship and training programs to be conducted by the Centers for Disease Control[5] to train individuals to develop skills in epidemiology, surveillance, testing, counseling, education, information, and laboratory analysis relating to acquired immune deficiency syndrome. Such programs shall be designed to enable health professionals and health personnel trained under such programs to work, after receiving such training, in national and international efforts toward the prevention, diagnosis, and treatment of acquired immune deficiency syndrome.

(b) PROGRAMS CONDUCTED BY NATIONAL INSTITUTE OF MENTAL HEALTH.—The Secretary, acting through the Director of the National Institute of Mental Health, shall conduct or support fellowship and training programs for individuals pursuing graduate or postgraduate study in order to train such individuals to conduct scientific research into the psychological and social sciences as such sciences relate to acquired immune deficiency syndrome.

(c) RELATIONSHIP TO LIMITATION ON NUMBER OF EMPLOYEES.—Any individual receiving a fellowship or receiving training under subsection (a) or (b) shall not be included in any determination of the number of full-time equivalent employees of the Department of Health and Human Services for the purpose of any limitation on the number of such employees established by law prior to, on, or after the date of the enactment of the AIDS Amendments of 1988.

(d) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each fiscal year.

[5] So in law. Section 312(d)(21) of Public Law 102–531 (106 Stat. 3505) provided that section 2341(a) is amended by striking "Centers for Disease Control" and inserting "Centers for Disease Control and Prevention". The amendment cannot be executed because it does not specify to which of the instances of such term the amendment applies.

PART D—OFFICE OF AIDS RESEARCH

Subpart I—Interagency Coordination of Activities

SEC. 2351. [300cc–40] ESTABLISHMENT OF OFFICE.

(a) IN GENERAL.—There is established within the National Institutes of Health an office to be known as the Office of AIDS Research. The Office shall be headed by a director, who shall be appointed by the Secretary.

(b) DUTIES.—

(1) INTERAGENCY COORDINATION OF AIDS ACTIVITIES.—With respect to acquired immune deficiency syndrome, the Director of the Office shall plan, coordinate, and evaluate research and other activities conducted or supported by the agencies of the National Institutes of Health. In carrying out the preceding sentence, the Director of the Office shall evaluate the AIDS activities of each of such agencies and shall provide for the periodic reevaluation of such activities.

(2) CONSULTATIONS.—The Director of the Office shall carry out this subpart (including developing and revising the plan required in section 2353) in consultation with the heads of the agencies of the National Institutes of Health, with the advisory councils of the agencies, and with the advisory council established under section 2352.

(3) COORDINATION.—The Director of the Office shall act as the primary Federal official with responsibility for overseeing all AIDS research conducted or supported by the National Institutes of Health, and

(A) shall serve to represent the National Institutes of Health AIDS Research Program at all relevant Executive branch task forces and committees; and

(B) shall maintain communications with all relevant Public Health Service agencies and with various other departments of the Federal Government, to ensure the timely transmission of information concerning advances in AIDS research and the clinical treatment of acquired immune deficiency syndrome and its related conditions, between these various agencies for dissemination to affected communities and health care providers.

SEC. 2351A. [300cc–40a] MICROBICIDE RESEARCH.

(a) FEDERAL STRATEGIC PLAN.—The Director of the Office shall—

(1) expedite the implementation of the Federal strategic plans required by section 403(a) of the Public Health Service Act (42 U.S.C. 283(a)(5)) regarding the conduct and support of research on, and development of, a microbicide to prevent the transmission of the human immunodeficiency virus; and

(2) review and, as appropriate, revise such plan to prioritize funding and activities relative to their scientific urgency and potential market readiness.

(b) COORDINATION.—In implementing, reviewing, and prioritizing elements of the plan described in subsection (a), the Director of the Office shall consult, as appropriate, with—

(1) representatives of other Federal agencies involved in microbicide research, including the Coordinator of United States Government Activities to Combat HIV/AIDS Globally, the Director of the Centers for Disease Control and Prevention, and the Administrator of the United States Agency for International Development;

(2) the microbicide research and development community; and

(3) health advocates.

SEC. 2352. [300cc–40a] ADVISORY COUNCIL; COORDINATING COMMITTEES.

(a) ADVISORY COUNCIL.—

(1) IN GENERAL.—The Secretary shall establish an advisory council for the purpose of providing advice to the Director of the Office on carrying out this part. (Such council is referred to in this subsection as the "Advisory Council".)

(2) COMPOSITION, COMPENSATION, TERMS, CHAIR, ETC.—Subsections (b) through (g) of section 406 apply to the Advisory Council to the same extent and in the same manner as such subsections apply to advisory councils for the national research institutes, except that—

(A) in addition to the ex officio members specified in section 406(b)(2), there shall serve as such members of the Advisory Council a representative from the advisory council of each of the National Cancer Institute and the National Institute on Allergy and Infectious Diseases; and

(B) with respect to the other national research institutes, there shall serve as ex officio members of such Council, in addition to such members specified in subparagraph (A), a representative from the advisory council of each of the 2 institutes that receive the greatest funding for AIDS activities.

(b) INDIVIDUAL COORDINATING COMMITTEES REGARDING RESEARCH DISCIPLINES.—

(1) IN GENERAL.—The Director of the Office shall establish, for each research discipline in which any activity under the plan required in section 2353 is carried out, a committee for the purpose of providing advice to the Director of the Office on carrying out this part with respect to such discipline. (Each such committee is referred to in this subsection as a "coordinating committee".)

(2) COMPOSITION.—Each coordinating committee shall be composed of representatives of the agencies of the National Institutes of Health with significant responsibilities regarding the research discipline involved.

SEC. 2353. [300cc–40b] COMPREHENSIVE PLAN FOR EXPENDITURE OF APPROPRIATIONS.

(a) IN GENERAL.—Subject to the provisions of this section and other applicable law, the Director of the Office, in carrying out section 2351, shall—

(1) establish a comprehensive plan for the conduct and support of all AIDS activities of the agencies of the National Institutes of Health (which plan shall be first established

under this paragraph not later than 12 months after the date of the enactment of the National Institutes of Health Revitalization Act of 1993);[6]

(2) ensure that the Plan establishes priorities among the AIDS activities that such agencies are authorized to carry out;

(3) ensure that the Plan establishes objectives regarding such activities, describes the means for achieving the objectives, and designates the date by which the objectives are expected to be achieved;

(4) ensure that all amounts appropriated for such activities are expended in accordance with the Plan;

(5) review the Plan not less than annually, and revise the Plan as appropriate; and

(6) ensure that the Plan serves as a broad, binding statement of policies regarding AIDS activities of the agencies, but does not remove the responsibility of the heads of the agencies for the approval of specific programs or projects, or for other details of the daily administration of such activities, in accordance with the Plan.

(b) CERTAIN COMPONENTS OF PLAN.—With respect to AIDS activities of the agencies of the National Institutes of Health, the Director of the Office shall ensure that the Plan—

(1) provides for basic research;

(2) provides for applied research;

(3) provides for research that is conducted by the agencies;

(4) provides for research that is supported by the agencies;

(5) provides for proposals developed pursuant to solicitations by the agencies and for proposals developed independently of such solicitations; and

(6) provides for behavioral research and social sciences research.

(c) BUDGET ESTIMATES.—

(1) FULL-FUNDING BUDGET.—

(A) With respect to a fiscal year, the Director of the Office shall prepare and submit directly to the President, for review and transmittal to the Congress, a budget estimate for carrying out the Plan for the fiscal year, after reasonable opportunity for comment (but without change) by the Secretary, the Director of the National Institutes of Health, and the advisory council established under section 2352. The budget estimate shall include an estimate of the number and type of personnel needs for the Office.

(B) The budget estimate submitted under subparagraph (A) shall estimate the amounts necessary for the agencies of the National Institutes of Health to carry out all AIDS activities determined by the Director of the Office to be appropriate, without regard to the probability that such amounts will be appropriated.

(2) ALTERNATIVE BUDGETS.—

(A) With respect to a fiscal year, the Director of the Office shall prepare and submit to the Secretary and the Director of the National Institutes of Health the budget es-

[6] Enacted June 10, 1993.

timates described in subparagraph (B) for carrying out the Plan for the fiscal year. The Secretary and such Director shall consider each of such estimates in making recommendations to the President regarding a budget for the Plan for such year.

(B) With respect to the fiscal year involved, the budget estimates referred to in subparagraph (A) for the Plan are as follows:

(i) The budget estimate submitted under paragraph (1).

(ii) A budget estimate developed on the assumption that the amounts appropriated will be sufficient only for—

(I) continuing the conduct by the agencies of the National Institutes of Health of existing AIDS activities (if approved for continuation), and continuing the support of such activities by the agencies in the case of projects or programs for which the agencies have made a commitment of continued support; and

(II) carrying out, of activities that are in addition to activities specified in subclause (I), only such activities for which the Director determines there is the most substantial need.

(iii) Such other budget estimates as the Director of the Office determines to be appropriate.

(d) FUNDING.—

(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out AIDS activities under the Plan, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1994 through 1996.

(2) RECEIPT OF FUNDS.—For the first fiscal year beginning after the date on which the Plan first established under section 2353(a)(1) has been in effect for 12 months, and for each subsequent fiscal year, the Director of the Office shall receive directly from the President and the Director of the Office of Management and Budget all funds available for AIDS activities of the National Institutes of Health.

(3) ALLOCATIONS FOR AGENCIES.—

(A) Each fiscal year the Director of the Office shall, from the amounts received under paragraph (2) for the fiscal year, allocate to the agencies of the National Institutes of Health (in accordance with the Plan) all amounts available for such year for carrying out the AIDS activities specified in subsection (c)(2)(B)(ii)(I) for such year. Such allocation shall, to the extent practicable, be made not later than 15 days after the date on which the Director receives amounts under paragraph (2).

(B) Each fiscal year the Director of the Office shall, from the amounts received under paragraph (2) for the fiscal year, allocate to the agencies of the National Institutes of Health (in accordance with the Plan) all amounts available for such year for carrying out AIDS activities that are not referred to in subparagraph (A). Such allocation shall,

to the extent practicable, be made not later than 30 days after the date on which the Director receives amounts under paragraph (2).

SEC. 2354. [300cc–41] ADDITIONAL AUTHORITIES.

(a) IN GENERAL.—In carrying out AIDS research, the Director of the Office—

(1) shall develop and expand clinical trials of treatments and therapies for infection with the etiologic agent for acquired immune deficiency syndrome, including such clinical trials for women, infants, children, hemophiliacs, and minorities;

(2) may establish or support the large-scale development and preclinical screening, production, or distribution of specialized biological materials and other therapeutic substances for AIDS research and set standards of safety and care for persons using such materials;

(3) may support—

(A) AIDS research conducted outside the United States by qualified foreign professionals if such research can reasonably be expected to benefit the people of the United States;

(B) collaborative research involving American and foreign participants; and

(C) the training of American scientists abroad and foreign scientists in the United States;

(4) may encourage and coordinate AIDS research conducted by any industrial concern that evidences a particular capability for the conduct of such research;

(5)(A) may acquire, improve, repair, operate, and maintain laboratories, other research facilities, equipment, and such other real or personal property as the Director of the Office determines necessary;

(B) may make grants for the construction or renovation of facilities; and

(C) may acquire, without regard to the Act of March 3, 1877 (40 U.S.C. 34) by lease or otherwise through the Administrator of General Services, buildings or parts of buildings in the District of Columbia or communities located adjacent to the District of Columbia for the use of the National Institutes of Health for a period not to exceed ten years; and

(6) subject to section 405(b)(2) and without regard to section 3324 of title 31, United States Code, and section 3709 of the Revised Statutes (41 U.S.C. 5), may enter into such contracts and cooperative agreements with any public agency, or with any person, firm, association, corporation, or educational institution, as may be necessary to expedite and coordinate research relating to acquired immune deficiency syndrome.

(b) PROJECTS FOR COOPERATION AMONG PUBLIC AND PRIVATE HEALTH ENTITIES.—In carrying out subsection (a), the Director of the Office shall establish projects to promote cooperation among Federal agencies, State, local, and regional public health agencies, and private entities, in research concerning the diagnosis, prevention, and treatment of acquired immune deficiency syndrome.

Subpart II—Emergency Discretionary Fund

SEC. 2356. [300cc–43] EMERGENCY DISCRETIONARY FUND.

(a) IN GENERAL.—

(1) ESTABLISHMENT.—There is established a fund consisting of such amounts as may be appropriated under subsection (g). Subject to the provisions of this section, the Director of the Office, after consultation with the advisory council established under section 2352, may expend amounts in the Fund for the purpose of conducting and supporting such AIDS activities, including projects of AIDS research, as may be authorized in this Act for the National Institutes of Health.

(2) PRECONDITIONS TO USE OF FUND.—Amounts in the Fund may be expended only if—

(A) the Director identifies the particular set of AIDS activities for which such amounts are to be expended;

(B) the set of activities so identified constitutes either a new project or additional AIDS activities for an existing project;

(C) the Director of the Office has made a determination that there is a significant need for such set of activities; and

(D) as of June 30 of the fiscal year preceding the fiscal year in which the determination is made, such need was not provided for in any appropriations Act passed by the House of Representatives to make appropriations for the Departments of Labor, Health and Human Services (including the National Institutes of Health), Education, and related agencies for the fiscal year in which the determination is made.

(3) TWO-YEAR USE OF FUND FOR PROJECT INVOLVED.—In the case of an identified set of AIDS activities, obligations of amounts in the Fund may not be made for such set of activities after the expiration of the 2-year period beginning on the date on which the initial obligation of such amounts is made for such set.

(b) PEER REVIEW.—With respect to an identified set of AIDS activities carried out with amounts in the Fund, this section may not be construed as waiving applicable requirements for peer review.

(c) LIMITATIONS ON USE OF FUND.—

(1) CONSTRUCTION OF FACILITIES.—Amounts in the Fund may not be used for the construction, renovation, or relocation of facilities, or for the acquisition of land.

(2) CONGRESSIONAL DISAPPROVAL OF PROJECTS.—

(A) Amounts in the Fund may not be expended for the fiscal year involved for an identified set of AIDS activities, or a category of AIDS activities, for which—

(i)(I) amounts were made available in an appropriations Act for the preceding fiscal year; and

(II) amounts are not made available in any appropriations Act for the fiscal year involved; or

(ii) amounts are by law prohibited from being expended.

(B) A determination under subparagraph (A)(i) of whether amounts have been made available in appropriations Acts for a fiscal year shall be made without regard to whether such Acts make available amounts for the Fund.

(3) INVESTMENT OF FUND AMOUNTS.—Amounts in the Fund may not be invested.

(d) APPLICABILITY OF LIMITATION REGARDING NUMBER OF EMPLOYEES.—The purposes for which amounts in the Fund may be expended include the employment of individuals necessary to carry out identified sets of AIDS activities approved under subsection (a). Any individual employed under the preceding sentence may not be included in any determination of the number of full-time equivalent employees for the Department of Health and Human Services for the purpose of any limitation on the number of such employees established by law prior to, on, or after the date of the enactment of the National Institutes of Health Revitalization Act of 1993. [7]

(e) DEFINITIONS.—For purposes of this section:

(1) The term "Fund" means the fund established in subsection (a).

(2) The term "identified set of AIDS activities" means a particular set of AIDS activities identified under subsection (a)(2)(A).

(f) FUNDING.—

(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of providing amounts for the Fund, there is authorized to be appropriated $100,000,000 for each of the fiscal years 1994 through 1996.

(2) AVAILABILITY.—Amounts appropriated for the Fund are available until expended.

Subpart III—General Provisions

SEC. 2359. [300cc–45] GENERAL PROVISIONS REGARDING THE OFFICE.

(a) ADMINISTRATIVE SUPPORT FOR OFFICE.—The Secretary, acting through the Director of the National Institutes of Health, shall provide administrative support and support services to the Director of the Office and shall ensure that such support takes maximum advantage of existing administrative structures at the agencies of the National Institutes of Health.

(b) EVALUATION.—Not later than 5 years after the date of the enactment of National Institutes of Health Revitalization Act of 1993, [7] the Secretary shall conduct an evaluation to—

(1) determine the effect of this section on the planning and coordination of the AIDS research programs at the institutes, centers and divisions of the National Institutes of Health;

(2) evaluate the extent to which this part has eliminated the duplication of administrative resources among such Institutes, centers and divisions; and

(3) provide recommendations concerning future alterations with respect to this part.

(c) DEFINITIONS.—For purposes of this part:

[7] Enacted June 10, 1993.

(1) The term "AIDS activities" means AIDS research and other activities that relate to acquired immune deficiency syndrome.

(2) The term "AIDS research" means research with respect to acquired immune deficiency syndrome.

(3) The term "Office" means the Office of AIDS Research.

(4) The term "Plan" means the plan required in section 2353(a)(1).

PART E—GENERAL PROVISIONS

SEC. 2361. [300cc–51] DEFINITION.

For purposes of this title:

(1) The term "infection", with respect to the etiologic agent for acquired immune deficiency syndrome, includes opportunistic cancers and infectious diseases and any other conditions arising from infection with such etiologic agent.

(2) The term "treatment", with respect to the etiologic agent for acquired immune deficiency syndrome, includes primary and secondary prophylaxis.